ISBN 978-82-326-1654-1 (printed ver.)
ISBN 978-82-326-1655-8 (electronic ver.)
ISSN 1503-8181

Lene Elisabeth Blekken

Doctoral thesis

Doctoral theses at NTNU, 2016:158

Lene Elisabeth Blekken

Faecal incontinence, constipation and laxative use:

Epidemiology and development of an implementation strategy for improving incontinence care in nursing homes

NTNU
Norwegian University of
Science and Technology
Thesis for the Degree of
Philosophiae Doctor
Faculty of Health and Social Sciences
Department of Nursing Science

NTNU
Norwegian University of
Science and Technology

Doctoral theses at NTNU, 2016:158

NTNU

NTNU
Norwegian University of
Science and Technology

Lene Elisabeth Blekken

Faecal incontinence, constipation and laxative use:

Epidemiology and development of an implementation strategy for improving incontinence care in nursing homes

Thesis for the Degree of Philosophiae Doctor

Trondheim, June 2016

Norwegian University of Science and Technology
Faculty of Health and Social Sciences
Department of Nursing Science

NTNU
Norwegian University of
Science and Technology

NTNU
Norwegian University of Science and Technology

Faculty of Health and Social Sciences
Department of Nursing Science

Thesis for the Degree of Philosophiae Doctor

ISBN 978-82-326-1654-1 (printed ver.)
ISBN 978-82-326-1655-8 (electronic ver.)
ISSN 1503-8181

Doctoral theses at NTNU, 2016:158

Printed by NTNU Grafisk senter

Avføringsinkontinens, obstipasjon og bruk av avføringsmidler blant pasienter på sykehjem: Epidemiologi og utvikling av en implementeringsstrategi for kunnskapsbasert håndtering av avføringsinkontinens på sykehjem.

Mange pasienter på sykehjem har problemer med avføringsinkontinens og obstipasjon. De har også et høyt forbruk av avføringsmidler. Både avføringsinkontinens og obstipasjon kan oppleves svært plagsomt og fører ofte til redusert livskvalitet. Mye tyder på at helsepersonell er lite oppmerksomme på mulighetene for å forebygge og behandle avføringsinkontinens.

Hensikten med studien var å undersøke forekomst av og assosiasjoner til avføringsinkontinens, obstipasjon og bruk av avføringsmidler blant pasienter på sykehjem ved hjelp av det standardiserte og omfattende instrumentet Resident Assessment Instrumet for Long-Term Care Facilities (interRAI LTCF). For å få noe tilleggsinformasjon ble St. Mark's inkontinensskår benyttet. I tillegg var hensikten å utvikle en implementeringsstrategi for kunnskapsbasert kartlegging og håndtering av avføringsinkontinens med mål om å oppnå reduksjon i forekomst.

Studiens to tverrsnittsstudier inkluderte 261 pasienter. Funnene viste at forekomst av avføringsinkontinens varierte fra 42.1% til 70.1% avhengig av hvordan inkontinens ble definert og hvilket instrument som ble brukt. Avføringsinkontinens var assosiert med svikt i evne til å ivareta aktiviteter i dagliglivet (ADL), kognitiv svikt, urininkontinens og diare. Det å delta i aktiviteter og skrøpelighet/ustabilt sykdomsbilde var beskyttende faktorer. Funnene viste videre en forekomst av obstipasjon på 23.4 %, og at 67.1 % av pasientene brukte avføringsmidler. Obstipasjon var assosiert med balanseproblemer, urininkontinens, Hypotyreose og Parkinsons sykdom. Bruk av avføringsmidler var assosiert med det å ha kommunikasjonsproblemer og antall andre medikamenter. Anti-demensmidler og å delta i aktiviteter var beskyttende faktorer.

Studien bekrefter at avføringsinkontinens, obstipasjon og bruk av avføringsmidler er vanlig blant pasienter på sykehjem. Resultater fra flernivåanalyse viste at det meste av den totale variansen kunne forklares med forskjeller mellom pasientene og ikke forskjeller mellom sykehjemsavdelingene. Dette betyr at en grundig kartlegging med påfølgende individualisert pleie kan være en nøkkel i arbeidet med forebygging og behandling. To forskjellige utdanningsprogram for ansatte med fokus på kunnskapsbasert og individualisert håndtering av avføringsinkontinens ble prøvd ut i en pilot. Erfaringene fra pilot var av vesentlig betydning for protokoll for en cluster-randomisert kontrollert studie for å evaluere effekt av et «multifaceted educational program» for ansatte på sykehjem.

Navn kandidat: Lene Elisabeth Blekken
Institutt: Institutt for samfunnsmedisin, NTNU
Veileder(e): Sigrid Nakrem, Anne G. Vinsnes, Kari Hanne Gjeilo, Siv Mørkved, Christine Norton
Finansieringskilde: Institutt for sykepleievitenskap, NTNU

Ovennevnte avhandling er funnet verdig til å forsvares offentlig
for graden Doctor Philosophiae i samfunnsmedisin
Disputas finner sted i Auditoriet, Medisinsk teknisk forskningssenter, Trondheim
Fredag 3. juni 2016, kl. 12.15

CONTENT

SUMMARY

Background Faecal incontinence (FI) and constipation affects a significant amount of the nursing home (NH) patients. In addition, many of the patients use laxatives regularly. Both faecal incontinence and constipation are bothersome conditions associated with increased risk of morbidity and reduced quality of life. There is a lack of studies investigating bowel problems among NH patients using validated and comprehensive instruments able to capture the complexity in NH patients. The level of awareness among health care staff regarding assessment and treatment options for FI seems limited.

Aim The aim of this thesis was to investigate prevalence and associations of faecal incontinence, constipation and laxative use among NH patients using the standardized and comprehensive Resident Assessment Instrument for Long-Term Care Facilities (interRAI LTCF). Secondly, the aim was to develop an implementation strategy for change in FI care in order to achieve a reduction in FI prevalence rates among patients.

Results Study I and II had a cross-sectional design including 261 patients in NHs in one Norwegian municipality. Study I showed prevalence rate of FI was 42.1 % or 54 %, depending on the chosen cut-off on the scale measuring FI in interRAI LTCF. In order to get some additional information on FI St. Mark's Incontinence score was used, resulting in a prevalence rate of 70.1 %. This illustrates the importance of using clear definitions together with standardized instruments when investigating FI. Deficiencies in ADL, cognitive impairment, urinary incontinence and diarrhea were identified as risk factors, and involvement in activities and instability in health/frailty were identified as protective factors. In study II the prevalence of constipation was 23.4 % and 67.1 % of the patients used laxatives regularly. Balance problems, urinary incontinence, hypothyroidism, and Parkinson's disease were identified as risk factors for constipation. Risk factors for laxative use were reduced ability to communicate and number of drugs other than laxatives, while anti-dementia drugs and being involved in activities were protective factors.

Analyses using mixed effects models showed that most of the total variance in prevalence rates of faecal incontinence (88 %), constipation (90.3 %) and laxative use (97 %), was due to differences in individual patient characteristics, not variance between NH units. Study III was a pilot study preceding a cluster-randomized controlled trial (C-RCT). The pilot was designed as a three armed external pilot study investigating feasibility, acceptability, and adherence of two educational programmes for care staff concerning NH patients' FI. Data was collected at baseline (t_0) and after 3 months (t_1). The study included patients (t_0 n = 62, t_1 n = 57) and registered nurses (t_0 n = 7, t_1 n = 7) in NHs. Quantitative data was analysed by descriptive statistics. Qualitative data from one focus group interview and four individual interviews were analysed by qualitative content analyses. The pilot study found the planned C-RCT to be feasible with one major and some minor modification. The major modification was the necessity to reduce the main study from a three-armed design to a two-armed design. Important barriers identified were sub-optimal use of skill-mix, problems of communicating assessments and care plans, and isolated RNs with an indistinct nurse identity. Paper IV is the protocol describing the C-RCT evaluating a multifaceted educational programme for care staff on assessment and treatment of patients' FI.

Conclusion Prevalence of FI, constipation and laxative use are confirmed high. Variance in prevalence rates is mainly explained by different patient characteristics/ health deficiencies. Hence, individualized care matching the patients' deficiencies might be a key to managing bowel problems. There is a need for studies evaluating interventions targeting bowel problems in NHs. Further, there is a need for studies evaluating different implementation strategies. The interRAI LTCF is a useful instrument by its combination of a comprehensive range of individual items and scales that make it possible to capture a holistic picture of the complex NH patient, allowing for comparison of immediate and long-term change in patients across settings.

ACKNOWLEDGEMENTS

This thesis has been carried out at the Norwegian University of Science and Technology (NTNU), Department of Public Health and General Practice. The project was financed by former Sør-Trøndelag University College, Faculty of Nursing, now NTNU, Faculty of Health and Social Science, Department of Nursing Science, and a grant from the Norwegian Nurses Organisation. Without this funding the project would not have been possible to carry out. It has been a privilege. I would also like to express my gratitude to the persons who have stood by me in this process, mainly professionally, but also emotionally. Even though the work has been very meaningful, I have also experienced frustration, stress and feelings of inadequacy. Several persons have been of fundamental importance in supporting me in this process, and I wish to express my thanks to:

Associate Professor Sigrid Nakrem (main-supervisor), for important professional views throughout the process, constructive criticism when needed, and support when the "going got rough". I am special thankful for being available for me when I just dropped into your office in need for some advice.

Professor Anne Guttormsen Vinsnes (co-supervisor and principal investigator for the research area Fecal Incontinence Care in Nursing Homes), for having the idea for this project, and for always believing in me. Your professional views, feedback and positive enthusiasm have been important to me.

Associate Professor Kari Hanne Gjeilo (co-supervisor), for your always fast and constructive feedback on written material, discussions and statistical support. You have an eye for details, and have helped me revise my article drafts after the saying "less is more". I myself have just a little tendency to wordiness.

Professor Christine Norton (co-supervisor), for sharing your enormous expertise and experience in both bowel problems and research methodology, for giving me feedback and asking me questions that made me think things through one more time. Moreover, you have been invaluable in editing my English.

Professor Siv Mørkved (co-supervisor), for your supervision, constructive criticism and warm support. Your pragmatic way of seeing things have helped me see that things doesn't have to be considered so complicated.

Associate Professor Øyvind Salvesen (the projects statistician), for listening to all my statistical worries and your patience in supporting me in the statistical analyses. I have learned a lot from you.

I also wish to thank Trondheim municipality, and the registered nurses and authorized social educators who thoroughly filled in the questionnaires and printed relevant material from the electronic patients record. A special thanks to the registered nurses who participated in the pilot study and gave their invaluable feedback in the planning of the preceding cluster-randomized controlled trial. In addition, I wish to thank Signe Nyrønning and Geir-Tore Stensvik from Søbstad Helsehus for valuable feedback on the educational programme and the FI-guideline in the planning phase of the pilot study. Geir-Tore has also assisted me in the data-collection procedure. Thank you for a job well done!

Furthermore, I wish to thank my colleges at the Department of Nursing Science, in special those of you located together with me at "Fischebygget". Our professional and non-professional discussions have been invaluable. Of my colleges, I wish to give my special thanks to Susan Saga, Ann Oddrun Medby, Torunn Hatlen Nøst and Sigrun Aasen Frigstad for your everlasting interest in me and my project. And, Torunn, I don't think you know how important feedback you have provided during many of our weekly running sessions.

Last, but not least, I am grateful to my family: my dear partner in life, Gunnleif, who never stopped believing in me, who patiently have listened to my worries, and encouraging me when needed. Finally, I will be forever grateful to my children, Kristine and William, and my grandchild Olivia. You fulfil my life ☺

ABBREVIATIONS

ABS	Aggressive Behaviour Scale
ADL	Activities of Daily Living
ADLlf	Activities of Daily Living long form scale
ASE	Authorised Social Educator
CHESS	Changes in Health, End-Stage disease, and Signs and Symptoms scale
CPS	Cognitive Performance Scale
C-RCT	Cluster-Randomized controlled trial
DRS	Depression Rating Scale
EBP	Evidence-based practice
EPR	Electronic patient record
EPOC	Cochrane Effective Practice and Organisation of Care
FI	Faecal incontinence
GP	General Practitioner
InterRAI LTCF	The Resident Assessment Instrument for Long-Term Care Facilities
ICC	Intra-Cluster Correlation Coefficient
LPN	Licenced practical nurse
MI	Multifaceted intervention
MDS	Minimum Data Set
MRC	Medical Research Council
NH	Nursing home
OECD	Organisation for Economic Co-operation and Development
RISE	Revised Social Engagement Scale
REK	Regional Committee for Medical and Health research Ethics
RN	Registered nurse
SI	Single intervention
WHO	Worlds Health Organization

LIST OF PAPERS

This thesis is based on the following four papers:

I. Blekken LE. Vinsnes AG, Gjeilo KH, Norton C, Mørkved S, Salvesen Ø & Nakrem S (2016) Exploring faecal incontinence in nursing home patients: a cross-sectional study of prevalence and associations derived from the Resident Assessment Instrument for Long-Term Care Facilities. *Journal of Advanced Nursing* doi: 10.1111/jan.12932.

II. Blekken LE, Nakrem S, Vinsnes AG, Norton C, Mørkved S, Salvesen Ø and Gjeilo KH (2016). Constipation and Laxative Use among Nursing Home Patients: Prevalence and Associations Derived from the Residents Assessment Instrument for Long-Term Care Facilities (interRAI LTCF). *Gastroenterology Research and Practice* doi: 10.1155/2016/1215746

III. Blekken LE, Nakrem S, Gjeilo KH, Norton C, Mørkved S and Vinsnes AG (2015). Feasibility, acceptability, and adherence of two educational programs for care staff concerning nursing home patients' fecal incontinence: a pilot study preceding a cluster-randomized trial. *Implementation Science* **10**:72.

IV. Blekken LE, Vinsnes AG, Gjeilo KH, Mørkved S, Salvesen Ø, Norton C and Nakrem S (2015). Effect of a multifaceted educational program for care staff concerning fecal incontinence in nursing home patients: study protocol of a cluster randomized trial. *Trials* **16**:69.

1. INTRODUCTION

The objective of this thesis was to investigate prevalence and associations of FI, constipation and laxative use among NH patients, and to develop an implementation strategy to improve FI care in nursing homes.

Bowel function is a major concern in older people. Constipation is one of their commonest complaints, and the fear of constipation and the need for regular bowel movements have troubled generations of older people. FI is also a prevalent condition, but seems to be a more taboo subject suffered in silence (Potter 2003). The embarrassment associated with FI can be one of the greatest threats to personal dignity and quality of life (Bliss et al. 2013), and despite the prevalence of the conditions, older people are often reluctant to volunteer the problem to their general practitioner or nurse to seek help (Potter & Wagg 2005, Wagg et al. 2013). In addition, health care personnel do not routinely enquire about the symptom (Wagg et al. 2013). For both FI and constipation, there are great costs in terms of management including time resources for health care personnel dealing with the problem, costs of incontinence products and the prescribing of laxatives and antidiarrheal agents (Pekmezaris et al. 2002, Frank et al. 2002, Norton et al. 2009). For older people living at home, bowel care can put great strain on next of kin and carers, resulting in bowel problems being an important factor for moving to a NH (Potter & Wagg 2005, Wagg et al. 2013).

NH institutions and NH patients worldwide have gone through a great change during the last decades, with increasingly frail patients characterised by high age, functional and cognitive impairment, multiple comorbidities, and high mortality (OECD 2013, Mørk et al. 2014), making independent toileting difficult. These dependencies, combined with changes in anorectal function in late old age, constitute significant challenges regarding bowel care in general, and FI care in particular (Saga 2014).

In the field of healthcare, an enormous number of valuable insights, procedures, and technologies are available. Even so, patients can be needlessly deprived of effective care or receive unnecessary, out-dated, or, even worse, harmful care. It is a general observation that in

healthcare the situation is often one of "underuse, overuse and misuse of care" (Grol 2013). In the case of FI care in NH patients', the level of awareness and knowledge regarding appropriate assessment and treatment options for FI seems limited among primary care physicians and among care personnel in NHs (Magnall et al. 2006, Thekkinkattil et al. 2008, Bliss et al. 2013, Wagg et al. 2013, Saga et al. 2014). In addition, both health care personnel and patients themselves seem to be under the influence of the common misperception that FI is part of the normal aging process and therefore nothing can be done about it (Norton et al. 2009). These may all be reasons why FI most often is managed passively with the use of incontinence pads (Roe et al. 2011, Saga et al. 2014) even though several of the risk factors associated with FI are treatable and/or preventable. Therefore, it is important that great care is taken not only to develop innovations and scientific insights but also to take care that the knowledge and procedures are implemented into daily practice (Grol 2013), and thereby improve the quality of FI care. However, because of complexity both in the individual NH patient and between patients, the causes of FI will be multifactorial, making assessment and treatment challenging. The same complexity also makes research challenging as there has been a lack of validated research instruments able to capture a reliable, holistic picture of NH patients.

The interRAI organization has developed a comprehensive assessment instrument that measures patients' functional, medical, cognitive, and psychosocial status for use both in clinical care and in research. As constipation and FI both are complex conditions and are interconnected, we wanted to study prevalence and associations using the Norwegian version of the validated and comprehensive instrument the Resident Assessment Instrument for Long-Term Care Facilities (interRAI LTCF) (interRAI 2016). In addition we wanted to develop an implementation strategy for change of daily practice of FI care in NHs.

2. BACKGROUND

2.1 BOWEL FUNCTION AND ELIMINATION OF FAECES

The pelvic floor consists of superficial and deep muscle layers that envelop the rectum, bladder and uterus. The superficial muscle layer consists of internal and external anal sphincters, the perineal body and the transverse perineal muscles. In contrast, the pubococcygeus, ileococcygeus and puborectalis muscles compose the deep pelvic muscles. These structures are largely innervated by the sacral nerve roots (S2-S4) and the pudental nerve (Rao & Go 2010). Continence is the ability to retain faeces until it is socially conductive to defecate, while defecation is the evacuation of faecal material from colon. Both functions are regulated by voluntary and involuntary reflex mechanisms, anatomic factors, and rectal compliance. The gastrocolic reflex involves an increase of motility in the colon as response to stretch in the stomach. Thus, this reflex is responsible for the urge to defecate following a meal. Defecation starts when the cerebral cortex receives an awareness and perception of critical level of filling in the rectum. When the individual adopts a sitting or squatting position, the anal sphincters and the puborectalis relax, straightening the anorectal angle. Simultaneously, the voluntary effort of bearing down increases the intra-abdominal pressure, facilitating the development of a peristaltic wave, resulting in stool evacuation (Rao & Go 2010).

2.2 FAECAL INCONTINENCE

The definition of FI by the International Consultation on Incontinence is *"the involuntary loss of liquid or solid stool that is a social or hygienic problem"*(Norton et al. 2009: 1323) According to a review by Wagg et al. (2013) few new studies were identified since the review by Norton et al. (2009) reporting prevalence rates of FI in nursing homes or long-term care facilities (Wagg et al. 2013). As a part of her doctoral thesis, Saga (2014) reviewed studies from 1980 up to 2011 on prevalence and associations of FI in NH patients. Prevalence rates in NHs varied from 10 % to 67 %, with a center between 40 % and 55 %. However, the reported data were limited by lack of a coherent definition of FI, including different frequency labeling, poor definition of the institutional units (the nursing homes) and poor descriptions of patient

characteristics (Saga 2014). Little is known about the FI incidence rates in the NH population, with one study reporting a rate of 20 % during a 10-month period (Chassagne et al. 1999).

Age has been confirmed as a risk factor for FI in many population-based studies (Wagg et al. 2013). A review by Norton et al. (2009) found the results from physiological studies on the ageing bowel to vary due to a) a variety of different techniques used in measuring anorectal function, b) unclear definition of the normative range of manometric measures for older people, c) poor matching between cases and controls of clinical factors which may affect gut function (e.g. level of mobility), or inadequate clinical information and d) usually small subject numbers. However, studies on healthy older adults report that the anorectal function is characterized by a tendency towards an age-related reduction in internal anal sphincter tone (basal pressure) after the age of 70 years in both genders, but to a greater degree in women. There also seems to be a decline in external anal sphincter tone (squeeze pressure), in women after the age of 70, and in men from the age of 90 years. There seems to be an age-related increase in anorectal sensitivity thresholds, and a reduced rectal compliance. However, rectal motility seems to be well preserved (Norton et al. 2009). Overall, the physiological data suggest that FI should not be considered an inevitable consequence of aging alone (Norton et al. 2009, Wagg et al. 2013). In addition, in the general population, the prevalence of FI is higher among women compared to men (Wagg et al. 2013). Among frail older people, and especially in the NH population, it seems that the prevalence of FI is equal, or even higher, among men compared to women (Nelson et al. 1998, Brocklehurst et al. 1999, Wagg et al. 2013, Saga et al. 2013).

Stool consistency is an important factor associated with FI. Loose stool (Johansen et al. 1997, Chassagne et al. 1999, Akpan et al. 2007, Saga et al. 2013) as well as hard stool (Kinnunen 1991, Nelson et al. 1998, Chassagne et al. 1999, Akpan et al. 2007) can be related to FI. Potential reversible causes of loose stool may include excessive laxative use, lactose intolerance, drug-related side effects and bacterial overgrowth (Wagg et al. 2013). “Overflow” FI secondary to constipation and impaction is also important to consider in older adults, potentially more so among nursing home patients (Wagg et al. 2013). Evidence suggests that symptoms of constipation are common among NH patients with FI (Schnelle et al. 2009). Urgency associated with bowel movements is also an important factor related to FI (Wagg et al. 2013). Many studies do not evaluate urgency as an independent risk factor. However, among

the studies that evaluated a sense of urgency associated with bowel movements, urgency is consistently and strongly related to FI (Wagg et al. 2013). Other bowel-related disorders, such as hemorrhoids, posterior vaginal prolapse, irritable bowel syndrome, or complications of prior surgery, can contribute to FI in older adults who otherwise would be continent. This might especially become a problem when functional status, mobility and cognition become impaired. Hence, bowel-related disorders and surgery should be a part of the focused history in older people with FI (Wagg et al. 2013).

In NH patients, some diseases seem to increase the risk of FI. Akpan et al. (2007) found that comorbidity in general was associated with FI. In male NH patients, Aslan et al. (2009) found diabetes mellitus to be associated with FI, possibly due to impaired rectal sensitivity and sphincter weakness. Neurological diseases associated with FI in NH patients include neurological disease in general (Chassagne et al. 1999) cognitive impairment/dementia (Borrie & Davidson 1992, Johansen et al. 1997, Nelson et al. 1998, Brocklehurst et al. 1999, Chassagne et al. 1999, Nelson & Furner 2005, Akpan et al. 2007, Saga et al. 2013) and stroke (Nelson et al. 1998, Brocklehurst et al. 1999, Aslan et al. 2009). However, epidemiological studies suggest that FI is associated more with disability-related factors (e.g. locomotion, other functional impairment), than stroke-related factors (e.g. severity, lesion location) (Wagg et al. 2013). In addition, poor mobility and an increase in dependency in activities of daily living (ADL) are shown to be risk factors (Borrie & Davidson 1992, Brocklehurst et al. 1999, Akpan et al. 2007, Saga et al. 2013), also after controlling for other variables in the analyses (Nelson et al. 1998, Chassagne et al. 1999, Wang et al. 2009, Aslan et al. 2009, Saga et al. 2013). These finding lead to what may be defined as functional FI, associated with mobility problems or restraints that restrict accessibility to the toilet despite normal bowel sensation and capacity. In older people, FI most often co-exists with urinary incontinence (Wagg et al. 2013).

As described above, in NH patients the causes of FI seem to be multifactorial. A symptom with multifactorial aetiology is likely to require multi-component interventions in order to treat the condition. Overall, there are very few trials on treatment of FI in the NH population. Treatment of FI in NH patients often needs to involve treatment of constipation and faecal impaction as well (Wagg et al. 2013). Ouslander et al. (1996) investigated the effect of prompted voiding on FI. They found no significant change in the frequency of incontinent bowel movements, but

they did experience a significant increase in number of continent bowel movements and percentages of bowel movements that were continent (Ouslander et al. 1996). Chassagne et al. (2000) studied the effect of lactulose alone (group I) compared to lactulose together with daily suppositories and weekly tap water enemas (group II) for reducing FI episodes. There were no significant differences between the groups, but the patients in group II achieving complete rectal emptying experienced a significant reduction of FI episodes. Schnelle et al. (2010) studied the effect of a three months multicomponent intervention for improving FI and constipation in NH patients. The intervention group received toileting assistance and exercise. In addition, to increase NH patients' caloric intake, patients were offered a choice of food and fluids several time a day between meals. The intervention was compared to a usual care control group. The intervention group had improvements in bowel movement frequency and the percentage of bowel movements in toilet, but not fewer episodes of FI. Goodman et al. (2013) tested the effect of a clinical bench-marking tool to improve bowel related care in patients living in care homes. The study did not demonstrate a significant reduction in bowel related problems. However, one care home experienced a reduction in episodes of avoidable FI

A Cochrane review (Norton & Cody 2012) has investigated and compared the effect of biofeedback, pelvic floor exercises, electrical stimulation and sacral nerve stimulation in adults. The limited number of identified trials, together with methodological weaknesses of many, did not allow for definite conclusions, but there are indications on that biofeedback and electrical stimulation may enhance the outcome of treatment compared to electrical stimulation alone or exercises alone. Exercise appears to be less effective than implanted sacral nerve stimulator (Norton & Cody 2012). However, evidence for biofeedback treatment for improving FI in older adults with cognitive impairment or physical limitations was not found, but there is no reason why NH patients with FI may not benefit from biofeedback and exercises if they are able to comply (Wagg et al. 2013). In addition, if associated with loose stools, the constipating drug loperamide may reduce frequency of FI (if infection and other causes have been excluded), but should be used with caution (Lauti et al. 2008).

2.3 CONSTIPATION

Constipation is not a well-defined disease entity, but a general term used to describe the difficulties that a person experiences with moving the bowels. The prevalence of constipation varies dependent on how it is defined, whether it is self-reported or based on criteria, and on the population studied (El-Salhy et al. 2013, Roque & Bouras 2015). Health care staff typically defines constipation as stool frequency of less than 3 bowel movements per week. In contrast, patients tend to define constipation as any form of ”difficult defecation”, such as straining, hard stool, feeling of incomplete evacuation, pain, bloating, and non-productive urge (Rao & Go 2010). Compared to younger patients, self-reported constipation in the elderly is most strongly associated with straining and hard bowel movements in addition to self-digitation, feeling of anal blockage, and two or fewer bowel movements per week (Harari et al. 1997).

The Rome foundation was established in 1991 primarily to standardize consensus-derived criteria of functional gastrointestinal disorders. The Rome III criteria for constipation were published in 2006 and use a combination of subjective (straining, lumpy or hard stools, incomplete evacuation, sensation of anorectal obstruction) and objective (stool frequency, manual maneuvers needed for defecation) symptoms to define constipation (Drossman 2006). Also, constipated patients rarely have loose stools without laxatives and symptoms are distinct from having irritable bowel syndrome (Drossman 2006). For constipation to be defined as chronic, a patient must be symptomatic for at least 6 months with applicable criteria for the previous 3 months (Leung et al. 2011). There is a known disparity between criteria-based and self-reported prevalence rates (Leung et al. 2011), where self-reported prevalence rates seem to be higher (Gallegos-Orozco et al. 2012). Evidence from both disease-specific and generic quality of life instruments has shown that constipation is associated with impaired health-related quality of life (Glia et al. 1997, O’Keefe et al. 1995), and has been linked to physical aggression in the NH population (Leonard et al. 2006).

The prevalence of constipation increases with age, with the largest increase in prevalence after the age of 70 years (Mugie et al. 2011, Leung et al. 2011). Women are 2-3 times more likely to have constipation than men (Mugie et al. 2011, Leung et al. 2011). Between 17-40 % of community-dwelling older adults (O’Keefe et al. 1995, Talley et al. 1996, Wald et al. 2007), and over 50 % of NH patients experience chronic constipation (Gallegos-Orozco et al. 2012). In a review by Roque & Bouras (2015) the age related physiologic colonic changes are reported

as: delayed colonic transit time, thinning/atrophy of internal and external anal sphincter, and decreased rectal sensation, rectal compliance and rectal capacity. These changes may lead to slow transit time, weak sphincters, decreased sensorimotor function and impaired reservoir function. Also, pelvic floor dysfunction has been described in 50 % or more in NH populations. However, the prevalence of pelvic floor dysfunction in constipation in the elderly is not well known (Roque & Bouras 2015). NH patients, dependent on others due to cognitive impairment or mobility dysfunction, may ignore the call to defecate. Suppression of rectal sensation may lead to faecal retention. Increased rectal compliance and impaired rectal sensation can require larger stool volumes to trigger the defecatory urge, with resultant difficulty in evacuation of small stools (Rao & Go 2010).

As in the general population, constipation in older people can be classified as primary (idiophatic or functional) or secondary (iatrogentic or consequence to organic disease), the latter being more common in older people) (Gallagher & O'Mahony 2009). Diseases that are associated with constipation are endocrine or metabolic disorders such as diabetes mellitus and hypothyroidism, gastrointestinal disorders like rectal prolapse, rectocele, colorectal carcionoma, haemorrhoids or anal fissures, neurological diseases such as Parkinson's disease, dementia or cerebrovascular disease, and psychogenetic disorders including depression and anxiety (Gallagher et al. 2008, Roque & Bouras 2015). Several medicines e.g. analgesics, anticholinergic agents, calcium supplements, antipsychotics and iron supplements, are associated with constipation side-effects listed in the medication description (Roque & Bouras 2015). In addition, elderly people are at risk of psychological and social distress since they suffer from decreased mobility and dependence on others, and issues that may develop from social isolation (Roque & Bouras 2015). Also insufficient dietary fibre, caloric intake and exercise have been widely described as risk factors, but the evidence is inconsistent and of low to medium quality (Leung et al. 2011).

In the elderly, chronic constipation can lead to faecal impaction. Although a definition of faecal impaction is elusive, it usually refers to the accumulation of hard faeces in the rectum and colon that the person cannot evacuate alone (Rey et al. 2014). Liquid stools from the proximal colon can bypass the impacted stool, causing overflow incontinence, often mistaken for diarrhoea (Wagg et al. 2013). The research on prevalence and risk factors of impaction is very limited but indirect data suggest that it is highly prevalent among institutionalized elderly patients (Rey et al. 2014). One recent study investigating prevalence and risk factors for impaction in NH

patients found a prevalence of 28 % with a frequency labeling of impaction as a record of at least two episodes of impaction in the last year, and 47 % with a frequency labeling of at least one impaction episode the last year. The same study found a prevalence of 7 % based on a rectal examination performed by a physician when the physician described the faeces as hard and impacted. They also found that the prevalence of FI was 16 % among patients without history of faecal impaction, and 28 % among those with a history of faecal impaction (Rey et al. 2014). In severe cases, faecal impaction can cause stercolar ulcerations, intestinal obstruction or bowel perforation. Although very rare, left untreated, these complications can be life threatening (Rao & Go 2010). Other complications of constipation in older people are related to excessive straining that can contribute to haemorrhoids, anal fissures and rectal prolapse. Excessive straining can affect the cerebral and coronary circulation with resultant syncope or cardiac ischemia (Gallagher & O'Mahony 2009).

The most recent review (Roque & Bouras 2015) of management options for constipation in elderly patients recommends an initial assessment of possible clinical factors that may impact bowel function e.g. drug side effects, defecatory dysfunction, decreased dietary/fluid intake, decreased mobility and dependence on others. This means that treatment needs to be tailored to the patients' medical history, medications, overall clinical status, mental and physical abilities, tolerance to various agents, and realistic treatment prospects. Hence, patients in NHs need individualized bowel programmes (Roque & Bouras 2015). However, in addition to conservative treatments such as dietary fibre, physical activity, fluids etc, laxatives are the cornerstone in the treatment of constipation. Between 50-84 % of NH patients are reported to use laxatives regularly (Hosia-Randall et al. 2007, Gage et al. 2010, Leung et al. 2011, Cusach et al. 2012, Fosnes et al. 2012, Chen et al. 2014). All groups of laxatives are superior to placebo (Ford & Suares 2011). But in contrast to the overall good results in clinical trials, patient satisfaction with everyday use of laxatives is low, only 47 % were satisfied in a survey in the general population (Johanson & Kralstein 2007). However, among laxatives, Roque & Bouras (2015) suggest bulking agents as the reasonable first step, before introducing osmotic laxatives for patients not responding. As there is no clear superior osmotic agent, the dose should be titrated to clinical response. Stimulant laxatives may be introduced to patients who fail to respond to osmotic agents, and may be required in the management for opioid-induced constipation. Suppositories, e.g. bisacodyl, help initiate rectal evacuation. They may be used alone, but preferably with meals to utilise the gastrocolic reflex. Suppositories may be tried as

part of a bowel-training programme in NH patients. Enemas may be used judiciously on as-needed basis, particularly for obstructed defecation and to avoid faecal impaction. Stool softeners seem to have an overall limited effect.

2.4 NURSING HOMES, PATIENTS AND CARE MODELS

To heighten the probability to succeed with an implementation strategy in the health care setting it is important to have relevant knowledge on e.g. how it is organized, the care staff and the patient group. Nursing homes are health care institutions offering 24h health care, social care and accommodation to older people. Most Norwegian NHs are owned and run by the municipality. Some NHs are owned and managed by voluntary organizations but staffed by health-care professionals and funded by the municipality. Only a few NHs are organized and operated as commercial enterprises (Ringard et al. 2013). All NHs are accounted for and subject to governmental control. Despite the fact that both the quality and access to municipal NHs are strictly regulated in national legislation, the services are continuously being criticized. The municipalities are criticized for offering an inadequate number of beds and the health care services are often reported to not living up to official quality standards in terms of time spent with the elderly, the quality of nutrition or medical attention (Pedersen 2014). Although several NHs have a special care unit for patients with dementia, the majority of cognitively impaired patients stay together with cognitively intact patients in general wards. Moreover, some beds in NHs are allocated to palliation and end of life care, and for respite and rehabilitation, often named “short term care” (Ringard et al. 2013). In accordance with the trend worldwide, Norwegian NHs constitute an important part of the national public health care system, and are primarily intended for the frail elderly population (Mørk et al. 2014). In 2014 about 47 % of all yearly deaths in Norway happened in NHs, 32 % occurred in hospitals and 14 % at home (Norwegian Institute for Public Health 2014). In 2011 it is estimated that Norway spends an amount equivalent to 2 % of GDP on services for the elderly. In the same year just below 9 % of the population above 65 and 23 % of the population above 80 lived in publicly financed NHs (Pedersen 2014).

The level of education of the Norwegian NH professionals is to some degree regulated by laws and regulations (Lov om kommunale helse- og omsorgstjenester 2011, Forskrift for sykehjem

og boform for heldøgns omsorg og pleie 2013). NHs are most often managed by Registered Nurses (RNs) and have an agreement with a general practitioner (GP) who visits the NH. Currently, international studies and reports are indicating a shortage of adequately trained staff to take care of the patients' complex health problems and care needs (Harrington et al. 2012, OECD 2013). In Norway, there are no legal requirements for staff-to-patient ratios or specifications for qualifications required for care workers (Ringard et al. 2013). However, Norwegian NHs have RNs on duty 24-hours a day, and according to Statistics Norway the staff comprises on average 31 % RNs/Authorized Social Educators (ASE), 45 % licenced practical nurses (LPN) who are care staff with high school education, and 24 % healthcare aides with no formal health care education (Statistics Norway 2014). In Norway, an ASE has a bachelor's degree and provides daily care to persons in need of it, particularly in connection with people with intellectual disability, including dementia. ASEs have a defined health care and pharmacological competence (SAK 2014). Even though some ASEs were involved in the data collection procedure and were eligible for the intervention, they are very few compared to RNs. Hence, in the rest of this thesis I will use the term RN only.

Nursing home patients

Statistics of Norway report that 81 % of the long-term care patients in NHs have extensive care needs (Mørk et al. 2014). This proportion have risen by 12 % in the period 2007-2013 indicating that the threshold for getting a place in a NH is harder and patients are more vulnerable with more complex care needs (Mørk et al. 2014). The four most prevalent causes for submission in NH are cognitive impairment (42 %), stroke (15 %), mental illness (9 %) and heart and lung diseases (8 %) (Hauge 2014). Most of the NH patients have a combination of two or more chronic medical conditions (Hauge 2014). A study investigating 32 nursing homes including 704 patients in Nord-Trøndelag municipality in Norway, found the mean age for patients to be 84.5 years, 71 % were female, and 82 % had some kind of dementia. The mean number of drugs used was 6.7, and 50 % were registered with some kind of serious somatic disease (Bergh et al. 2012). Among NH patients in Trondheim municipality (n = 980), Saga et al. (2013) found the mean sum score on Barthel's ADL Index with the scores from 0-20 (20 is the best score) to be 9.5 (SD 5.6), mean age to be 85.5 (SD 7.3) years, and 80% of the patients were reported with some kind of cognitive impairment.

Care models and staffing in health services

Rigid schedules and unregulated care providers with limited care education and training often characterizes the NH setting worldwide (Harrington et al. 2012). Historically, four classic models have been used to organize the delivery of nursing care: patient allocation or total patient care, functional or task-oriented nursing, team nursing, and primary nursing (Duffield et al. 2010). Each model varies in work allocation, accountability and communication patterns, and informs different staff mix. There is no evidence in the literature that one particular model is most prevalent, suggesting that the use of nursing care delivery models is subject to local (unit and organization) circumstances. However, some studies have proposed that the level and type of staff, as well as work environment characteristics, might influence which particular models are used (Harris & McGillis Hall 2012, Nakrem 2015).

Two additional concepts of importance in nursing are person-centered care and evidenced based practice (EBP). There is no unified definition of person-centered care, and different terms are used to describe the model. Brendan McCormack (2003: 203) has defined person-centered care as "*the formation of a therapeutic narrative between professional and patient that is built on mutual trust, understanding and a sharing of collective knowledge"*. Being person-centered is about focusing care on the needs of the person rather than the needs of the service. In Morgan & Yoders' (2012) concept analyses they found the following defining attributes for person-centered care: holistic, individualized, respectful and empowering, with the term individualized as the most frequently attribute of person-centered care.

Within the health care community, the contents of EBP are discussed predominantly under the heading "evidence-based medicine". Evidence-based principles, standards, and procedures with regard to other professions, such as nursing, have traditionally played a less dominant role (Hasseler 2006). However, increasing demands have been made for ensuring quality in nursing, stating that the quality of nursing must improve in order to attain better outcomes (Polit & Beck 2012). It must also be borne in mind that patients now have higher expectations of health services and that health is given an important place in our societies (Hasseler 2006). David Sackett (1996) and his colleges have produced the most prominent definition of evidence-based medicine as *"the conscientious, explicit and judicious use of current best external and scientific evidence in making decisions about medical care of individual patients"* (Sackett et al. 1996).

The definition of evidence-based nursing is to a great extent borrowed from medicine, and is defined as *"a method of critically selecting and appraising scientific literature and applying the scientific evidence that has been found to a specific nursing situation"* (Hasseler 2006: 217). In order to include the concept of individual care, an addition was made to the above definition *"an approach to decision making in which the clinician uses the best evidence available, in consultation with patients, to decide upon the option which suite the patient best"* (Gray 2009: 20). The consequence of this is that by using EBP, the individual experience of the nurse (clinical expertise) and the preference of the patient are to be combined with scientific evidence of clinically relevant research (Hasseler 2006). According to Sackett et al. (1996) the individual experience and the expertise of those practicing RBP are an essential requirement for judging whether clinically relevant research should be used in treating the patient (Sackett et al. 1996). Patients' preferences, their social surroundings, and their personal attitudes and outlook should always be taken into consideration (Hasseler 2006).

A growing body of literature is examining the relationship between nurse staffing levels, skill-mix and quality of care provided to patients (Seago 2001, Clark & Donaldson 2008, Harris & McGillis Hall 2012, Twigg et al. 2014). Current staffing in acute care leaves many tasks undone (Ausserhofer et al. 2014), with the tasks essential for safety being prioritized and "relationship" aspects of nursing neglected. "Comfort/talk to patients" was felt to have been left undone by 53 % of the nurses across Europe because of insufficient time (Norway 39 %), develop or update nursing care plans/care pathways was felt to have been left undone by 42 % of the nurses (Norway 39 %), and adequate patient surveillance was felt left undone by 27 % of the nurses (Norway 26 %) (Assuerhofer et al. 2014). There is now substantial evidence related to staffing in acute care settings (Harris & Hall 2012). A meta-analyses concluded that there is a strong association between increased nurse staffing (including both RNs and LPNs) in hospitals and improved patient outcomes, particular in intensive care units and with surgical patients (Kane et al. 2007). As well, a number of reviews have emerged, supporting the association between a richer skill-mix, that is, higher levels of RN staff, and better patient outcomes (Harris & McGillis Hall 2012). Results from a 9 country multinational study by Aiken et al. (2014) showed that an increase in a RNs workload increased the likelihood of an inpatient dying. In addition, the result showed that an increase in the proportion of bachelor's degree RNs was associated with a decrease of an inpatient dying.

Long-term care facilities have received much less attention in staffing-outcomes research, compared with hospitals (Clark & Donaldson 2008, Harrington et al 2012). It is reasonable to assume that even more tasks might be left undone in the NH setting because of lower staff-patient ratios and a skill-mix with relatively few RNs and a relatively high proportion of unskilled care staff compared to the skill-mix in a hospital setting (Harrington et al. 2012). Increasing RN levels has been specifically linked with improved quality of care (Harris & McGillis Hall 2012). As well, long-term care facilities with higher numbers of total nurses are more likely to report higher patient satisfaction, suggesting that richer skill-mix is more important than staff numbers size when attempting to improve patients' outcomes (Harris & McGillis Hall 2012). However, a Cochrane review regarding effectiveness of staffing models in the long-term care setting concluded that additional methodologically sound studies are necessary before any conclusions can be drawn (Hodgkinson et al. 2011).

2.5 IMPLEMENTATION SCIENCE AND CHANGE OF CARE

Early implementation research was empirically driven, and the mixed results of implementation of EBP in various settings might partly be attributed to a limited theoretical basis (Eccles et al. 200, Davies et al. 2010). Poor theoretical underpinning makes it difficult to understand and explain how and why implementation fails or succeeds, thus restraining the development of better strategies to achieve more successful implementation (Nilsen 2015).

Implementation science was born out of a desire to address challenges associated with the use of research to achieve more EBP in health care. Implementation science can be defined as: *the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence to improve the quality and effectiveness of health services* (Bauer et al. 2015). The terms knowledge translation, knowledge exchange, knowledge transfer, knowledge integration and research utilization are used to describe overlapping and interrelated research on putting various forms of knowledge, including research, to use (Grol & Wensing 2013, Nilsen 2015). Implementation is a part of a diffusion-dissemination-implementation continuum: diffusion is the passive, untargeted and unplanned spread of new practices; dissemination is the active spread of new practices to the target audience using planned strategies; and implementation is the process of putting to use or

integrating new practices within a setting (Nilsen 2015). Implementation studies can be either to assess naturalistic variability or measure change in response to planned intervention (Bauer et al. 2015).

There are many examples worldwide of the need for clinical improvements (Grol & Wensing 2013). Clinicians, researchers and policy makers have noticed it takes a long time before research results, or insights relating to effective, efficient, safe and patient-centered care find their way into daily practice (Grol & Wencing 2013). Morris et al. (2011) reported that it takes on average 17 years to incorporate EBP into routine care. Grol & Wensing (2013) suggest that about 40 % of patients across sectors are not receiving care based on current evidence.

The state of the provision of care based on best evidence in the care of older adults is less well understood, but it is indicated that the field may be less developed (Boström et al. 2012, Rahmann et al. 2012). The slow transfer of new research findings into the NH setting can be attributed to a lack of knowledge and understanding of the complex and dynamic mechanism of the social processes that support and hinder this transfer since most of the implementation research has been conducted in acute and primary care settings. This work may not be applicable to the NH setting due to 1) characteristics of the population, 2) the skill-mix of the health care staff, 3) the resources available, and 4) the institutional setting. Understanding the complexity of these elements is important, as change of practice is associated with both organizational and individual factors (Cummings et al. 2007, Boström et al. 2009, Squires et al. 2011, Stokke et al. 2014). These include lack of staff knowledge, staffs attitudes and beliefs towards research, high turnover rates, understaffing, inconsistence regulatory practices, poor or no financial incentives to improve care, and weak management (Rahman et al. 2012).

A review by Boström et al. (2012) found 53 systematic reviews regarding knowledge translation in health care (excluding children, pregnant women and articles published before 1998), including 1709 unique articles, where only 61 investigated knowledge translation relevant for the care of older adults. Of these, 30 articles involved knowledge translation in the long-term care setting. Most (43) of the 61 articles included one type of knowledge translation intervention, primarily targeted at physicians. The topics were most about translation of

evidence related to geriatric syndromes of diseases, medication management and preventive care. However, relatively little of the research involved care processes, probably due to the increased complexity compared to drug trials (Boström et al. 2012). Drug innovations are compatible with existing routines, and are more likely to be adopted than care process innovations such as promoting continence. Continence care is a complex intervention involving coordination of work and relationships among team members with different degrees of education and professional autonomy (Garnham et al. 2009). Another possible reason for the research - practice gap is that traditionally, little has been known about EBP in the NH setting. Today there is growing consensus about a number of best-care practices, ranging from pain assessment to incontinent management and even bathing. Despite these advances, studies have shown that relatively few NHs implement recommended care practices (Rahman et al. 2012).

Effective implementation strategies can be defined as: those strategies, actions, and programmes that lead to the adoption of evidence-based or recommended practices that in turn are associated with change/improvement in NH processes or outcomes (Rahman et al. 2012). The Cochrane Effective Practice and Organization of Care (EPOC) group supports reviews of interventions to improve healthcare systems and healthcare delivery. There is a substantial evidence base to guide choice of implementation strategies targeting health care professionals both at an institutional and at an individual level (Grimshaw et al. 2004, O'Brien et al. 2008, Titler 2008, Forsetlund et al. 2009, Cheater et al. 2010, Flodgren et al. 2011, Grimshaw et.al 2012, Boström et al. 2012, Rahman et al. 2012). EPOC (2015) list and define various implementation activities (EPOC 2015), e.g. distribution of educational materials, educational meetings (workshops), recruitment of local opinion leaders, audit and feedback, patient-mediated interventions, clinical incidence reporting and educational games. Multifaceted interventions are defined by EPOC (2015) as *"an intervention with two or more components",* and may be more or less tailored. Tailored interventions are defined as *"interventions to change practice that are selected based on an assessment of barriers to change"* (EPOC 2015). Grimshaw et al. (2004) reviewed whether there was a dose response curve for multifaceted interventions and observed that effect size did not necessarily increase with increased number of components, and despite this substantial evidence base on implementation strategies, there is no single best strategy; rather a range of implementation strategies can be useful (Rahman et al. 2012). However, they concluded that multifaceted interventions, built upon a careful assessment of barriers and a coherent theoretical base, probably are more effective than single

interventions (Grimshaw et al. 2004, Rahman et al. 2012). Further, that active approaches seem more effective than passive approaches, and that transmission of knowledge seem more likely to be successful if the choice of implementation strategy is informed by an assessment of the likely barriers and facilitators (Grimshaw et al. 2004, Titler 2008, Gresham et al. 2012). Implementation strategies have so far mainly been targeted at improving the knowledge, attitudes or behaviour of health care staff. These strategies appear to achieve a clinically and economically relevant change. However, since many outcomes are not only influenced by performance of individual care providers, organizational changes could offer important mechanism for quality improvement (Wensing et al. 2006).

With background in the knowledge described in this section, we chose to pilot two implementation strategies for change in FI care: a single intervention (SI) involving an interactive workshop and a multifaceted intervention (MI) involving an interactive workshop together with the recruitment of a local opinion leader and educational outreach meetings. In addition we developed and evidence-based guideline for nurse led assessment and treatment of FI (section 4.3, table 2). As mentioned earlier, in addition to making thorough investigations on different implementation strategies, a thorough theoretical underpinning is considered important in the development of an implementation strategy (Grol et al. 2013). Different theories may be relevant to interventions at different levels; for example, theories of individual behaviour are more relevant to interventions directed towards individuals, whereas theories of organizational change may be more relevant to interventions directed at hospitals or NHs (Grol et al. 2013). Several theories can be used to guide the development of an implementation strategy in order to facilitate change, e.g. cognitive theories, motivational theories and pedagogic theories (Grol et al. 2013). For this study, we used pedagogic theory in the development and carrying out the educational intervention.

2.6 TRANSFORMATIVE THEORY AND LEARNING

Implementation of research in health care requires that clinicians gain knowledge of the new procedure, or best practice, and change their everyday practice accordingly. Pedagogy is the discipline that deals with the theory and practice of learning, teaching, education and personal development (Egidius 1994). Transformative learning has become an important theory where

adult learning processes are considered qualitatively different from children, where adults are considered more active problem solvers by constructing meaning of new knowledge based on pre-existing experience and understandings (Tøsse 2011). Transformative theory is created by Jack Mezirow (Mezirow 1997, 2000, 2003). According to Mezirow (1997) a defining condition of being human is that we have to understand the meaning of our experience. In contemporary societies, we must learn to make our own interpretations rather than act on the purpose, beliefs, judgments, and feelings of others. The main goal of transformative learning is to facilitate the development of autonomous thinking among individuals where learning is the process of effecting change in a frame of reference. Adults have acquired a coherent body of experience. Frames of experience are the structures of assumptions through which we understand our life world. We selectively shape and delimit expectations, perceptions, cognitions and feelings. We set "our line of action". Once set, we automatically move from one specific activity (mental or behavioral) to another. We have a strong tendency to reject ideas that fail to fit our perceptions, labeling those ideas as unworthy, irrelevant or mistaken (Mezirow 1997, 2000).

Following Mezirow, a frame of reference encompasses cognitive, behavioral and emotional components, and is composed of two dimensions: habits of mind and a point of view. Habits of mind are broad, abstract, habitual ways of thinking, feeling and acting. Habits of mind are the basic codes that control how we understand and interpret the outside world. Points of view are habitual, implicit rules for interpretation of the world outside that are more easily articulated and more accessible to awareness and feedback from others compared to habits of mind. Thereby, habits of mind are more durable than points of view. Out of this, learning in adulthood is not just to add something new, but also to transform what you already know. In this process, it is essential for learners to become critically reflective of the assumptions underlying intentions, values, beliefs, and feelings. Mezirow distinguishes between two forms of learning: instrumental learning and communicative learning, where instrumental learning includes task-oriented problem solving that are objectively verifiable and where dialogue and discussion plays an insignificant role. In communicative learning, it becomes essential for learners to become critically reflective. The goal is to become automatous, responsible thinkers (Mezirow 1997, Mezirow 2000).

To facilitate learning, educators must help learners become aware and critical of their own and others' assumptions. Learners need practice in recognizing frames of reference and using their imagination to redefine problems from a different perspective. Finally, learners need to be assisted to participate effectively in discussions. Discussion is necessary to validate what and how one understands, or to arrive at a best judgment regarding a belief. In this sense, learning is a social process, and discourse become central to making meaning. The emphasis is on creating an environment in which learners become increasingly adept at learning from each other and at helping each other learn in problem-solving groups. The educator functions as a facilitator and provocateur rather than as an authority on subject matter (Mezirow 1997). Since learning in transformative theory includes establishing new points of view, transform point of view or to transform habit of mind, it might lead to self-threatening situations and exclusion from social groups stating your "old" habits of mind and point of view. This can especially be a problem inside a work place if a person changes through transformative learning and risks social exclusion in his workplace if his new points of view and habits of mind are perceived threatening to the co-workers (Mezirow 2000). Mezirow's transformative theory strongly emphasises empowerment of the individual and the training in the ability of critical thinking (Mezirow 1997, 2000). Therefore, in an implementation strategy involving an educational intervention, the pedagogical framework needs to focus on interactive pedagogical methods to engage the health professionals in conversations and develop relationships that support self-reflection, critical thinking and self-empowerment (Rantz et al. 2001, Benner et al. 2008).

Critical thinking and clinical reasoning

Critical thinking is the disciplined, intellectual process of applying skillful reasoning as a guide to belief or action (Benner et al. 2008). In nursing, critical thinking for clinical decision-making refers to the ability to think in a systematic and logical manner with openness to questions and reflect on the reasoning process used to ensure safe nursing practice and quality care (Benner et al. 2008). In USA, nursing education has emphasised critical thinking as an essential nursing skill for the last 50 years. The ability of critical thinking was emphasised as necessary in the nursing profession (Benner et al. 2008). Later, critical thinking as a concept has been implemented in the curriculum for nursing students in several other countries (Granum et al. 2012). In the Norwegian curriculum for nursing education the concept critical thinking is not explicitly described. In Norwegian higher education the concept "learn to use research and

experience in everyday practice" is used to describe a goal with the aim of educating independent and reflective nurses (Granum et al. 2012).

The definition of critical thinking has evolved over the years. The American Philosophical Association (APA) has one definition of critical thinking, which Scheffer & Rubenfeld (2000) have expanded on through a consensus process, resulting in the following definition: *"Critical thinking in nursing is an essential component of professional accountability and quality nursing care. Critical thinkers in nursing exhibit these habits of the mind: confidence, contextual perspective, creativity, flexibility, inquisitiveness, intellectual integrity, intuition, openmindness, perseverance, and reflection. Critical thinkers in nursing use their cognitive skills of analyzing, applying standards, discrimination, information seeking, logical reasoning, predicting, and transforming knowledge"* (Scheffer & Rubenfeld 2000: 357)

The growing body of research, patient acuity, and complexity of care demand higher-order thinking skills. Critical thinking involves the application of knowledge and experience to identify patient problems and to direct clinical judgments and actions that result in positive patient outcomes. Critical thinking is inherent in making sound clinical reasoning. Clinical reasoning stands out as a situated, practice-based form of reasoning that requires a basis of scientific and technological research-based knowledge about general cases. It also requires practical ability to discern the relevance of the evidence behind general scientific and technological knowledge and how it applies to a particular patient. In doing so, the clinician considers the patient's particular clinical trajectory, their concerns and preferences, and their particular vulnerabilities (e.g. having multiple comorbidities) and sensitivities to care interventions when forming clinical decisions. Situated in a practice setting, clinical reasoning occurs within social relationships or situations involving patient, family, community, and a team of health care providers (Benner et al. 2008).

2.7 THE IMPLEMENTATION OF CHANGE IN FI CARE IN NURSING HOMES

Among NH patients, FI has a high prevalence and potential severe consequences. In addition, FI is often suffered in silence and is associated with embarrassment, shame and reduced quality of life (Wagg et al. 2013, Bliss et al. 2013). Although there are some documented age related

changes in anorectal functioning, FI should not be regarded as a physiological consequence of normal aging alone (Wagg et al. 2013). Potential reversible risk factors are loose stool, impaction, medication, inappropriate laxative use, toilet access, and quality of continence care (Norton et al. 2009, Saga et al. 2013). Constipation and laxative use are prevalent in NH patients, and might be considered interconnected with FI. Because of the complexity of the conditions, there is a need for epidemiological studies investigating the conditions with comprehensive and validated instruments to ensure a reliable reporting of prevalence rates and associations. The interRAI LTCF is a comprehensive, validated and standardized tool to assess patients' holistic health status in the long-term setting that also enables comparison between different setting and countries.

A challenge in NH research is that the units of observations are clustered as patients are grouped in NHs, and there is a need to investigate how this might affect the results in this population (Rabe-Hesketh & Skrondal 2012). In addition, prevalence of FI (Brocklehurst et al. 1999, Saga et al. 2015), constipation and laxative use (Gage et al. 2010) have been found to vary to a large degree between NHs. The variation in FI, constipation and laxative use rates between patients and between NHs is poorly understood (Wagg et al. 2013). Hence, we need more studies with a design that includes analyses that discriminate between variability due to individual patient factors and factors related to the NH unit.

Even though both constipation and FI are prevalent and interconnected conditions in NH patients, this project group wanted to emphasise FI when planning an implementation strategy for change of bowel care in NHs. Despite the importance of epidemiological studies investigating FI with a validated instrument, it is also important to act on what we already know: many NH patients do not receive best practice FI care (Wagg et al. 2013, Saga et al. 2014). One of the research recommendations in Norton et al. (2009) and again in Wagg et al. (2013) is to investigate whether education of health care staff with regards to heightening awareness of the problem plus evidence-based methods for identification, assessment and management of FI will lead to a change in FI care and reduced prevalence of FI in NH patients. In general, there are few studies investigating strategies for implementing change of care in the NH setting (Boström et al. 2012, Rahman et al. 2012), and to our knowledge there are no studies investigating implementation of best practice related to FI care.

3. AIMS

The objective of this thesis was to investigate prevalence and associations of FI, constipation and laxative use among NH patients, and to develop an implementation strategy to improve FI care in nursing homes. This was achieved by conducting studies with the following aims.

Paper I: Investigating FI in NH patients using the validated instrument interRAI (LTCF). Secondly, to investigate the effect of clustering of observations and to study variance on both the NH level and the patient level.

Paper II: Investigating constipation and laxative use in NH patients using the validated instrument interRAI (LTCF). Secondly, to investigate the effect of clustering of observations and to study variance on both the NH level and the patient level.

Paper III: Investigating feasibility, acceptability, and adherence of two educational programs for care staff concerning nursing home patients' FI.

Paper IV: Developing a detailed protocol for a planned cluster-randomized controlled trial (C-RCT) investigating effect of a multifaceted educational program for care staff concerning FI in NH patients.

4. METHODS

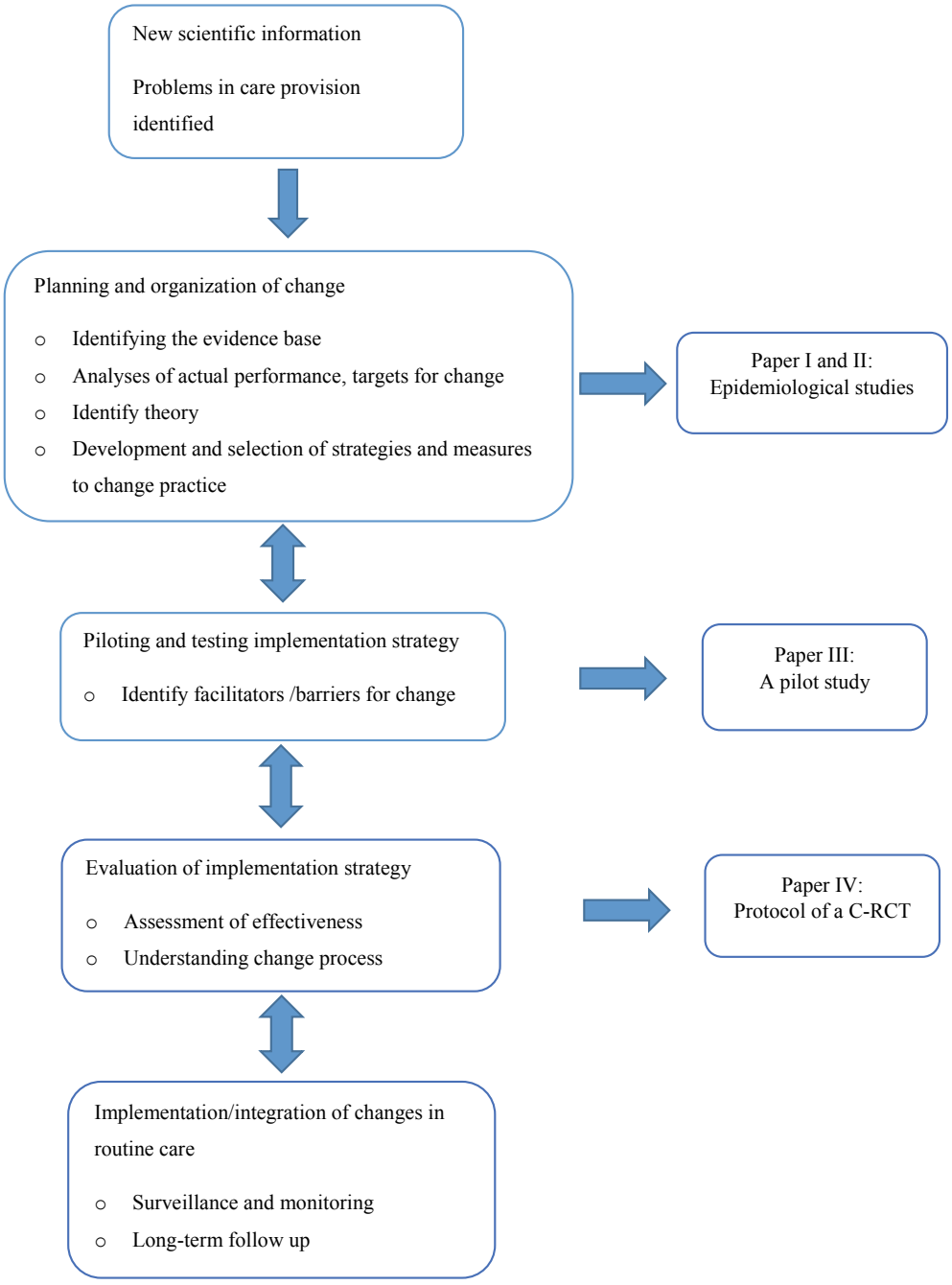
The model described in figure 1 depicts the working process for this thesis. Even though the figure might give an impression of a linear process, this was not the case. The project group, comprising project manager, PhD-candidate and four researchers, worked back and forth between the already published evidence-base, theory and our own research where we originally planned to start directly on testing the effect of an educational programme on change of FI care for care staff. In the planning phase, we acknowledged that we needed to include a pilot study (Paper III). Even though the epidemiological studies on FI, constipation and laxative use (paper I and II) in reality did not come first in time, I chose to present them first in this thesis. They are a result of a continuum of the already published evidence base and our own research. The protocol of the planned C-RCT (paper IV) is part of the phase of evaluating an implementation strategy for change in FI care in NHs.

4.1 STUDY DESIGN

The studies in paper I and II have a cross-sectional design based on data collected as part of baseline (t_0) in the planned C-RCT. Data were collected in the period August to October 2014. Paper IV presents the protocol of the planned C-RCT. For the C-RCT first follow up (t_1) was collected in the period January to February 2014, and second follow-up (t_2) was collected in the period May to June 2014. Results of the C-RCT based on t_1 and t_2 are not part of this thesis.

The study in paper III was designed as an external pilot study with pre-post measurements. The duration of the educational intervention was 3 months. Data were collected in August-September 2013 (t_0) and in January 2014 (t_1). The pilot study was designed as an external pilot which is a small scale version of larger study under planning which is not intended to be a part of the planned study (Thabane et al. 2010, Eldridge & Kerry 2012). An educational intervention is defined as a complex intervention, and piloting and feasibility work are highly recommended before evaluating the intervention in a trial (Craig et al. 2008, Eldridge & Kerry 2012). Three NHs were recruited representing each intervention arm in the planned C-RCT: single intervention (SI), multifaceted intervention (MI) and control (table 2).

Figure 1. The working process for this thesis for implementing change in FI care in NHs[1]



[1] Based on the The Grol and Wensing Implementation of Change Model (Grol & Wensing 2013: 46) and MRC guidance for developing and evaluating complex interventions (Craig et al. 2008: 8)

4.2 SETTINGS, RECRUITMENT AND UNITS OF INVESTIGATION

The setting for the study as a whole was NHs in one urban municipality. The recruitment process started by obtaining an approval from the director for health and social affairs in the municipality. For papers I, II and IV, the study was presented in a meeting where managers from the NHs were gathered and they were invited to participate. NHs accepting the invitation were eligible for inclusion. NH units were enrolled until the target patient sample size for the C-RCT was reached. For papers I, II and IV, out of 27 available NHs, 20 NH units from 10 NHs were recruited. For paper III, out of the 27 available NHs in the same municipality, six NH units from three NHs were recruited (figure 2). The three NHs recruited for the pilot study (paper III), were not eligible for recruitment for the C-RCT.

NH units with comparable staff/patient ratio on the day shift and GP coverage were selected. NH units designated with a specialty or with an enhanced care staff/patient ratio were excluded. All long-term care patients with a stay of four weeks or longer, were eligible for inclusion. For paper III and IV, RNs working half time or more were eligible for participation in the workshop and to be recruited as an opinion leader in the intervention group (see table 2). Exclusion criteria were working less than half time or only night shifts. All care staff members were invited to the educational outreach meetings throughout the intervention period. Table 1 shows units of investigation in the different papers.

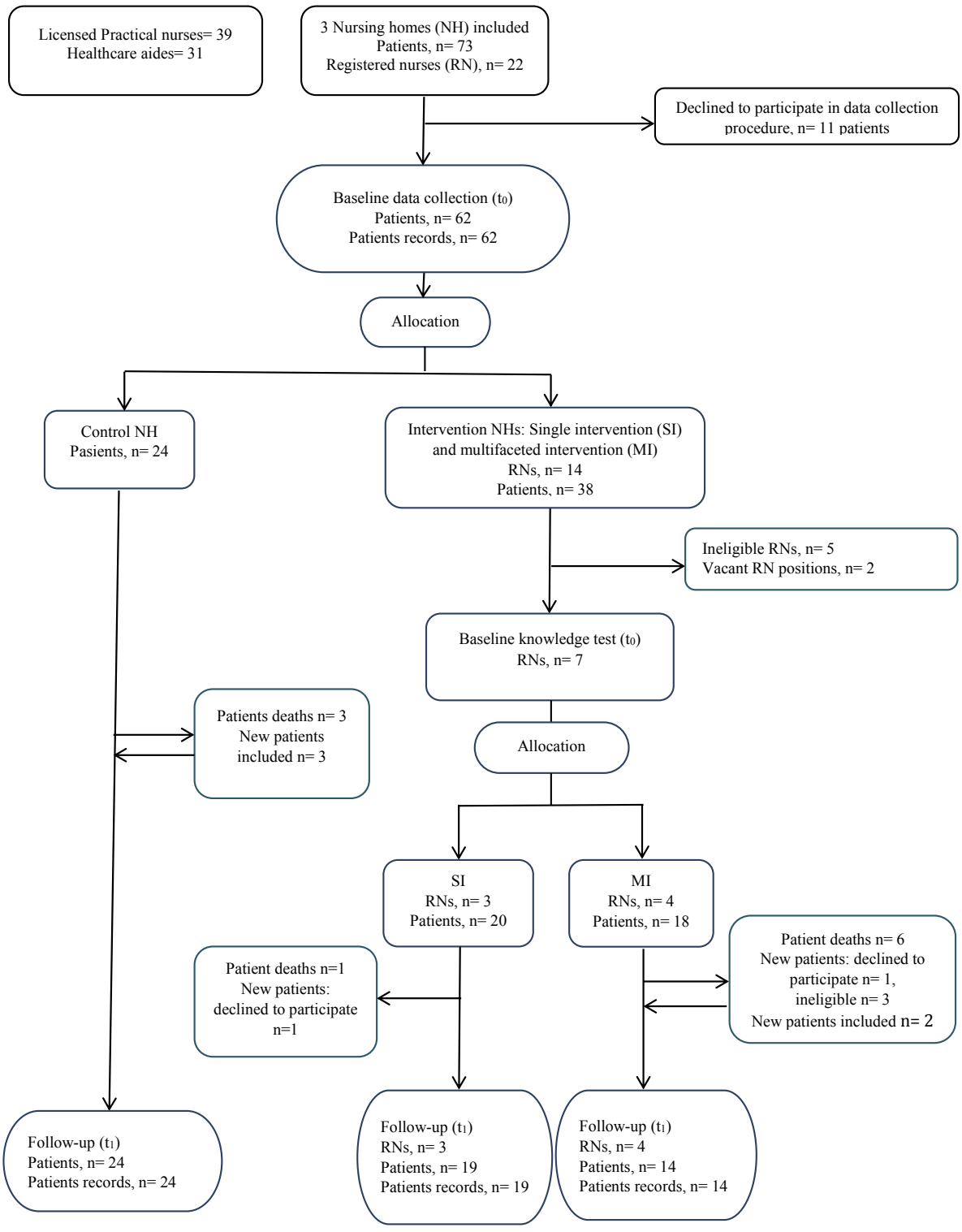
Table 1 Units of investigation in the different papers

Theme	Units of investigation
Prevalence and associations of FI[1]	Nursing home patients
Prevalence and associations of constipation and laxative use	Nursing home patients
Feasibility of two educational programmes for health care staff on patients FI	Registered nurses EPR[2] Nursing home patients
Effect of an educational programme for health care staff on patients FI: a protocol	Registered nurses EPR Nursing home patients

[1] Faecal incontinence

[2] Printed nursing documentation from the electronic patient record (EPR) in accordance with the audit instrument N- Catch

Figure 2. Flow chart of the inclusion and allocation of nursing homes (paper III)



4.3 THE IMPLEMENTATION STRATEGY: AN EDUCATIONAL PROGRAMME

The educational programmes were developed according to recommendations from implementation science and pedagogic theory as presented in the theory base of this thesis (Mezirow 1997, Mezirow 2000, Mezirow 2003, Grimshaw et al. 2004, O'Brian et al. 2008, Titler 2008, Forsetlund et al. 2009, Cheater et al 2010, Flodgren et al. 2011, Boström et al. 2012, Rahman et al. 2012, EPOC 2015) (Table 3). To ensure a realistic intervention, one of the researchers (PhD-candidate) had two meetings with experienced NH nurses to collect their comments on content and intensity of the educational programme and on the FI-guideline (see below).

The project group developed a FI-guideline for nurse led assessment and treatment of FI based on international best practice recommendations (NICE 2007, Norton et al. 2009, Herdman 2012, Bulech 2013). The FI-guideline facilitated a systematic assessment and included questions related to bowel symptom history and bowel patterns. As FI among NH patients is considered to have a complex aetiology, the guideline facilitated the RNs to consider a range of possible causes. Examples are loose stools, immobility, cognitive impairment, impaction, use of laxatives. Based on this assessment, the RN defined a nursing diagnosis, for example: *FI related to loose stools, possible due to incorrect doses of sodium picosulphate, urgency and reduced mobility. This leads to FI episodes with loose stool and red perineal skin.* The guideline then offered a range of possible interventions. Individualization of the nurses' diagnoses and the interventions for each patient was emphasised. The FI-guideline was introduced during a workshop (see below).

The workshops were organized by having all RNs sitting around a table together with the educator (PhD-candidate). It was important that the care managers were present at the workshop. As a consequence of the chosen theoretical frame from adult learning and Mezirows' (1997, 2000, 2003) transformative theory, it was important to recognise the knowledge and experience present among RNs and health care staff in general. The health care staff in the NHs has the best knowledge of the patients living there. The theoretical content, including topics for discussion and the FI-guideline, was introduced through a power point presentation. During the cased-based discussions, the RNs used real patient cases where they used the guideline to assess the patients' bowels and develop a care plan. How to integrate the use of the guideline to the electronic documentation system was an important issue. The electronic patient record (EPR)

is the most important tool for care staff to communicate their assessments and care plans in order to secure continuity in care. This was addressed by having access to a "learning module" in their local EPR, and the result of the assessment was input into the EPR during the workshop. The topics for the workshop were made available for the RNs as printed educational material. The most important pedagogic tool for the educator through the intervention as a whole was to empower the RNs clinical reasoning and critical thinking by asking questions in order to facilitate discussions among the RNs on assessment and realistic best practice options for the individual patient. The local opinion leader was recruited after the workshop based on the informant method (Flodgren et al. 2011). This was done by discussing with the care manager which of the RNs was considered to be able to influence and motivate the staff in general. The care manager had the responsibility for facilitating adherence to the programme and the guideline together with the opinion leader. The local opinion leader and care manager received a 1.5h additional educational meeting on how to fulfill their roles in the programme.

Table 2 Content of the educational programmes with an intervention period of 3 months

Single intervention (SI)[1]	**Multifaceted intervention (MI)**
Workshop** (7 hours) • 3 hours theoretical introduction • 3.5 hours cased-based discussion using the FI-guideline	Workshop[2] (7 hours) • 3 hours theoretical introduction • 3.5 hours cased-based discussion using the FI-guideline Recruitment of a local opinion leader[3] Six 1.5 hours educational outreach meetings[4]

[1] Analyses of data from the pilot study (paper III) resulted in the use of the multifaceted intervention in the planned C-RTC (paper IV).

[2] Educational meeting defined by EPOC as "participation of health-care providers in conference, lectures, workshops, or traineeship" (Grimshaw et al. 2012)

[3] Local opinion leader defined by EPOC as "use of provider nominated by their colleges as educational influential" (Grimshaw et al. 2012), recruited after the workshop based on the informant method (Flodgren et al. 2010)

[4] Educational outreach meetings defiend by EPOC as " use of a trained person who meets with providers in their practice setting to give information with the intention of changing the providers practice" (Grimshaw et al. 2012)

4.4 DATA COLLECTION

After accepting the invitation to participate, meetings were arranged where RNs were trained in how to fill in the questionnaires. In the pilot study (paper III) we tested a strategy where the researcher (PhD-candidate) arranged two information meetings per NH: one 1 hour meeting on general information and to initiate the procedure for consent from patients or their next of kin, and one 3 hour meeting for information and training in the data collection procedures. Both meetings were arranged in the NHs. Participants were the RNs who were selected by the care manager to fill in the questionnaires. The care managers were also present. The meetings also included training in using the interRAI LTCF standardized coding guidelines provided in the instrument's training manual (Morris et al. 2012). The care managers were trained in the procedure for extracting data from the electronic patient record (EPR) in accordance with the audit instrument N-Catch (Johnsen et al. 2014, Nøst et al. 2015), and were responsible for the filling in of the organizational characteristics.

In the pilot study (paper III) we recruited one RN from each unit, a total of six RNs to be included in the data collection procedure. The RNs in the same NHs were advised to work together to enhance the clinical judgment when filling in the forms. In addition, RNs used information from the EPR, co-workers and the patients when completing the questionnaires. In order to obtain additional information on feasibility, adherence and acceptability in paper III, qualitative data were collected by one focus group interview one month after the end of the intervention. In this study we used a purposive sampling strategy in order to obtain cases deemed information-rich for the purpose of the study (Sandelowski 2000). All RNs and care managers from the two NHs receiving intervention participated in the interview. To receive additional information, we conducted four focused individual interviews by interviewing one RN and the care manager from the two intervention NHs. One of the researchers not involved in the intervention moderated the focus group interview. The responsible researcher (PhD-candidate) was present and could ask questions to explore a theme. The responsible researcher performed the individual interviews.

RNs and care managers reported the procedure for information and training in data collection to be satisfactory. Therefore, the same procedure was followed for collection of base-line data

for the C-RCT, and thereby the cross-sectional studies (paper I and II). One important difference was that the ethical committee released the study from gathering consent from the patients; hence the procedure involving gathering consent from patients was excluded from the C-RCT. A total of 20 RNs were recruited for data collection, one per NH unit (two per NH). NHs received economic compensation in order to release the RNs from daily work for filling in the questionnaires.

4.5 MEASURES

A description of the measures in the papers is presented in table 3. A more thorough description of the individual variables, scales and criteria is presented in the different papers.

Table 3 Measures and criteria for feasibility, adherence and acceptability used in the papers

Paper	Theme	Measures and criteria
I	Prevalence and associations of FI	interRAI LTCF[1], section C-O. FI[2] measured by section H3: Bowel continence St. Mark's Incontinence Score Fecal Incontinence in Nursing Home Questionnaire
II	Prevalence and associations of constipation and laxative use	interRAI LTCF, section C-O. Constipation measured by section J3l: Constipation. Laxatives use measured by section N: Medications Fecal Incontinence in Nursing Home Questionnaire
III	Feasibility of two educational programmes for health care staff on patients FI	**Feasibility criteria:** 1. Acceptable recruitment process 2. ≥ 80% completed questionnaires returned 3. ≤ 10% missing data in each completed questionnaire 4. ≥ 0.5 mean change on the frequency scale on the primary outcome measure 5. Acceptable time use for RN[3]'s involved in the data collection **Adherence criteria:** 6. ≥ 95% of the recruited RNs participated in the workshop 7. ≥ 70% of the health personnel participated in the educational outreach on each actual day 8. ≥ 90 of the patients assessed by the FI-guideline 9. ≥ 80% of the assessment specified by the FI-guideline reported in the electronic patient record **Acceptability criteria:** 10. Acceptable performance of the knowledge test according to sensitivity to change in knowledge 11. Satisfaction from RNs regarding the educational intervention 12. Satisfaction and acceptability from RNs regarding the FI guideline 13. Acceptable level of barriers versus facilitators for change in the nursing homes
IV	Protocol describing a C-RCT investigating on educational programme for health care staff on patients FI	interRAI LTCF, section C-O. Planned primary outcome, FI, measured by interRAI LTCF section H3: Bowel continence Knowlegde-test N-Catch St. Mark's Incontinence score Fecal Incontinence in Nursing Home Questionnaire Process evaluation form

[1] Resident Assessment Instrument for Long-Term Care Facilities
[2] Faecal incontinence
[3] Registered nurse

The Resident Assessment Instrument for Long-Term Care (InterRAI LTCF)

Today, most NH patients have complex health problems and care needs (Harrington et al. 2012, Mørk et al. 2014). The complexity of these patients translates into various degrees of functional, cognitive, social and psychological impairments, and the result is a tangle of interdependent factors that connect in different patterns in different patients. Only by using comprehensive and reliable data with understandable and comparable constructs can one begin to make progress in determining cost effective services that maintain quality of care. There has been an evolution in the process of developing assessment instruments in order to obtain reliable patient data. First generation instruments were a large number of standalone scales designed to measure a single construct for a single purpose (e.g. Barthels Index for Activities for Daily Living). The strengths of these instruments lies in their discrete measurement rules and, for the best, extensive testing for psychometric properties and use in clinical trials. However, these instruments cannot be used together to produce efficient and reliable integrated multidimensional assessment tools. Attempts to use clusters of these instruments often result in cumbersome assessment approaches employing overlapping assessment items and conflicting assessment methods (Carpenter & Hirdes 2013).

In the United States, major scandals in long-term care of older people led to a need for a uniform comprehensive resident assessment system and the development of the Minimum Data Set that was implemented in all US nursing homes in 1990-92. A comprehensive assessment of physical, cognitive, psychological and social status was seen as the cornerstone of high quality care, identifying the issues requiring individualized care planning so that the best outcome of care can be achieved. A revised version with over 400 data items, MDS 2.0, was released in 1995 (Carpenter & Hirdes 2013).

Based on the earliest reliability findings, questions were raised as to the suitability of the MDS for research purposes (Poss et al. 2008). The international collaboration interRAI was founded in 1992, and is a not-for-profit corporation. Ongoing development by interRAI has resulted in a revised suite of instruments that was announced in 2005, including a revised version of MDS known as the Resident Assessment Instrument for Long-Term Care Facilities (interRAI LTCF). Design considerations have included measures of reliability along with clinical utility and the capability to harmonize measures with instruments used in other settings (Poss et al. 2008). The

interRAI LTCF is substantially shorter than the MDS and reliability performance was one of the central considerations in determining the inclusion or exclusion of items (Carpenter & Hirdes 2013). InterRAI LTCF comprises 257 items and measures patients' functional, medical, cognitive, and psychosocial status. A study investigating and comparing reliability in the different instruments (interRAI Long-Term Care Facility, interRAI Home Care, interRAI Post Acute Care, interRAI Palliative Care, and interRAI Menthal Health) in 12 countries, found the majority of the items to exceed standard cut-offs for acceptable reliability, and the interRAI LTCF had the highest mean kappa (0.74) (Hirdes et al. 2008). Also Onder et al. (2012) found interRAI LTCF a reliable instrument which can be used to assess the characteristics of NH patients, and that it can be used to compare characteristics of NH patients across Europa. Both Mor et al. (2003) and Hirdes et al. (2008) found urine and faecal incontinence among the items with the best kappa values.

In addition to the individual assessment items, interRAI LTCF generate scales to provide severity measures. The Cognitive Performance Scale (CPS) (Morris et al. 1994, Poss et al. 2008, Shin & Sherer 2009), Activity of Daily Living long form scale (ADLlf) (Morris et al. 1999, Poss et al. 2008, Shin & Sherer 2009), The Aggressive Behavior scale (ABS) (Perlman & Hirdes 2008), and the Revised Social Engagement Scale (RISE) (Gerritsen 2008) are overall reliable and valid measures. The Depression Rating Scale (DRS) has shown more varying results on validity (Burrows et al. 2000, Shin & Sherer 2009, Liang et al. 2014). The Changes in Health, End-Stages Disease, and Signs and Symptom (CHESS) scale has been found reliable in predicting mortality (Hirdes et al. 2003, Poss et al. 2008, Armstrong et al. 2010, Hirdes et al. 2014). However, as a measure of frailty, when compared to other frailty measures, the correlations between CHESS and two other frailty measures (Edmonton Frail Scale, and the frailty index) were low (Armstrong et al. 2010). Hogan et al. (2012) investigated three different frailty measures, including CHESS, and found the clinical implications and opportunities of detecting frailty in more vulnerable older adults to require further investigation.

St. Mark's incontinence score

In order to get some additional information of type of FI (gas, loose, or solid stool), urgency, and impact on daily life a Norwegian version of the St. Mark's anal incontinence score (University Hospital of North Norway 2015) was used. On the St. Mark's score, the frequency

of leakage of solid and liquid stool, gas and alternation of lifestyle are measured on a five-point scale (never, rarely, sometimes, weekly and daily). St. Mark's score also includes three questions with dichotomous items regarding the use of pads, constipating medicines (no = 0, Yes = 2), and the ability to defer defecation for 15 minutes (no = 4, yes = 0). The total St. Mark' score gives a score from 0 (complete continence) to 24 (complete incontinence). Evaluations have shown various evidence of the psychometric properties of the total and individual St. Mark's score (Sansoni et al. 2013), were the item about flatus incontinence as the one with the poorest evaluations (Bols et al. 2010, Sansoni et al. 2013). However, the total St. Mark's score and the four individual items were found to have excellent or adequate test-retest reliability (Bols et al. 2010). Maeda et al. (2007) found St. Mark's score to correlates moderately well with patients' subjective perception and as reliable regardless of type of incontinence, patients' age, or gender (Maeda et al. 2007). However, the instrument has not been tested on the NH population where it is difficult to ask patients about their FI because of cognitive impairment, and where the questionnaire has to be completed by a RN as proxy.

Fecal Incontinence in Nursing Home questionnaire

We also used a questionnaire developed by Saga et al. (2013) to measure change of bowel care in NH. The questionnaire was piloted in one NH by several RNs. A research nurse administered the testing, and gathered feedback regarding the questionnaire from the participating RNs (Saga et al. 2013). The questionnaire included items about FI, constipation, diarrhoea, urinary incontinence, cognitive impairment, medical diagnosis and drugs. It also included Barthels ADL Index and questions about RNs management of FI, constipation and diarrhea where RNs were offered a list of interventions relevant for the conditions, and asked to identify what is done for each individual patient (Saga et al. 2013).

N-Catch

N-Catch was used as a measure of change in care as reported in the EPR. The feasibility of the instrument was investigated in the pilot study (paper III). N-Catch is a validated audit instrument for care staff reports in the EPR (Paans et al. 2010, Johnsen et al. 2014, Nøst et al. 2015). N-Catch measures the quality of the content in the EPR on a scale from 0-32 where 0 is low quality and 32 is high quality. The instrument includes criteria for both quantity and quality

of content. In order to get a score on quantity the different parts only need to be present in the EPR (health status and a nursing care plan including nursing diagnoses, outcome, interventions and evaluations). To get a high quality score, the content is assessed according to criteria reflecting clinical reasoning and critical thinking: does the assessment of health status seem sufficient, do the nurses' diagnoses have a logical focus and aetiology, and are the outcomes and interventions individualized, relevant and realistic (Fesler-Birch 2005, Banning 2008, Lunney 2010, Paans et al. 2010, Herdman 2012, Bulechec 2013, Johnsen et al. 2014).

Knowledge test

In order to measure change in knowledge among RNs, a study specific knowledge test was developed and investigated for feasibility in the pilot study (paper III). The test was designed as a multiple choice test and developed by the researchers according to established guidelines (Sirnes 2005). The knowledge test had 26 questions related to anatomy and physiology of the gastrointestinal tract and bowel care. During the development of the test, it went back and forth between members in the project group before it was tested in the pilot study. The included RNs reported no need to make changes in any of the questions. In addition, four colleagues in the university college were invited to answer the test. This resulted in a minor change in two of the questions.

Background data

For all papers background information on patients' gender, date of birth and length of stay was obtained. For paper III and for the planned C-RCT we also obtained organizational characteristics for each unit; number of patients beds, number of RNs, LPNs and health care aides in full-time equivalent and total number of each category employed, and number of formalized meetings with GP per week. We also gathered information on RNs age, gender, educational level, years since qualified and length of employment at the present site.

4.6 SAMPLE SIZE AND POWER CALCULATIONS FOR THE PLANNED C-RCT

Sample size calculations were based on the primary outcome: prevalence of FI among patients. The power calculations have taken into account the results from the pilot study (paper III). Based on these we hypothesized that a reasonable and clinical important effect size in the intervention group compared to the control group would be 15% between the two groups in proportions with FI. As the design was a cluster-randomized trial, we needed to adjust for clustering. Intra-cluster correlation coefficient (ICC) was estimated to 0.04. The estimate was based on published patterns in ICCs (Eldridge et al. 2004, Eldridge & Kerry 2012, Health Services Research Unit in Aberdeen 2013) and results from the pilot study where the ICC was calculated to be 0.038. In addition, we had access to the FI variable with the categories 0-4 from an epidemiological study of 980 NH patients in Trondheim municipality (Saga et al. 2013) with an ICC calculated to 0.028. Based on the assumptions of the mixed logistic binominal model, 5% level of significance, test strength of 80 %, an average cluster size of 15 patients, and an ICC of 0.04, a study population of 103 patients in each arm of the C-RCT was needed. The number of individuals in each cluster is set because each unit has a fixed number of beds. Assuming a 15 % dropout, the sample needed was 120 patients in each arm. This means a total of 240 patients and about 20 NH units.

In addition, sample size according to patients' records was calculated. N-Catch measures the quality of the content in the EPR on a scale from 0 to 32 where 0 is low quality and 32 is high quality. Based on the assumption of a paired t-test, a 5 % level of significance, test strength of 80 %, an effect size of 3 points and an ICC of 0,04, records from 6 patients per cluster are needed. This requires a total of 146 records.

4.7 ANALYSES

Several types of statistical analyses were used depending on the research question, the variables and the distribution of the responses. Descriptive data were used to present and evaluate demographic and clinical characteristics of the samples, presented as frequencies (%), means (standard deviation, SD) and range. Statistical calculations were performed using IBM SPSS for Windows version 21 (paper III), and STATA version 13 for paper I and II. The C-RCT will

be analysed by Stata. For the qualitative research questions we used qualitative content analyses. Details regarding general and specific analyses are presented below and in each paper.

Paper I and II

InterRAI LTCF defines faecal incontinence on a scale from 0 to 5; 0 = continent, 1 = control with a stoma, 2 = seldom incontinent, 3 = occasionally incontinent, 4 = often incontinent, 5 = incontinent, and 8 no bowel movement the last three days. After investigating other studies (Kinnunen 1991, Borrie & Davidson 1992, Harrington et al. 2011), and what seemed clinical significant for the C-RCT based on the result from the pilot study (paper III), we set cut-off between 2 and 3, defining patients with the scores 3 to 5 as incontinent. Constipation was defined as no bowel movements the last three days or problems with hard stools with the scorings 0 = not constipated, 1 = problems with constipation, symptoms of constipation present, but not the lasts three days, 2 = symptoms of constipation present 1 of the last 3 days, 3 = symptoms of constipation present 2 of the last 3 days, 4 = symptoms of constipation present 1 daily for the last three days. All patients with the scores 1 to 4 were defined as constipated. Patients were defined as laxative users if they had a prescription for regular use of at least one laxative.

InterRAI LTCF offers a large number of variables for investigating associations with the dependent variables faecal incontinence (paper I), constipation and use of laxatives (paper II). Univariable logistic regression analysis was conducted on the variables identified under the section *data collection* in paper I and II. We used perceived clinical significance, Log likelihood, McFadden's R^2 and $p \leq 0.05$ to assess degree of impact on the outcome variable to inform the choice of variables to include in the multivariable model. To ensure sufficient events per explanatory variable in the multivariable model, the ratio was set at a maximum of 10:1 (Peduzzi et al. 1996). Effect sizes are presented as odds ratios (OR) with 95 % confidence interval (CI) and p-values. Variables were considered significant if $p < 0.05$, but p-values between 0.01 and 0.05 were interpreted with caution due to multiple comparisons. To investigate the effect of clustering, the multivariable logistic regression model was tested against a mixed effects logistic regression model with the NH units treated as a random effect. Investigation during the pilot study (paper III) revealed that units in NHs in the municipality

were comparable with the functional definition made by Estabrooks et al. (2011) and thereby one unit was defined as one cluster for the analyses.

Paper III

Descriptive statistical analyses were performed to evaluate feasibility criteria 1-10, while qualitative analyses were used to evaluate feasibility criteria 11-13 (table 3). All interviews were audiotaped, transcribed verbatim and analyzed by qualitative content analysis in accordance with Graneheim and Lundman (2004). First, two researchers (PhD-candidate and another researcher) reviewed the text independently several times to receive a general impression of the content and to write down preliminary topics addressing the criteria (11- 13). Second, the researchers met to critically discuss their individual general impressions and the preliminary topics. Third, words, sentences or paragraphs related to the content areas were identified and defined as meaning units. The meaning units were then condensed and labelled with a code. Fourth, the codes with similar meanings were grouped into categories. Related categories were then abstracted to themes with the intention to reveal the underlying meaning on an interpretive level (Graneheim & Lundman 2004). The process from meaning units to themes went back and forth as members of the project group gave their feedback in the process of analysis.

Paper IV

The primary outcome measure for the C-RCT is prevalence of faecal incontinence. See above (section 3.6, paper I and II) for description of the variable. Repeated measures mixed logistic binominal model will be used to determine the evolution of FI over the three time points of measurements. Because of the relatively high risk of death and movements out of clusters, data will be treated as cross-sectional time series, with the prevalence among all patients present in the cluster at baseline included as a covariate in the analyses.

4.8 ETHICAL CONSIDERATIONS

The study was approved by the Regional Committee for Medical and Health Research Ethics (REK) (Paper I, II, IV: 2013/1802/ REK North, paper III: 2013/755 REK North) and by The Norwegian Social Science Data Services (Paper I, II, IV: 36482/2/ MB, paper III: 35020). An essential ethical consideration in this study was whether or not informed consent should be obtained from patients or their representatives. For the pilot study (paper III) the patients were given written information about the study and had the opportunity to withdraw themselves from data being gathered. In cases were the RNs assessed a patient as not cognitively competent to read and understand the information, the letter was sent to the patients representatives. After evaluating the overall study involving paper I, II and the planned C-RCT, the REK authorized RNs with dispensations from the duty of confidentiality to gather relevant patient health information (proxy data). Since dispensation was given, patient consent was not obtained. The justifications of the conclusion were 1) the process of assessing the patients cognitive ability to read and understand information before distributing the information letter to the patients or their representatives, was considered as inconvenient for patients and time consuming for care staff who had to be the ones doing the task, 2) the gathering of data would not involve interviewing or examining patients, the data in question was based on assessments made by RNs with good knowledge of the patients, and 3) patients were not the ones recruited to participate in the intervention. Informed consent was obtained from RNs participating in the interviews (paper III) and for the RNs before answering the knowledge test. All patient information was de-identified by care staff before transfer to the researcher (PhD-candiate). The study was performed in concordance with the Declaration of Helsinki (Declaration of Helsinki 2013). Both the pilot study and the C-RCT are registered in the clinical trial registry with the numbers NCT01939821 and NCT02183740, respectively.

5. SUMMARY OF RESULTS

Paper I: Exploring Faecal Incontinence in Nursing Home Patients: a cross-sectional study of prevalence and associations derived from the Residents Assessment Instrument for Long Term Care Facilities.

The primary aim of the study in paper I was to invstigate prevalence and association of FI in NH patients using the comprehensive instrument interRAI LTCF and St Mark's incontinence score. A secondary aim was to investigate the effect of clustering of observations and to study variance on both the NH unit level and the patient level by analyzing data using mixed effects models. The study included all patients (n = 261) within eligibility criteria from 20 NH units. Prevalence of FI in NH patients was confirmed as high. However, prevalence rate varied due to definition and frequency labeling. In this study, dependent on the chosen cut off on the scale measuring FI in interRAI LTCF, prevalence varied from 42.1 to 54 %. By using frequency labeling defined by the St. Mark's score, at least one episode in the last four weeks, prevalence was 70.1 %. This displays the importance of using clear definitions together with standardized instruments when investigating FI.

InterRAI LTCF has a high number of variables which gave us the opportunity to explore a range of possible associations using univariable logistic regression. This resulted in 17 variables found to be significantly associated with FI. Because of the 10: 1 rule (Peduzzi et al. 1996), a maximum of 11 variables could be included in the multivariable model. The final results identified deficiencies in ADL, cognitive impairment, urinary incontinence and diahrrea as risk factors, and involvement in activities and instability in health/frailty as protective factors. Mixed effects analyses showed that the effect of clustering by NH unit was not statistically significant, and that most of the variance in faecal incontinence (88 %) could be attributed to differences in individual patient characteristics. FI is potentially preventable and treatable by offering NH patients' individualized FI care matching their patient characteristics.

RNs managed to fill in the questionnaire on all patients (n = 261), which indicates high feasibility with the instrument. A mean percentage of missing values in single items of the completed questionnaire was 0. 8 %. Cronbach's alpha for the summated scales were as

follows: ADLlf = 0.93, COMM = 0.88, ABS = 0.73, RISE = 0.81, DRS = 0.69. This study found InterRAI LTCF a very useful instrument because of its combination of a comprehensive range of individual items and scales giving a holistic picture of the patients, allowing for comparison of immediate or long-term change in patients status.

Paper II: Constipation and laxative use among nursing home patients: prevalence and associations derived from the Residents Assessment Instrument for Long-Term Care Facilities (interRAI LTCF).

The primary aim of the study in paper II was to investigate prevalence and association of constipation and laxative use in NH patients using interRAI LTCF. A secondary aim was to investigate the effect of clustering of observations and to study variance on both the NH unit level and the patient level by analyzing data using mixed effects models. The study included all patients (n = 261) within eligibility criteria from 20 NH units. The prevalence of constipation was 23. 4 %, and 67. 1 % of the patients used laxative regularly.

InterRAI LTCF has a high number of variables, which gave us the opportunity to explore a range of possible associations using univariable logistic regression. This resulted in 15 variables found to be significantly associated with constipation and 11 significantly associated with laxative use. The 10:1 rule (Peduzzi et al. 1996), together with consideration on clinical significance, was determinative on which variables to include in multivariable models. Balance problems, urinary incontinence, hypothyroidism, and Parkinson's disease were associated with constipation. Risk factors for laxative use were reduced ability to communicate and number of drugs other than laxatives, while anti-dementia drugs and being involved in activities during daytime were protective factors. Mixed-effect analyses of both the constipation model and the laxative use model identified variance between NH units as not statistically significant in explaining the total variance. Hence, variance of constipation (90.3 %) and laxative use (97 %) was mainly explained by differences in individual patient characteristics/health deficiencies. Hence, patients may benefit from individualized care to compensate for deficiencies.

Paper III: Feasibility, acceptability and adherence of two educational programs for care staff concerning nursing home patients' fecal incontinence: A pilot study prededing a cluster-randomized controlled trial

The aim of the study in paper III was to evaluate feasibility, acceptability, and adherence of two educational programs and the methods used preceding a planned C-RCT. The study included all patients (t_0 n = 62, t_1 n = 57) within eligibility criteria from 3 NH (6 NH units). All RNs (t_0 n = 7, t_1 n= 7) within eligibility criteria participated in the workshop and answered the knowledge test. Nursing documentation from the EPR with data on all included patients at t_0 (n = 62) and t_1 (n = 57) was analyzed (Figure 1). The result showed that the main study is feasible with one major change and some minor changes. The major change was to reduce the design for the planned C-RCT from a three-armed trial to a two-armed trial. The most important minor changes were a reduction in the data collection procedure, the need to recruit one opinion leader from each unit, the need to facilitate a reasonable work-plan between the educational meetings and to facilitate NH unit specific strategies to ensure continuity in FI care for the individual patient. N-Catch was considered and found feasible as instrument to measure change in critical thinking and clinical reasoning among care staff. Even though this is not the main purpose of the instrument, the qualitative criteria for evaluating content in the EPR can be considered equivalent with the criteria for critical thinking and clinical reasoning.

Paper IV: Effect of a multifaceted educational program for care staff concerning fecal incontinence in nursing home patients: A study protocol of a cluster-randomized controlled trial

The primary aim in paper IV was to develop a protocol detailing a C-RCT in order to test the hypotheses that a multifaceted educational program for NH care staff on assessment and treatment of FI reduces patients' frequency of FI. Secondary aims are to investigate the effect on 1) remission of FI in patients with FI present at baseline, or incidence of FI in patients identified as continent at baseline; 2) change in NH patients' FI related concerns; 3) change in knowledge among RNs, and 4) change in FI care among RNs and care staff in general. This study is the first randomized controlled trial specifically focusing on this neglected area. The result of the study will give evidence for best practice for FI care in NHs, and organizational advice concerning implementation strategies.

6. DISCUSSION

The findings reported in this thesis highlight the high prevalence and associations of FI, constipation and laxative use. Secondly, research related to the development of an implementation strategy to improve FI care in NH patients is presented. First in this chapter methodological issues related to study design, measures and the use of proxy reporting will be discussed. Then the findings on FI, constipation and laxative use in paper I and II will be discussed. Finally, issues related to findings in the pilot study investigating the feasibility of two educational interventions and the implications for the planned C-RCT are discussed.

6.1 METHODOLOGICAL CONSIDERATIONS

Strengths and limitations related to design and study population

Paper I and II – The cross-sectional study

The first two studies used a cross-sectional design. A cross-sectional design is well suited to investigate prevalence of diseases and conditions in a population, and to investigate possible associations (Rosner 2006, Bowers 2014). An important strength in these studies are the use of interRAI LTCF. InterRAI LTCF offers a large number of reliable items and thereby the opportunity to analyze a broad range of associations. However, sample size for the cross-sectional studies was determined by the power and sample size calculation for the C-RCT resulting in a possible underpowered sample regarding some of the less frequent conditions, e.g. related to the association between FI and hypothyroidism. This might lead to that results appear to have a lower level of significance than they actually do (type-II error) (Rosner 2006). Even so, the strategy for model building in this study was first to investigate the impact (Log likelihood, McFadden's R^2) of the individual variables by univariable logistic regression before entering the variables in the multivariable model. This gave us the opportunity to investigate the impact of a large number of conditions before entering the variables into the multivariable model, resulting in a thorough adjustment for possible confounders (Rosner 2006, Bowers 2014).

One of the challenges in conducting studies in NHs is the possible dependence between observations as a result of "within-cluster homogeneity". Observations from patients within the same NH unit may be more similar than observations from different NH units (Eldridge & Kerry 2012, Rabe-Hesketh & Skrondal 2012). This may violate one of the assumptions for logistic regression analyses (Eikemo & Clausen 2012). Using analysis methods which fails to take account of clustering may lead to confidence intervals which are too narrow, and increased type-I error; that is, results may appear to have a higher level of statistical significance than they actually do (Eldridge & Kerry 2012). Mixed effects models are models of analyses accounting for the clustered nature of data. A strength in paper I and II is that we used mixed effects models to test whether clustering of data significantly affected the results causing type I errors. In both papers, the effect of clustering was not statistical significant.

Mixed effects models also gave us the opportunity to investigate variance on both the NH level and the patient level. Even though some studies have found significant differences in prevalence rates of FI, constipation and laxative use between NHs (Brocklehurst et al. 1999, Gage et al. 2010, Saga et al. 2015), they have not studied the patterns of variability between the two levels of NH units and patients. The results of the mixed effects analyses found most of the variability in prevalence rates explained by differences between patients. The results from this study imply that even if there are differences in prevalence rates between NH units (Brocklehurst et al. 1999, Gage et al. 2010, Saga et al. 2015), most of the differences are explained by differences between patients. This means that in order to prevent or treat the conditions, one need to target the factors associated with the conditions in the individual patient, thus making individualized care important.

The sources and methods of recruitment of participants in the cross-sectional studies were determined by the procedures designated for the planned C-RCT. Only NHs agreeing to participate after being informed about the C-RCT were included. It is possible that characteristics of NHs saying yes to participate differ from characteristics of the NHs declining to participate. This may violate the external validity of the results. Maybe the included NHs are more well-functioning due to e.g. lower staff-turnover, lower sick leave rates among staff, less vacant care staff positions or lower degree of disability among patients. During the recruitment process for pilot study (paper III), managers from NHs declining to participate were asked why.

The reason for asking was to get information regarding the future recruitment process for the C-RCT. The most frequent reasons given were lack of time, major staff turnover, and vacant RN positions. The mixed effects models resulted in placing most of the variability of FI, constipation and laxative use to differences in patient characteristics, but in general, patients in NHs have extensive care needs (Mørk et al. 2014) and are dependent on care staff to compensate for deficiencies. Hence, both differences in general disability among patients and staffing difficulties may affect care staffs' ability to prevent or treat bowel problems. This might affect generalizability of the results in a sense that better functioning NHs to a larger degree have the resources to prevent or treat bowel problems among patients. However, when comparing the results from paper I and paper II to other studies (Gage et al. 2010, Fosnes et al. 2012, Saga et al. 2013, Jerez-Roig et al. 2015), prevalence rates of FI, constipation and laxative use are quite similar, or even higher, in our study. When comparing prevalence rates between studies, it is important to keep in mind that the definitions vary between studies. Altogether, we consider the potential selection bias as a bigger challenge for the external validity for the planned C-RCT, than for the cross-sectional studies.

Paper III and IV – The pilot study and the planned C-RCT

FI and constipation can potentially affect mortality, morbidity and health related quality of life (Wald et al. 2007, Bliss et al. 2013). Researchers and experts in the area agree that the conditions for many NH patients are potentially both preventable and treatable (Norton et al. 2009, Wagg et al. 2013). Results in paper I and II support the notion that evidence-based individualized bowel care might be key to managing the conditions. However, the level of awareness among heath care personnel regarding appropriate assessment and treatment options seems limited (Wagg et al. 2013). Therefore, studies investigating effect of interventions on prevention and treatment, and implementation strategies on change of care in NHs are warranted (Wagg et al. 2013, Saga 2014).

As previously described, this project group wanted to focus on FI and wanted to develop and test an implementation strategy involving an educational programme for health care staff on evidence-based FI care. An educational programme can be defined as a complex intervention (Craig et al. 2008). Complex interventions might have some methodological challenges related to e.g., the difficulty of standardizing the design and delivery of the intervention, their

sensitivity to characteristics in the local context, and the length and complexity of the causal chain linking interventions with outcome (Craig et al. 2008). Pilot studies are explicitly recommended prior to a full-scale trial involving complex interventions (Craig et al. 2008, Thabane et al. 2010, Eldridge & Kerry 2012). In addition, it is considered important to test and refine implementation strategies under usual care conditions taking into account feedback from end users (Rahman et al. 2012).

The study design was based on published guidance for designing pilot studies in the process of developing and testing complex interventions (Craig et al. 2008, Eldridge & Kerry 2012, Thabane et al. 2012). As described in section 4.3, design and content of the educational programmes emerged from exploring existing evidence and from experience in the project group. This resulted in two educational programmes with different complexity as described in table 2. Most of the existing evidence suggests that multifaceted interventions are more effective than single interventions (Grol & Grimshaw 2003, Grimshaw et al. 2004, Grimshaw et al. 2012, Grol & Wensing 2013). However, they are far more resource demanding. Therefore, we found it interesting to evaluate and compare feasibility and potential effect of the two educational programmes: a multifaceted intervention (MI) and a single intervention (SI). With this as background, together with guidance from Eldridge & Kerry (2012) and Thabane et al. (2012), we decided on criteria for feasibility, adherence and acceptability as shown in table 3.

We did not do any sample-size calculations for the pilot study. Out of practical and economic reasons, we decided to recruit one NH (two units) for each arm in the planned C-RCT. In addition to the economic argument, an important feature was the intention of recruiting from the same NH population for the main study and that we could not use too many of the available NHs for the pilot study. In the recruitment process for the pilot study, the intention was not to recruit to gain a broad feedback on the intervention and methods used, but to get some feedback on potentially adjustment needed. However, if the pilot had given us unclear results, more piloting would have been needed before proceeding with a full-scale C-RCT. By making this choice, we lost the opportunity to use the results from the pilot to gain enough power to perform sample size calculations for the main study. Even so, with lack of other reliable sources to inform the sample size calculations, we obtained valuable information from the data in order to inform the choice of effect-size, cut-off for the primary outcome variable (FI), and together

with other sources (Eldridge et al. 2004, Eldridge & Kerry 2012, Health Services Research Unit in Aberdeen 2013) the choice of ICC. Also for the other measures in the pilot, we obtained valuable information for drawing conclusions on necessary changes in the design of the C-RCT. We Also got knowledge about time use for RNs to fill in the questionnaires making us able to offer more reliable information when recruiting for the C-RCT.

The qualitative data was gathered by one focus group interview and four individual interviews. For analyses we used qualitative content analyzes in accordance with Graneheim & Lundman (2004). Sample size in qualitative studies is a matter of judgment and experience in evaluating the quality of the information collected against the intended use of the information (Sandelowski 2000). The original plan for the pilot study was to perform one focus group interview including RNs from the intervention NHs, which resulted in recruiting three RNs from each NH including the care managers from both NHs. An interview guide was constructed based on what was stated in the feasibility criteria for the study together with information processed during carrying out the pilot study. The interview resulted in rich data. However, when doing the preliminary review of the interview, we found that we needed more information on some specific themes. Therefore, we invited four of the RNs who participated in the focus group interview for focused individual interviews in order to get some additional information. Focused individual interviews are found useful when the themes for the interview are limited and focused (Tjora 2012).

According to Malterud (2011), reflections upon one's background and position are important in the process of planning and analyzing qualitative material in order to prevent these from confounding the interpretations of the phenomenon being studied. Even though several strategies were used to validate the findings, the researchers' (PhD-candidate) background might have influenced the results. The researcher's professional background as a nurse, several years in clinical practice and in educating RNs, and a specific interest in and knowledge about the nursing role and function both in primary care and in hospitals may have increased sensitivity to some themes over others. On the other hand, the same experience, knowledge and interest might facilitate valuable insights in the process of analysis (Graneheim & Lundman 2004). To ensure the study's reliability and validity, we aimed at systematic design including a verification of the study throughout the research process. Verification refers to the actions used

during the research process involving consciousness on when to continue, when to stop, or modify the research process in order to achieve reliability and validity (Morse et al. 2002). In this study, we transcribed the interviews verbatim, and two researchers (PhD-candidate an one other researcher) read the interviews separately to receive a general impression of the content before meeting to discuss the further analyses. Further, the process of analyzes, from the initial phase of defining content areas to the final phase of abstracting related categories to themes, went back and forth between members in the project group in the work of reaching consensus of the results.

Strengths and limitations related to the questionnaires/instruments

One of the strengths of the studies in paper I and II is the comprehensive data collection using interRAI LTCF that enabled us to explore possible associations in this complex patient group. It is reasonably well established that NH patients differ from the general population and from older people living at home, by a larger degree of complexity in their health characteristics; higher degree of comorbidity and polypharmacy, together with deficiencies of activities of daily living and cognitive impairment (Mørk et al. 2014). This complexity often makes it difficult to know whether a condition, e.g. FI, is associated with a specific disease e.g. stroke and dementia or deficiencies of ADL or ability to communicate, which also might be consequences of stroke or dementia. Hence, we consider it important to use instruments that capture a holistic picture of the patient, rather than using standalone items or scales in order to measure one or several specific conditions. The risk of confounding might be larger in this population than in the general population because of the complexity. Using comprehensive instruments together with regression models makes it possible to adjust for confounding on a broad specter of relevant conditions (Rosner 2006). On the other hand, the strategy for model building in paper I and II, is by some considered problematic based on the argument that all possible associations ideally should have been acknowledged on beforehand in order to avoid "fishing" for statistically significant associations (Freedland et al. 2009). However, as long as the researchers give a thorough description on the measures used and strategies for analyses, this should not be a problem. In our opinion, it is more important to investigated data for new possible associations in order to get a broader understanding of the conditions in question. This being especially important in populations where little research has been conducted with validated and reliable measures accounting for the complexity in the patient group.

In paper I we investigated FI prevalence and associations. In the interRAI LTCF, the variables on continence have been found reliable as measured by weighed kappa coefficients (Mor et al. 2003, Hirdes et al. 2008). We have not found any studies investigating criterion validity for the FI variable. However, as far as we know, there is no other "gold standard" measure for FI in the NH population. This includes the St. Mark's score that has been tested for validity and reliability (Bols et al. 2010, Sansoni et al. 2013) but not among NH patients, and not for proxy scoring. However, two large studies have found that the variable bowel continence has substantial reliability according to cut-offs for interpreting the kappa statistic. Mor et al. (2003) found the inter-rater reliability statistic weighted kappa, to be 0.88, and Hirdes et al. (2008) found the inter-rater reliability statistic weighted kappa to be 0.90.

In addition to interRAI LTCF we used the St. Mark's score. Some studies reporting reliability and validity of St. Mark's are described earlier (section 4.5). Unlike the FI item in interRAI LTCF, St. Mark's score measures anal incontinence and includes incontinence of gas. St. Mark's score is intended to be filled in by the patients themselves, or by staff interviewing the patients. In paper I, we used the RNs as proxy. During the information meeting where RNs learned how to fill in the questionnaire, they found most of the individual items in St. Mark's score easy to fill in based on clinical judgment. They found two items challenging: incontinence of gas and alteration of lifestyle. For the incontinence of gas item, we informed the RNs to grade the severity by asking the patients when it was possible and to observe frequency of gas leakage during e.g. locomotion, transfer from bed to chair, or from sitting to standing position. Considering alteration of lifestyle, in order to help the RNs understand what it could mean, we asked them to observe or consider whether patients for example did not want to participate on trips outside, visit the cafeteria, or wanting to sit by the toilet, for evaluation if incontinence caused alteration of the patients' lifestyle. Although St. Mark's score is found to correlate moderately well with patients' subjective perception and as reliable regardless of type of FI, patients' age, or gender (Maeda et al. 2007), it is not tested in the NH population. Because of this, we did not use St. Mark's score as the main instrument, but found it interesting to use it to get some additional information on FI among NH patients. This will also be the case for the C-RCT where the primary outcome, FI, will be measured by the incontinence variable in interRAI LTCF, and the St Mark's score will be used for additional information. For instance, St Mark's

incontinence score is found useful and sensitive to change in persons over time (Maeda et al. 2008). Several of the scales and indexes embedded within interRAI are found useful in evaluating change in clinical status over time (interRAI 2015), but to our knowledge there have been no studies evaluating interRAI LTCFs FI variable's sensitivity to change.

The aim of paper II was to explore constipation and laxative use among NH patients. Constipation is a condition not easily defined or diagnosed because of complex aetiology and a complexity in symptoms. Therefore, the ROME criteria were developed, and are now often used as a measure for constipation in research (Drossman 2006). In the NH population the ROME criteria might be considered challenging for several reasons. First, many of the patients use laxatives, and second, several of the criteria ask for the patients' sensation of e.g. incomplete evacuation or sensation of anorectal obstruction/blockage, which can be challenging to determine for many patients living in NH due to cognitive impairment. The constipation variable in interRAI LTCF is not based on the ROME-III criteria. In interRAI LTCF a patient is defined as constipated by the clinical judgment of a RN by the criteria no bowel movements the last three days or problems with hard stool. A weakness is that we have not found studies investigating the reliability of the variable measuring constipation in interRAI LTCF. However, studies have found the different items in the interRAI instruments to have a substantial overall reliability (Hirdes et al. 2008, Onder et al. 2012). Laxative use was measured by laxatives prescribed as regularly used in the patient record and recorded in interRAI LTCF, section N, Medications, and grouped according to the Anatomical-Therapeutic-Chemical Classification System (ATC) (WHO 2015a). A possible weakness is that only patients according to their patient record used laxatives regularly were defined as user. Patients with an "on demand" prescription were defined as nonusers. Hence, patients defined as nonusers may have used laxatives and thereby influenced the results.

In the pilot study (paper III) we included the Fecal Incontinence in Nursing Homes Questionnaire. As a consequence of the use of time related to data collection was evaluated as unacceptable in the pilot study, it was concluded to remove most of the items from this questionnaire, only keeping the items involving care staffs' interventions for constipation, FI and diarrhoea. For paper I and II we used only the variables "use of incontinence pads" (paper I) and the variables describing RNs administration of laxatives and micro-enemas (paper I and

II). For the C-RCT the whole section will be used to measure change in care, and as an instrument to collect information about care activities in the control group. In controlled trials, if "care as usual" is used to describe the control NHs, it is an important methodological issue to have some information about what this implies (Polit & Beck 2012). For the planned C-RCT, an important pedagogic strategy is to empower clinical and critical thinking in the individual RNs. Hence, we found it important to measure change in these qualities among care staff. In the pilot study N-Catch was considered and found feasible for this purpose. This will require a qualitative approach in the data analysis. Qualitative content analyses as described by Graneheim and Lundman (2004) can be used for this purpose.

Strengths and limitations of the planned C-RCT

One strength of the planned C-RCT includes the thorough investigation of both what is considered best practice for assessment, care and treatment of FI among NH patients and what is considered the most effective implementation strategy. The intervention is classified as a complex intervention, and the study has been designed according to published recommendations (Craig et al. 2008, Grimshaw et al. 2012, Eldridge & Kerry 2012), where a thorough planning phase included an evaluation of the fit of the different components with a pilot study. It is of special interest that the educational intervention integrates the FI-guideline of best practice into the EPR as a means to communicate the assessment and care plan to the staff as a whole. Because of this, we will have the opportunity to evaluate change of practice by investigating the EPR together with the use of the FI-guideline and patient's health information.

Despite a thorough and rigorous design, a possible weakness of the C-RCT is the complexity of the intervention with limited possibility to evaluate which of the components in the educational intervention are effective. The more complex the intervention, the harder it is to measure effect (Craig et al. 2008, Grimshaw et al. 2012). With an educational intervention, pedagogical ideals might challenge the ideals for a RCT. An important pedagogic ideal is to individualize and adjust pedagogical methods according to the needs of the actual person/ group in front of you (Mezirow 2003, Kvalsund 2011, Tøsse 2011). On the other hand, an important ideal of an RCT is for the intervention to be as similar as possible for all the participants (Fayers et al. 2010). In this study, we will agree on which components will be the same, and on which

will be allowed to vary. For instance, the format of the workshop will be the same, (total hours and themes to be covered), while empowerment strategies, guidance and timeframes for individual themes during the day may vary. During educational outreach all participants will receive the same number of visits within the same time frame with the same main themes to be covered, while when and how will vary. In addition, we will include a process evaluation in order to measure adherence. These are: 1) proportions of RNs within eligibility criteria participating in the workshop, 2) how many and who of the care staff participated in the outreach meetings, 3) proportions of intended outreach meetings held, 4) proportions of patients assessed with the FI guideline, and 5) proportion of assessments reported in the EPR as health status and nursing care plan. The educators will also record their reflections from the educational meetings.

The use of proxy reporting

In NHs, most of the patients have a cognitive impairment (Nylenna 2014), which makes it difficult for them to answer questions or fill in questionnaires. Hence, in order to get a representative sample and comprehensive data on the NH population, the forms were completed by RNs. However, it may be considered a weakness of this study that the patients did not fill in the questionnaires themselves, especially St Mark's score that is designed for self-reporting, and in general for items that measure subjective experiences that might be difficult to capture for others than the patients themselves. The reliability and validity of proxy data is found to be high for tasks of daily living and health conditions easily observed, and relatively low for conditions more private and less likely to be reported (Snow et al. 2005). To counter for that, both the interRAI LTCF manual and the information meetings focused on how to include the patient when possible. We also advised the RNs responsible for filling in the questionnaire to work together to enhance the clinical judgment when filling in the forms. FI might be considered especially difficult to measure by proxy reporting because of an assumed need of privacy and shame regarding FI episodes, which might threaten reliability of the measures. On the other hand, NH patients' dependency of care staff in managing their bowels in general, in cleaning after FI episodes and administration of incontinence pads, makes FI easier to observe in this population and measures more reliable.

6.2 DISCUSSIONS OF THE MAIN FINDINGS

Overall, the results of the epidemiological studies in this theses demonstrate that FI, constipation and the use of laxatives affects many of the patients in NHs, that variability in prevalence rates are mostly due to patient differences, and that the associations are multifaceted and complex among NH patients.

Prevalence and associations of FI

The prevalence of FI is confirmed high in this study. Measured by St Marks score, about 70 % of the patients were reported to have had at least one FI episode in the last four weeks. Results derived from interRAI LTCF gave a prevalence rate on 42.1 % and 54 % depending on the cut-off on the FI-variable. This spread of prevalence rates in the same population using different instruments and cut-offs demonstrates the importance of using standardized instruments and informing about definitions in use and frequency labeling.

The unadjusted analyses of the explanatory variables identified 17 covariates statistically significantly associated with FI. Because of the 10:1 ratio criteria, the 11 variables with the strongest impact (Log likelihood, McFaddens R^2) on FI were included in the multivariable model. In the adjusted analyses only 6 explanatory variables remained statistically significant: urinary incontinence, deficiencies in ADL, cognitive impairment and diarrhea as risk factors, and being involved in activities and instability in health/ frailty as protective factors. A coexistence of urinary incontinence, and the risk factors ADL deficiencies/ impaired mobility, cognitive impairment and diarrhea are consistent with most studies over the years (Wagg et al. 2013). The variable time involved in activities expresses the patients' involvement in activities either alone or in a group when he/ she is awake and not receiving treatment or care related to activities of daily living. To our knowledge this patient characteristic has not been investigated before. Being involved in activities as a protective factor might indicate that being active really prevents patients from having FI. On the other hand, it can also mean that patients with no FI are more likely to be involved in activities, while incontinent patients are not. It can also be understood as a consequence of patients with FI not wanting to participate because they are socially affected of their FI. InterRAI LTCF's measure for instability of health/frailty, CHESS, was a protective factor in the adjusted analyses. In the review from Wagg et al. (2013), poor

general health and comorbidity are considered risk factors. Our interpretation of the result in our study, is that instability in health/frailty in patients might lead to care staff being more observant about the patients' care needs in general, including bowel care. It can also mean that among the frailest patients the bowels are to a larger degree more easily controlled by scheduled toileting/ laxative regimes resulting in fewer FI episodes.

As opposed to findings reported in the review by Wagg et al. (2013), none of the medical diagnoses had high enough impact on FI to be considered for the adjusted analyses. On one hand this might be explained by these studies comprehensive set of variables making confounding less likely. On the other hand it might be explained by the relatively small sample resulting in too low power for some of the less common diagnoses, e.g. Multiple Sclerosis, Parkinson's disease, hypothyroidism. Wagg et al. (2013) reported urgency to be related to FI. In this study, urgency was reported in 41 % of NH patients, and although urgency was a statistically significant risk factor in the univariable analyses, it was not in the adjusted analyses.

As explained earlier, mixed effects models revealed 88 % of the variance in FI rates on the patient level, meaning that 88 % of the variability in FI rates may be explained by differences in patients characteristics making individualized patient care key in managing the symptom. This should not be surprising to most of health care personnel and researchers. Because of the complexity in FI aetiology both between patients and in the individual patient, it might be challenging to identify sufficient diagnostic information upon which to base management choice in individual patients. However, our study identified deficiencies in ADL, cognitive impairment and diarrhea as the most important risk factors. On one hand this information can make it easier to do a targeted assessment to get sufficient diagnostic information. However, it remains for the health care personnel to find the exact etiology related to ADL and cognitive impairment in the individual patient. Deficiencies in ADL and cognitive impairment have different consequences for different patients leading to different consequences for bowel function and continence. In addition, the diagnostic process is complicated by the high prevalence of cognitive impairment among patients. But first and foremost the value of evidence-based FI care needs to be emphasised, as it is indicated that NH care staff do not necessarily consider FI as an important problem to deal with, and that both health care staff and the patients themselves might consider FI something that must be "put up" with (Wagg et al.

2013, Bliss et al. 2013). It is important to raise awareness among health care staff that FI might be prevented, improved or treated with conservative interventions (Wagg et al. 2013, Bliss et al. 2013).

Prevalence and associations of constipation and laxative use

There were 23.4 % patients reported with constipation, and 67.1 % of the patients were reported to use laxatives regularly. In this study, patients were reported to have constipation based on the clinical judgment of RNs by the definition: no bowel movements for three days or problems with hard stools. In the NH setting the reported prevalence of constipation varies from 10 % up to 72 % (Kinnunen et al. 1991, Fosnes et al. 2012, Moore et al. 2012, Saga et al. 2013), probably due to variation in the definition and diagnosing of constipation, including whether constipation is self-reported or not. Often the prevalence is reported to be higher in studies where constipation is self-reported (Leung et al. 2011, Gallagos-Orozco et al. 2012). This might also be a consequence of constipation not being a well-defined disease entity, but a general term used to describe difficulties with moving the bowels. The picture is further complicated because many of the NH patients use laxatives, resulting in some studies using laxative use as a proxy for constipation (Harari et al. 1995, van Dijk et al 1998), or include the use of laxatives in the definition of constipation together with other criteria (Fosnes et al. 2012). Other studies have reported prevalence of laxative use among NH patients in a range from 50 % to 74 % (Leung et al. 2011, Fosnes et al. 2012).

There is an enormous range of possible risk factors for constipation, including endocrine or metabolic disorders, gastrointestinal disorders, neurological disorders, myopathic disorders, psychogenic disorders, and medication side effect, insufficient dietary fiber, fluids, and exercise (Leung et al. 2011, Gallagher et al. 2008). A risk factor suggested by Roque & Bouras (2015) is the elderly patient's dependence on others for assistance. Our adjusted analyses on constipation and associated factors resulted in poor balance, urinary incontinence, hypothyroidism, and Parkinson's disease as risk factors, where the last two are well documented in other studies (Gallagher et al. 2008, Leung et al. 2011). As far as we know, poor balance has not been investigated before. It is reasonable to think that poor balance might be an important factor in a process of the older person getting more immobile and getting more dependent in ADL functioning. For the association between urinary incontinence and constipation, it might

be seen as a consequence of co-existence rather than a risk factor, as for the association between urinary incontinence and FI. Although identified as risk factors in two reviews (Gallagher et al. 2008, Leung et al. 2011), we did not get a statistical significant association between constipation and cognitive impairment as measured by the CPS or the medical diagnoses dementia/Alzheimer's disease. Nor did we get a statistical significant association between constipation and depression both as measured by the depression scale (DRS) or the medical diagnosis depression.

Two reviews (Gallagher et al. 2008, Leung et al. 2011) have identified reduced mobility and functional decline as risk factors for constipation. In our study, the variables measuring ADL functioning and mobility/physical activity were not statistically significant in the univariable analyses or had too little impact on constipation to be considered in the multivariable analyses. On the other hand, the variable with the strongest impact on constipation was "balance". Together these findings suggest that balance problems are of greater importance than ADL deficiency and immobility in the understanding of constipation. Also, type of food (regular/soft or liquid), or hydration had too little impact to be considered for the multivariable analyses. It is often suggested that insufficient diet, hydration and fibre are associated with constipation, but the evidence behind these factors is inconsistent and of low to medium quality (Gallagher et al. 2008, Leung et al. 2011). If this is the case, our results confirm these factors having weak impact on constipation. However, Leung et al. (2011) conclude that increasing fiber, exercise and fluids might benefit patients with actual deficiencies. A weakness in our study is that interRAI LTCF offers no measures for fibre intake.

In the adjusted analyses on laxative use and associated factors we included 17 variables in the model. Of these, number of drugs and reduced capability to communicate were risk factors, and involved in activities from 1/3 to 2/3 of daytime and use of antidementia drugs were protective factors. As stated above, none of the variables measuring mobility/physical activities was associated with constipation. On the other hand, the results from analyzing laxative use support the hypothesis that an active living is protective against constipation if the use of laxatives is considered a sign of constipation. Antidementia drugs have diarrhoea as an adverse effect (Felleskatalogen 2016) that might explain the protective effect for the need for laxatives. As far as we know, the ability to communicate has not been investigated as a potential risk factor for

laxative use earlier and is an interesting finding indicating that being able to communicate bowel needs is important to maintain normal bowel functioning. Other studies investigating factors associated with laxative use in NHs have reported age, Parkinson's disease, inability to move independently, low fluid intake and chewing problems as risk factors, and snacks between meals as a protective factor (Hosia-Randell et al. 2007), and number of medications, dementia/Alzheimer's, and length of stay as risk factors (Gage et al. 2010).

Without having investigated all other diseases and their related drug, there are indications that the relationship between constipation and laxative use is challenging (Ford et al. 2011, Johansen et al. 2007). In the NH setting it is possibly more so due to a coexistence of very high prevalence of laxative use and at the same time high levels of symptoms for constipation. Fosnes et al. (2011) found that NH patients diagnosed with constipation and with a prescription for laxatives did not achieve normalization of stool frequency and consistency. In addition, patients reported with normal bowel functioning according to diagnostic criteria experienced persistent problems such as straining, manual maneuvers to facilitate bowel movement, feeling of incomplete bowel movements or a feeling of anorectal obstruction (Fosnes et al. 2011).

Feasibility of the educational programmes and consequences for the planned C-RCT

Even though we have studied both FI and constipation in addition to laxative use, the emphasis is on FI in the planned C-RCT. Results from the pilot study (paper III) support the results from the studies indicating that RNs do not necessarily consider FI as a problem among patients, and that they have low awareness on the possibilities of preventing and treating the symptom (Saga et al. 2014, Wagg et al. 2013). This in spite of expert opinions and research the last 30 years indicating that several of the risk factors are potentially reversible and preventable also in the NH population (Wagg et al. 2013). The results from the pilot study also confirms the research-practice gap related to what is considered best practice related to FI-care and what seem to be delivered FI-care in NHs today. This highlight the need for research focusing on how to implement this knowledge to the practice setting so health care staff can change their practice.

There exists a comprehensive amount of implementation research and pedagogic/educational theories, which could have been useful in guiding our educational intervention. These take in a

different degree the individual, the group, the organization, the different parts/levels of society into account. After investigating several theories, we chose theories emphasizing adult learning, with the main focus on the individual. We found Mezirow (1997, 2000, 2003) and his focus on empowering the learner through self-reflections and critical thinking, with discussion in groups as the main instrument, useful for our purpose. This said, although using Mezirow as the main theoretical platform, we also found guidance in theories that to a larger degree include teams/groups and organization in their educational theories, especially Argyris (2000), Tøsse (2011) and Kvalsund (2011). Although mixed results in previous research on the most effective implementation strategies, our results confirm research indicating that a single intervention with workshops is not effective in implementing change of care (Grimshaw et al. 2004, Grimshaw et al. 2012). On the other hand, in a newly published review investigating implementation strategies in NHs, no single intervention component, or combinations of components consistently resulting in improvements in staff practices, were found. Nor did increasing the number of intervention components (Low et al. 2015). Despite a comprehensive amount of implementation research in different settings, context, patients, health care staff, and the research/practice to be implemented are potentially so different that to find the "one best way for all situations" is probably impossible. This might be even more difficult when the intervention itself is complex making it hard to say which component work on what. Hence, in future implementation research it is important to make thorough investigations before deciding on an implementation strategy involving both theory base and practical implications such as: what should be implemented, by whom should the knowledge/research be implemented and how should it be implemented (Grimshaw et al. 2012). In addition, it is important to investigate potential barriers and facilitators in the target group/organization.

The most important result from the pilot study was the decision to reduce the C-RTC from a three-armed study to a two-armed study. The selections of control and intervention groups are important features in clinical trials, and several designs are applicable (Polit & Beck 2012). In this process, we did consider a design using NHs receiving SI as control group. However, generally in cluster-randomized trials the control group is allocated to usual care, to determine what would happen in the absence of the intervention, as many primary care trials aim to test ways of improving the delivery of care in a real-life setting (Eldridge & Kerry 2012). Under the circumstances of the NH being a setting with limited resources, it might be considered unethical to expose them to a costly and ineffective intervention. Also for the project group

designing the C-RCT, a one-day workshop as control intervention would have added an unacceptable amount of cost and practical challenges.

The pilot study concluded that the different components of the educational intervention worked well together, but needed some minor adjustments. The first change was to help the RNs to make a reasonable work plan until the next meeting, including who of the licensed practical nurses should be included in the work. The original plan was to let the local opinion leader decide topics for discussion for the educational meetings based on clinical situations between meetings. In the pilot study, we also invited the LPNs to participate in the meetings. As this did not work as planned, mainly due to difficulties in being absent from the unit at the same time as the RNs, we tried a strategy where RNs included the LPN in the work between meetings. Another important change was to recruit one opinion leader per unit, instead for one per NH.

Because of the chosen pedagogic theory-base (Mezirow 1997, 2000, 2003), the single most important pedagogic approach was to find ways to empower the RNs and facilitate clinical reasoning and critical thinking. This was also the approach during the workshop where the educator (PhD-candidate) and the RNs sat together around a table for the whole session. However, during the first 2.5 hours the educator had a leading role guiding theoretical input on bowel function in general, but mainly on FI and consequences of FI for patients and staff. It was considered important through the session to encourage discussions and questions, and to recognize the knowledge already present among the participating RNs.

The result from the pilot study confirmed the hypothesis that the awareness of FI as preventable and treatable is low among health care staff, and therefore some theoretical input at the beginning of the workshop was necessary before doing the case-based discussions. The RNs found the FI-guideline comprehensive, but very useful as it facilitated individualized care through clinical reasoning and critical thinking. According to the RNs, the use of the FI-guideline led to the patients experiencing fewer episodes of FI, which worked as an important motivation for adherence to the care plan. Also Palese et al. (2010) found that a change towards person-centered care improved constipation symptoms among patients. However, as always with treatment algorithms, standardized clinical pathways and clinical guidelines, it is important

not to jump to conclusions on the care for the individual patient based on general knowledge of the patient group. Therefore, it is not enough to offer evidence based knowledge in general; one also need to enhance the ability of clinical reasoning and critical thinking among health care staff. The ability for clinical reasoning and critical thinking is perceived by many as one of the key features in the individual RN to secure good quality care for the individual patient (Benner et al. 2008, Lunney 2009, 2010). In addition, in a review by Squires et al. (2011), critical thinking was identified as an important individual characteristic associated with RNs' use of research evidence in clinical practice.

Results from the qualitative interviews with the RNs after the intervention identified some barriers for change. One barrier reported by the RNs was a perceived lack of time for the task involving assessment and development of care plans. In addition, the RNs felt that this task was not considered among the most important tasks to be prioritized in their everyday working schedule. Even though these results are based on information from RNs from only three NHs, the results confirm findings by Ausserhofer et al. (2014) who found that to develop or update care plans is among the tasks most often left undone among RNs. In the same study, 26% of the Norwegian RNs also reported that they did not have time to perform adequate patient surveillance. These results are from an acute care setting, and it is reasonable to think that the situation is worse in NHs due to lower staff-patient ratios and a skill-mix with relative few RNs and a relative high proportion of unskilled care staff (Harrington et al. 2012). As a consequence, the pedagogical approach, in addition to empowering the RNs' critical thinking and clinical reasoning, also need to empower the RNs in believing and to communicate to others that patient surveillance, assessments and making care plans are important work tasks.

Another important barrier was that even if individualized care plans were developed, the RNs found it hard to communicate the information to all care staff, especially those working few hours. The one most important communication tool for health care staff is the EPR. Health care staff works in groups in shifts for different hours. Even though an RN has carried out a thorough assessment and made an individualized care plan based on the FI-guideline, the results of the assessment and the care plan need to be communicated to all care staff to ensure that the patient receives the prescribed care. The pilot study confirmed that the EPR did not work as intended as a tool to communicate care due to uncertainty among care staff on how to find, report and

utilize assessments and care plans in the EPR. This result from the pilot study meant that in the C-RCT, we also need to facilitate NH unit specific strategies on how to "use" the EPR in order to ensure continuity in FI care for the individual patient. One important recommendation from O'Connell et al. (2011) is that in order to implement the use of a guideline, it is important to integrate the guideline with the existing EPR system.

Finally, an important barrier identified through the interviews was isolated RNs, vague RN identity and a sub-optimal use of skill-mix resulting in a tendency to distribute tasks equally between staff irrespective of the level of qualification. This often resulted in RNs doing many non-nursing tasks like washing and folding patients' clothes, cleaning and taking dishes in and out of the dishwasher. Lack of time to perform what nurses have been trained to and what they came into nursing for, leave many RNs feeling frustrated, stressed and burnt out (Bruynel et al. 2012, Aiken et al. 2012). In our study, an important facilitator for change was that RNs, when given the opportunity, found the professional discussions related to the use of the FI-guideline inspiring helping them to organize the knowledge about the patients and made them feel empowered in their nursing role. An important role for the researcher as part of the intervention will be to give them time and opportunity to also discuss their nurse identity and thereby help them find the courage to find ways to a more optimal use of the skill-mix. In this work, the support from the care manager is essential.

7. CONCLUSIONS

This thesis explores prevalence and association of FI, constipation and use of laxative using the standardized and comprehensive instrument interRAI LTCF. Prevalence of FI, constipation and laxative use are confirmed high among NH patients. In addition, this thesis illustrates that it is the variation between the individual patients in e.g. cognitive impairment and ADL deficiencies, not the NH units, which explains the variation in prevalence rates. Hence, individualized bowel care matching the patients' deficiencies might be a key to managing bowel problems. Further, an implementation strategy involving educational programmes on individualized, evidence-based FI care was developed and found feasible in a pilot study. Consequently, a protocol for a cluster-randomized controlled trial for investigating effect of a multifaceted educational programmes for care staff was developed. This thesis also demonstrates interRAI LTCF as a useful instrument by its combination of a comprehensive range of individual items and scales capturing the complex nursing home patient, allowing for comparison of immediate and long-term change in patients across settings.

7.1 IMPLICATIONS FOR CLINICAL PRACTICE

Patients living in NHs emphasise the importance of RNs acknowledging their individual needs (Nakrem et al. 2011). Governments around the world together with World Health Organization WHO (2015b) and OECD (2013) are emphasizing the need for health care to be more centered on the needs of the individual patient. In spite of this recognition, NHs with few nursing resources dedicated to the care of older persons seem to a large degree to be based on standardization (Palese et al. 2010, Harrington et al. 2012, Harris & Hall 2012) and routine (Zisberg et al. 2007). In paper I we found that it was the variance between patients that was most important in explaining differences in FI rates, making continence care matching the individual patient characteristics key aspects in preventing and treating the condition. However, even though we found that FI rates mainly can be explained by differences in patient characteristics, most of the NH patients are dependent on health care staff to compensate for their deficiencies. To complicate the picture even more, it is not enough that the care is individualized, it also need to be evidence based. As recognized by Benner et al. (2008) and

Lynney (2009), in order to ensure that patients receive evidence based individualized care, care personnel also need to be trained in critical and clinical reasoning processes.

NH patients have a complex health situation with multi-morbidity and functional decline. In addition, most of the patients have some kind of cognitive impairment and are not necessarily capable of expressing their needs or telling care staff about their health problems. These facts make it especially important that RNs are trained in clinical reasoning and critical thinking in the process of decision-making and action. However, the individual RN alone cannot be made responsible for this change towards a more individualized and evidence-based care in NH. Care leaders and governments need to recognize that for this to happen they need to accept that thorough assessments and development of individual care plans is a task that takes time and that RNs, together with other relevant health care personnel, must be given the opportunity to sit down and discuss assessment and best evidence care options for the individual patient. We must recognize that the process of identifying the best care is extremely difficult and challenging because of the high complexity in NH patients' health conditions. In this thesis I have focused on FI care, but this will also apply towards all others areas of care needs in NH patients.

7.2 IMPLICATIONS FOR RESEARCH

This thesis has responded on research and experts saying that we need to investigate bowel problems in NH patients with reliable and valid instruments, and that there is a need for research on interventions and implementation strategies to improve FI care in NHs. Health-care systems are increasingly facing the problem of an ageing population, leading to a new and complex patients group. Therefore, quality of care in the NH setting is of major concern worldwide. Cost effective methods to improve quality of care and thereby improve the lives of people living in NHs in the future, is strongly warranted. Several next steps can be taken to build on the research in this thesis:

- This thesis has developed a multifaceted educational programme as implementations strategy for change of FI care in NHs. There is a need for studies investigating other kinds of implementation strategies related to bowel care, but also related to quality improvement in general.

- This thesis found that the effect of clustering was not statistical significant, and that the variance between NHs did not affect the results. In other countries with more varied ownership or management of NHs there might be more variability. Therefore, more studies need to include models of analyses that allow for clustering of observations.
- There is a need of studies investigating characteristics of the NHs as organizations, the teams and individuals working in NHs that make them more or less capable of research utilization and change.
- On the level of the individual RN and teams of health care personnel, there is a need for studies investigating critical thinking and clinical reasoning as an individual determinant of research utilization in order to achieve positive health outcomes in patients.
- A growing body of research has examined the relationship between different care models, nurse staffing, skill-mix and quality of care provided to patients in acute care. NHs has received much less attention. Research on staffing-outcomes in NHs is needed.

REFERENCES

Aiken L.H., Sloane D.M., Bruyneel L., Van den Heede K., Griffiths P., Busse R., Diomidous M., Kinnunen J., Kózka M., Lesaffre E., McHugh M.D., Moreno-Casbas M.T., Rafferty A.M., Schwendimann R., Scott P.A., Tishelman C., van Achterberg T. & Sermeus W. (2014) Nurse staffing and education and hospital mortality in nine European countries: a retrospective observational study. *Lancet* **383**,1824-1830.

Aiken L.H., Sermeus W., Van den Heede K., Sloane D.M., Busse R., McKee M., Bruyneel L., Rafferty A.M., Griffits P., Moreno-Casbas M.T., Tishelman C., Scott A., Brzostek T., Kinnunen J., Schwendimann R., Heinen M., Zikos D., Sjetne S.I., Smith H.L. & Kutney-Lee A. (2012) Patient safety, satisfaction, and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europa and the United States. *BMJ* **344**, e1717.

Akpan A., Gosney M.A. & Barrett J. (2007) Factors contributing to fecal incontinence in older people and outcome of routine management in home, hospital and nursing home settings. *Clinical Intervention in Ageing* **2**(1),139-145.

Argyris C. (2000) Organisatorisk læring - singel - og double loop. In *Tekster om læring* (Illeris K., ed.). Fredriksberg, Roskilde Universitets Forlag.

Armstrong J.J., Stolee P., Hirdes J.P. & Poss J.W. (2010) Examining three frailty conceptualizations in their ability to predict negative outcomes for home-care clients. *Age and Ageing* **39**(6), 755-758.

Aslan E., Beji N.K., Erkan H.A., Yalcin O. & Gungor F. (2009) The prevalence of and the related factors for urinary and fecal incontinence among older residing in nursing homes. *Journal of Clinical Nursing* **18**(23), 3290-3298.

Ausserhofer D., Zander B., Busse R., Schubert M., De Geest S., Rafferty A.M., Ball J., Scott A., Kinnunen J., Heinen M., Sjetne I.S., Moreno-Casbas T., Kòzka M., Lindqvist R., Diomidous M., Bruyneel L., Sermeus W., Aiken L.H. & Schwendimann R. (2014) Prevalence, patters and predictors of nursing care left undone in European hospitals: results from the multicountry cross-sectional RN4CAST study. *BMJ Quality & Safety* **23**, 126-135.

Banning M. (2008) Clinical reasoning and its application to nursing: concepts and research strategies. *Nurse Education in Practice* **8**, 177-183.

Bauer M.S., Damschroder L., Hagedorn H., Smith J. & Kilbourne A.M. (2015) An introduction to implementation science for the non-specialist. *BMC Psychology* **3**:32.

Benner P., Hughes R.G. & Sutphen M. (2008) Clinical Reasoning, Decision-making, and Action: Thinking Critically and Clinically. In *Patient Safety and Quality: An Evidenced-Baced Handbook for Nurses* (Hughes R.G., ed.). Rpckvill, AHRQ Publications.

Bergh S., Holmen J., Saltvedt I., Tambs K. & Selbæk G. (2012) Dementia and neuropsychiatric symptoms in nursing-home patients in Nord-Trøndelag County. *Tidsskrift for Den Norske lægeforening* **132** (17), 1956-1959.

Bliss D.Z., Mellgren A., Whitehead W.E., Chiarioni G., Emmanuel A., Santoro G.A., Zbar A., Peden-McAlpibe C., Northwood M., Slieker-Ten Hove M., Berghmans B. & Mimura T. (2013). Assessment and Conservative Management of Faecal Incontinence and Quality of Life in Adults. In *Incontinence* (Abrams B., Cardozo L., Khoury S. & Wein A. ed.) 5th International Consultation on Incontinence 2013. Retrived from http://www.ics.org/Publications/ICI_5/INCONTINENCE.pdf on 9 September 2015.

Bols E.M., Hendriks E.J., Berghmans B.C., Baeten C.G. & de Bie R.A. (2010) Inconclusive psychometric properties of the Vaizey score in fecally incontinente patients: a prospective cohort study. *Neurourology and Urodynamics* **29**(3), 370-377.

Borrie M.J. & Davidson H.A. (1992) Incontinence in institutions: cost and contributing factors. *Canadian Medical Association Journal* **147**(3), 322-328.

Boström A.M., Slaughter S.E., Chojecki D. & Estabrooks C. (2012) What do we know about knowledge translation in the care of older adults? A scoping review. *Journal of the American Medical Directors Association* **13**(3), 210-219.

Boström A.M., Ehrenberg A., Gustavsson J.P & Wallin L. (2009) Registered nurses' application of evidence-based practice: a national survey. *Journal of Evaluation of Clinical Practice* **15**(6), 1159-1163.

Bowers D. (2014) Medical Statistics from Scratch. An introduction for Health Professionals. Oxford, John Wiley & Sons Ltd.

Brocklehurst J, Dickinson E. & Windsor J. (1999) Laxatives and faecal incontinence in long-term care. *Nursing Standard* **13**(52), 32-36.

Bruyneel L., Li B., Aiken L., Lesaffre E., Van den Heede K. & Sermeus W. (2013) A multi-country perspective on nurses' tasks below their skill level: reports from domestically trained nurses and foreign trained nurses from developing countries. *International Journal of Nursing Studies* **50**(2), 202-209.

Bulechec G. (2013) *Nursing Interventions calissification (NIC)*. St Louis, Mosby Elsevier.

Burrows A.B., Morris J.N., Simon S.E., Hirdes J.P. & Phillips C. (2000) Development of a minimum data set-based depression rating scale for use in nursing homes. *Age and Ageing* doi: 10.1093/ageing/29.2.165.

Carpenter I. & Hirdes J.P. (2013) Using interRAI assessment systems to measure and maintain quality of long-term care. In *A good Life in Old Age? Monitoring and improving quality in long-term care*. OECD Health Policy Studies. Retrieved from http://www.uems.eu/__data/assets/pdf_file/0003/1497/A_Good_Life_in_Old_Age_2013_OECD-EC_EN.pdf on 3 November 2015.

Chassagne P., Jego A., Gloc P., Capet C., Trivalle C., Doucet J., Dennis P. & Bercoff E. (2000) Does treatment of constipation improve faecal incontinence in institutionalized elderly patients? *Age and Ageing* **29**(2), 159-164.

Chassagne P., Landrin I., Neveu C., Czernichow P., Bouaniche M., Doucet J., Denis P. & Bercoff E. (1999) Fecal incontinence in the institutionalized elderly: incidence, risk factors, and prognosis. *The American Journal of Medicine* **106**(2), 185-190.

Cheater F., Baker R., Gillies C., Hearnshaw H., Flottorp S., Robertson N., Shaw E.J. & Oxman A.D. (2010) Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. *Cochrane Database of Systematic Reviews* **3**.

Chen I-C., Huang H.J., Yang S.F., Chen C.C., Chou Y.C. & T.M. Kuo T.M. (2014) Prevalence and Effectiveness of Laxative Use Among Elderly Residents in a Regional Hospital Affiliated Nursing Home in Hsinchu County. *Nursing and Midwifery Studies* **3**(1), e13962.

Clark S.P. & Donaldson N.E. (2008) Nurse Staffing and Patient Care Quality and Safety. In *Patient Safety and Quality: An Evidence-Based Handbook for Nurses* (Hughes R.G., ed.). Rockville, AHRQ Publication.

Craig P., Dieppe P., Macintyre S., Michie S., Nazareth I. & Petticrew M. (2008) Developing and evaluating complex interventions: new guidance. Retrieved from https://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/ on 22 January 2016.

Cummings G.G., Estabrook C.A., Midodzi W.K., Wallin L. & Hayduk L. (2007) Influence of organizational characteristics and context on research utilization. *Nursing Research* **56**(4), 24-39.

Cusack S., Day M.R., Wills T. & Coffey A. (2012) Older people and laxative use: comparison between community and long-term care settings. *British Journal of Nursing* **21**(12),711-714.

Davies P., Walker A.E. & Grimshaw M. (2012) A systematic review of the use of theory in the design of guideline dissemination and implementation strategies and interpretation of the results of rigorous evaluations. *Implementation Science* **5**:14.

Declaration of Helsinki 2013. Retrieved from http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=[page]/[toPage] on 8. February 2016.

Drossman D.A. (2006) Rome III: the new criteria. *Chinese Journal of Digestive Diseases* **7**(4), 171-185.

Duffield C., Roche M., Diers D., Catling-Paull C. & Blay N. (2010) Staffing, skill mix and the model of care. *Journal of Clinical Nursing* **19**(15-16), 2242-2251.

Eccles M., Grimshaw J., Walker A., Johnston M. & Pitts N. (2005) Changing the behavior of healthcare professionals: the use of theory in promoting the uptake of research findings. *Journal of clinical epidemiology* **58**(2), 107-112.

Egidius H. (1994) *Psykologisk leksikon*. Oslo, Aschehoug.

Eikemo T.A. & Clausen T.H. (2012) *Kvantitativ analyse med SPSS. En praktisk innføring i kvantitativ analyseteknikker*. Trondheim, Tapir Akademiske Forlag.

Eldridge S. & Kerry S.M. (2012) *A practical guide to cluster randomised trials in health services research*. Chichester, John Wiley & Sons.

Eldridge S.M., Ashby D., Feder G.S., Rudnicka A.R. & Ukoumunne O.C. (2004) Lessons for cluster randomized trials in the twenty-first century: a systematic review of trials in primary care. *Clinical Trials* **1**(1), 80-90.

El‐Salhy M., Svensen R., Hatlebakk J.G., Gilja O.H. & Hausken T. (2013) Cronic constipation and treatment options. *Molecular Medicine Reports* **9**(1), 3-8.

EPOC (2015) Effective Practice and Organization of Care. Retrieved from http://epoc.cochrane.org/epoc-taxonomy on 22. january 2016.

Estabrooks C.A, Morgan D.G., Squires J.E., Boström A-M., Slaughter S.E., Cummings G.G. & Norton P.G. (2011) The care unit in nursing home research: Evidence in support of a definition. *Medical Research Methodology* **11.** doi: 10.1186/1471-2288-11-46.

Fayers P.M. & Machin D. (2010) *Randomized clinical trials: design, practice and reporting.* Chichester, Wiley-Blackwell.

Felleskatalogen (2016) Retrieved from http://www.felleskatalogen.no/medisin/atc-register/N06D on 8. February 2016.

Fesler-Birch D.M. (2005) Critical thinking and patient outcomes: a review. *Nursing Outlook* **53**(2), 59-65.

Flodgren G., Parmelli E., Doumit G., Gattellari M., O'Brien M.A. & Grimshaw J. (2011) Local opinion leaders: effects on professional practice and health care outcomes. *Cochrane database of systematic reviews* **8**.

Ford A.C. & Suares N.C. (2011) Effect of laxatives and pharmacological therapies in chronic idiopathic constipation: systematic review and meta-analysis. *Gut* **60**(2), 209-218.

Forsetlund L., Bjørndal A., Rashidian A., O'Brian M.A., Wolf F., Davis D., Ødegaard-Jensen J., Oxman A.D. (2009) Continuing education meeting and workshops: effects of professional practice and health care outcomes. *Cochrane database of systematic reviews* **2**.

Forskrift for sykehjem og boform for heldøgns omsorg og pleie (2013) FOR-1988-11-14-932. Helse- og omsorgsdepartementet. Retrieved from https://lovdata.no/dokument/SF/forskrift/1988-11-14-932 on 23 February 2016.

Fosnes G.S., Lydersen S. & Farup P.G. (2012) Drugs and Constipation in Elderly in Nursing Homes: What Is the Relation? *Gastroenterology Research and Practice* doi. *10.1155/2012/290231*.

Fosnes G.S., Lydersen S. & Farup P.G. (2011) Effectiveness of laxatives in elderly – a cross-sectional study in nursing homes. *BMC Geriatrics* **11**: 76.

Frank L., Schmier J., Kleinman L., Siddique R., Beck C., Schnelle J. & Rothman M. (2002) Time and economic cost of constipation care in nursing homes. *Journal of the American Medical Directors Association* **3**(4), 215-223.

Freedland K.E., Reese R.L., & Steinmeyer B.C. (2009) Multivariable models in biobehavioral research. *Psychosomatic Medicine* **71**(2), 205-216.

Gage H., Goodman C., Davies, S.L., Norton C., Fader M., Wells M., Morris J. & Williams P. (2010) Laxative use in care homes. *Journal of Advanced Nursing* **66**(6),1266-1272.

Gallagher P. & O'Mahony D. (2009) Constipation in old age. *Best Practice & Research Clinical Gastroenterology* **23**(6), 875-887.

Gallagher P.F., O'Mahony D. & Quigley E.M.M. (2008) Management of chronic constipation in the elderly. *Drugs & Aging* **25**(10), 807-821.

Gallagos-Orozco J.F., Foxx-Orenstein A.E., Sterler S.M. Stoa J.M. (2012) Cronic Constipation in the Elderly. *American Journal of Gastroenterology* **107**, 18-25.

Garnham B., Cheek J. & Alde P. (2009) The research/practice nexus: underlying assumptions about the nature of research uptake into practice in literature pertaining to care of the older person. *International journal of Older People Nursing* **4**(3), 219-226.

Gerritsen D.L.(2008) A Revised Index for Social Engagement for Long-Term Care. *Journal of Gerontological Nursing* **34** (4), 40-48.

Goodman C., Davies S.L, Norton C., Wells M., Morris J. & Gage H. (2013) Can district nurses and care home staff improve bowel care for older people using a clinical benchmarking tool? *British Journal of Community Nursing* **18**(12), 580-587.

Glia A. & Lindberg G. (1997) Quality of life in patients with different types of functional constipation. *Scandinavian Journal of Gastroenterology* **32**(11),1083-1089.

Graneheim U.H. & Lundman B. (2004) Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Education Today* **24**, 105-12.

Granum V., Opsahl G. & Solvoll B-A. (2012) Hva kjennetegner kritisk tenkning? *Sykepleien Forskning* **7**(1), 80-88.

Gray M. (2009) Evidence-based healthcare and public health. How to make decisions about health services and public health. London, Elsevier Limited.

Grimshaw J.M., Eccles M.P., Lavis J.N., Hill S.J. & Squires J.E. (2012) Knowledge translation of research findings. *Implementation Science* **7**, 3-17.

Grimshaw J.M., Thomas R.E., MacLennan G., Fraser C., Ramsay C.R., Vale L., Whitty P., Eccles M.P., Matowe L., Shirran L., Wensing M., Dijkstra R. & Donaldson D. (2004) Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technology Assessment*, **8**(6), 1-72.

Grol R. (2013) Introduction. In *Improving Patient Care. The implementation of change in health care* (Grol R., Wensing M., Eccles M. & Davis D., ed.). Oxford, Wiley Blackwell.

Grol R. & Wensing M. (2013) Implementation of change in health care: a complex problem. In *Improving Patient Care. The implementation of change in health care* (Grol R., Wensing M., Eccles M. & Davis D., ed.). Oxford, Wiley Blackwell.

Grol R., Wensing M., Bosch M., Hulscher M. & Eccles M. (2013) Theories on implementation on change in healthcare. In *Improving Patient Care. The implementation of change in health care* (Grol R., Wensing M., Eccles M. & Davis D., ed.). Oxford, Wiley Blackwell.

Grol R. & Wensing M. (2004) What drives change? Barriers to and incentives for achieving evidence-based practice. *The Medical Journal of Australia* **180**, 57-60.

Grol R. & Grimshaw J. (2003) From best evidence to best practice: effective implementation of change in patients' care. *Lancet* **362**(9391), 1225-1230.

Harari D., Gurwitz J.H., Avorn J., Bohn R. & Minaker K. (1997) How do Older People Define Constipation. Implications for Therapeutic Management. *Journal of General Internal Medicine* **12**(1), 63-66.

Harari D., Gurwitz J.H., Avorn J., Choodnovskiy I. & Minaker K.L. (1995) Correlates of regular laxative use by frail elderly persons. *The American Journal of Medicine* **99**(5), 513-518.

Harrington C., Choiniere J., Goldman M., Jacobsen F.F., Lloid L., McGregor M., Stamatopolous V. & Szebehely M. (2012). Nursing Home Staffing Standards and Staffing Levels in Six Countries. *Journal of Nursing Scholarship* **44**(1), 88-98.

Harrington C., Carrilo H., Dowdell M., Tang P.P., Blank B.W. (2011) *Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2005 Through 2010*. Department of Social and Behavioural Sciences. University of California, San Francisco. Retrieved at http://theconsumervoice.org/uploads/files/issues/OSCAR-2011-final.pdf on 27. February 2016.

Harris A. & McGillis Hall L. (2012). Evidence to Inform Staff Mix Decision-making: A Focused Literature Review. *Canadian Nurses Associations.* Retrieved from https://www.cna-aiic.ca/~/media/cna/page-content/pdf-en/staff_mix_literature_review_e.pdf?la=en on 27 February 2016.

Hasseler M. (2006) Evidence-Based Nursing for Practice and Science. In *Nursing theories Conceptual & Philosophical Foundations* (Kim H.S. & Kollah I., ed.) New York, Springer Publishing Company.

Hauge S. (2014) Sykepleie i sykehjem. In *Geriatrisk sykepleie* (Kirkevold M., Brodtkorp K. & Ranhoff A.H. ed.). Oslo, Gyldendal Akademiske Forlag.

Health Services Research Unit in Aberdeen. Retrieved from http://www.abdn.ac.uk/hsru/research/research-tools/study-design/ on 14. April 2013.

Herdman T. (2012) *Nursing Diagnoses. Definition and Classification (2012-2014)* North America Nursing Diagnosis Associations (NANDA). Chichester, Wiley-Blackwell/NANDA International.

Hirdes J.P., Poss J.W., Mitchell L., Korngut L & Heckman G. (2014) Use of the interRAI CHESS Scale to Predict Mortality among Persons with Neurological Conditions in Three Care Settings. *PLoS ONE* **9**(6): e99066.

Hirdes J.P., Ljunggren G., Morris J.N., Frijters D.H.M., Soveri H.F., Gray L., Björkgren M. & Gilgen R. (2008) Reliability of the interRAI suite of assessment instruments: a 12-country study of an integrated health information system. *BMC Health Services Research* **8**: 277.

Hirdes J.P., Frijters D.H. & Teare G.F. (2003) The MDS-Chess Scale: A New Measure to Predict Mortality in Institutionalized Older People. *Journal of the American Geriatrics Society* **51**, 96-100.

Hodgkinsons B., Haesler E.J., Nay R., O'Donnell M.H. & McAuliffe L.P. (2011) Effectiveness of staffing models in residential, subacute, extended aged care settings on patient and staff outcomes (review). *The Cochrane Collaboration* **6**.

Hogan D.B., Freiheit E.A., Strain L.A., Patten S.B., Schmalttz H.N., Rolfson D. & Maxwell C.J. (2012) Comparing frailty measures in their ability to predict adverse outcomes among older residents of assisted living. *BMC Geriatrics* **12**:56.

Hosia-Randell H., Suominen M., Muurinen S. & Pitkälä K.H. (2007) Use of laxatives among older nursing home residents in Helsinki, Finland. *Drugs & Aging* **24**(2), 147-154.

interRAI (2016) InterRAI web page. Retrieved at http://www.interrai.org on 21. February 2016.

interRAI (2015) Scales: Status and Outcome Measures. Retrieved from http://www.interrai.org/scales.html on 22 January 2016.

Jerez-Roig J., Souza D.B.D., Amaral F.L.J.S., and Lima K.C. (2015) Prevalence of fecal incontinence (FI) and associated factors in institutionalized older adults. *Archives of Gerontology and Geriatrics* **60**, 425-430.

Johanson J.F. & Kralstein J. (2007) Chronic constipation: a survey of the patient perspective. *Alimentary Pharmacology and Therapeutics* **25**(5), 599-608.

Johanson J.F., Irizarry F. & Doughty A. (1997) Risk factors for fecal incontinence in a nursing home population. *Journal of Clinical Gastroenterology*, **24**(3), 156-160.

Johnsen K.M.F., Ehrenberg A., Fossum M. (2014) Dokumentasjon av sykepleie i sykehjem. En Vurdering av innhold og kvalitet på sykepleiedokumentasjon og vurdering av reliabiliteten til instrumentet N-Catch. *Vård i Norden* **34**(2), 27–32.

Kane R.L., Shamliyan T.A., Mueller C., Duval S. & Wilt T.J. (2007) The Associations of Registered Nurse Staffing Levels and Patients Outcomes; Systematic Review and Meta-analyses. *Medical Care* **45**(12), 1195-1204.

Kinnunen O. (1991) Study of constipation in a geriatric hospital, day hospital, old people's home and at home. *Aging Clinical and Experimental Research* **3**(2), 191-170.

Kvalsund R. (2011) Organisering av kompetanseutvikling i arbeidslivet. In *Voksne, læring og kompetanse* (Aarsand L., Håland E., Tønseth C. & Tøsse S., ed.). Oslo, Gyldendal Akademiske.

Lauti M., Scott D. & Thompson-Fawcett M.W. (2008). Fibre supplementation in addition to loperamide for faecal incontinence in adults: a randomized trial. *Colorectal Disease* **10**(6), 553-562.

Leonard R., Tinetti M.E., Allore H.G., & Drickame M.A. (2006) Potentially Modifiable Resident Characteristics That Are Associated With Physical or Verbal Aggression Among Nursing Home Residents With Dementia. *Archives of Internal Medicine* **166**(12), 1295-1300.

Leung L., Riutta T., Kotecha J. & Rosser W. (2011) Chronic Constipation: An Evidence-Based Review. *Journal of the American Board of Family Medicine* **24**(4), 436-445.

Liang C.-K., Chen L.-K., Tsai C.-F., Su T.-P., Lo Y.-K. Lan C.-F. & Hwang S-J. (2014) Screening Depression Among Institutionalized Older Chinese Men by Minimum Data Set: We Need a New Instrument. *Journal of Geriatric Psychiatry* **24**(4), 79-83.

Lov om kommunale helse- og omsorgstjenester (2011) LOV-2011-06-24-30. Helse- og omsorgsdepartementet. Retrieved from https://lovdata.no/dokument/NL/lov/2011-06-24-30 on 23. February 2016.

Low L-F., Fletcher J., Goodenough B., Jeon Y-H., Etherton-Beer, MacAndrew M. & Beattie E. (2015) A systematic review of Interventions to Change Staff Care Practices in Order to Improve Resident Outcome in Nursing Homes. *International Journal of Nursing Practice* **21**, 820-830.

Lunney M. (2010) Use of critical thinking in the Diagnostic Process. *International Journal of Nursing Terminologies and Classification* **21**(2), 82-88.

Lunney M. (2009) *Critical Thinking to Achieve Positive Health Outcomes: Nursing Case Studies and Analyses*. Ames, Wiley-Blackwell.

Maeda Y., Parés D., Norton C., Vaizey C.J. & Kamm M.A. (2008) Does the St. Mark's Incontinence Score Reflect Patients' Perception? A review of 390 Patients. *Diseases of the Colon & Rectum* **51**, 436-442.

Magnall J., Tyler P., Thomas S. & Watterson L. (2006) Continence problems in care homes: auditing assessment and treatment. *Nursing Older people* **18**, 20-22.

Malterud K. (2011) *Kvalitative metoder i medisinsk forskning: en innføring*. Oslo, Universitetsforlaget.

McCormack B. (2003) A conceptual framework for person-centered practice with older people. *International Journal of Nursing Practice* **9**(3), 202-209.

Mezirow J. (2003) Transformative Learning as Discourse. *Journal of Transformative Education* **1**(1), 56-63.

Mezirow J. (2000) *Learning as Transformation: Critical Perspectives on a Theory in Progress.* San Francisco, Jossey-Bass.

Mezirow J. (1997) Transformative Learning: Theory to Practice. *New Directions for Adult & Continuing Education* **74**, 5-12.

Moore K. L., Boscardin W.J., Steinman M.A. & Schwartz J.B. (2012) Age and Sex Variation in Prevalence of Chronic Medical Conditions in Older Residents of U.S. Nursing Homes. *Journal of the American Geriatrics Society* **60**(4), 756-764.

Mor V., Angelelli J., Jones R., Roy J., Moore T. & Morris J. (2003) Inter-rater reliability of nursing home quality indicators in the U.S. *BMC Health Services Research* **3**:20.

Morgan S. & Yoder L.H. (2012) A Concept Analysis of Person-Centered Care. *Journal of Holistic Nursing*, **30**(1), 6-15.

Morris J.N., Belleville-Taylor P., Fries B.E., Hawes C., Murphy K., Mor V., Nonemaker S., Phillips C.D., Berg K., Björkgren M., Frijters D., Gilgen R., Gray L., Henrard J.C., Hirdes J.P., Ljunggren G., Steel K. & Zimmerman D. (2012) *interRAI Long-Term Care Facilities (LTCF) Assessment Form and User's Manual*. Verson 9.1 Norwegian version. interRAI, Washington DC.

Morris Z.S., Wooding S. & Grant J. (2011) The answer is 17 years, what is the question: understanding time lags in translational research. *Journal of the Royal Society of Medicine,* **104**(12), 510-520.

Morris J.N., Fries B.E. & Morris S.A. (1999) Scaling ADLs Within the MDS. *Journal of Gerontology* **54**(11), 546-553.

Morris J.N., Fries B.E., Mehr D.R., Hawes C., Philops C., Mor V. & Lipsitz L. (1994) MDS Cognitive Performance Scale. *Journal of Gerontology* **49**(4), 174-182.

Morse J.M., Barrett., Mayan M., Olson K. & Spiers J. (2002) Verification strategies for establishing reliability and validity in qualitative research. *International Journal of Qualitative Research* **1**(2), 13-22.

Mugie S.M., Benninga M.A. & Di Lorenzo C. (2011) Epidemiology of constipation in children and adults: a systematic review. *Best Practice & Research Clinical Gastroenterology* **25**(1), 3-18.

Mørk E., Sundby B., Otnes B. & Wahlgren M. (2014) Pleie- og omsorgstjenesten 2013. Statistikk om tjenester og tjenestemottakere. Reports, Statistics Norway.

Nakrem S. (2015) Understanding organizational and cultural premises for quality of care in nursing homes: an ethnographic study. *BMC Health Services Research* **13:**15.

Nakrem S., Vinsnes A.G., & Seim A. (2011) Residents' experiences of interpersonal factors in nursing home care: A qualitative study. *International Journal of Nursing Studies* **48**(11), 1357-1366.

Nelson R.L. & Furner S.E. (2005) Risk factors for the development of fecal and urinary incontinence in Wisconsin nursing home residents. *Maturitas* **52**(1), 26-31.

Nelson R., Furner S. & Jesudason V. (1998) Fecal Incontinence in Wisconsin Nursing Homes. Prevalence and Associations. *Diseases of the Colon & Rectum* **41**(10),1226-1229.

NICE (2007) National Institute for Health and Clinical Exellence. Faecal incontinence: management of faecal incontinence in adults. *NICE clinical guideline 49*.

Nilsen P. (2015) Making sense of implementation theories, models and frameworks. *Implementation Science* **10**:53.

Norton C., Whitehead W., Bliss D.Z., Harai D. & Lang J. (2013) Conservative and Pharmacological Management of Faecal Incontinence in Adults. In *Incontinence (*Abrams B., Cardozo L., Khoury S. & Wein A. ed.). 4th International Consultation on Incontinence 2009 Retrived from http://www.ics.org/Publications/ICI_4/book.pdf on 27 February 2016.

Norton C. & Cody J.D. (2012) Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane Database of Systematic Reviews* **7**.

Nylenna M. (2014) *Helsetjenesten i Norge: et overblikk*. Oslo, Gyldendal akademisk

Nøst T.H., Tettum B.I., Frigstad S.A., Woldstad K., Haugan B., Oppheim A.E., André B. & Rotegård A.K. (2015) D-Catch blir norsk. *Sykepleien* **103**(5), 33-43.

O'Brien M.A., Rogers S., Jamtvedt G., Oxman A.D., Odgaard-Jensen J., Kristoffersen D.T., Forsetlund L., Bainbrigde D., Freemantle L., Davis D., Haynes R.D. & Harvey E. (2007) Educational outreach visits: effects on professional practice and health care outcomes. *Cochrane Database of Systematic Reviews* 2007, **4**.

O'Connell B., Ostaszkiewicz J. & Hawkins M. (2011) A suite of evidence-based continence assessment tools for residential aged care. *Australas Journal of Ageing* **30**, 27-32.

OECD/European Commission (2013) A Good Life in Old Age? Monitoring and Improving Quality in Long-term Care. OECD Health Policy Studies, OECD Publishing.

O'Keefe E.A., Talley N.J., Zinsmeister A.R. & Jacobsen S.J. (1995) Bowel Disorders Impair Functional Status and Quality of Life in the Elderly: A population-Based Study. *The Journals of Gerontology* **50**(4), 184-189.

Onder G., Carpenter I., Finne-Soveri H., Gindin J., Frijters D., Henrared J.C., Nikolaus T., Topinkova E., Tosato M., Liperoti R., Landi F. & Barnabei R. (2012) Assessment of nursing home residents in Europa: the Services and Health for Elderly in Long TERm care (SHELTER) study. *BMC Health Services Research* **12**. doi: 10.1186/1472-6963-12-5.

Ouslander J.G., Simmons S., Schnelle J., Uman G. & Fingold S. (1996) Effects of prompted voiding on fecal incontinence among nursing home residents. *Journal of the American Geriatrics Society* **44**(4), 424-428.

Paans W., Sermeus W., Nieweg R.M. & van der Schans C.P (2010) D-Catch instrument: development and psychometric testing of a measurement instrument for nursing documentation in hospitals. *Journal of Advanced Nursing* **66**(6), 1388-1400.

Palese A., Granzotto D., Broll M.G. & Carlesso N. (2010) From health organization-centred standardization work process to a personhood-centred care process in an Italian nursing home: effectiveness on bowel elimination model. *International Journal of Older People Nursing* **5**(2), 179-187.

Pedersen A.W. (2014) Pensions, health care and long term care. Annual report 2014. Brussel, European Commission.

Peduzzi P., Concato J., Kemper E., Holford T.R. & Feinstem A.R. (1996) A simulation study of the number of events per variable in logistic regression analysis. *Journal of Clinical Epidemiology* **49**(12), 1373-1379.

Pekmezaris R., Aversa L., Wolf-Klein G., Cedarbaum J. & Reid-Durant M. (2002) The Cost of Chronic Constipation. *Journal of the American Medical Directors Association* **3**(4), 224-228.

Perlman C.M. & Hirdes J.P. (2008) The aggressive behavior scale: a new scale to measure aggression based on the minimum data set. *Journal of the American Geriatrics Society* **56(**12), 2298-2303.

Polit D.F. & Beck C.T. (2012) *Nursing Research: Generating and Assessing Evidence for Nursing Practice*. Philadelphia, Wolters Kluwer/Lippincott Williams & Wilkins.

Poss J.W., Jutan N.M., Hirdes J.P., Fries B.E., Morris J.N., Teare G.F. & Reidel K. (2008) A review of evidence on the reliability and validity of Minimum Data Set data. *Healthcare Management FORUM* **21**(1), 33-39.

Potter J. & Wagg A. (2005) Management of bowel problems in older people: an update. *Clinical Medicine* **5**(3), 289-295.

Potter J. (2003) Bowel care in older people. *Clinical medicine* **3**(1), 48-51.

Rabe-Hesketh S. & Skrondal A. (2012) *Multilevel and Longitudinal Modeling Using Stata. Volume I: Continious Responses*. Texas, Stata Press Publication.

Rahman A.N., Applebaum R.A., Schnelle J.F. & Simmons S.F. (2012) Translating research into practice in nursing homes: can we close the gap? *The Gerontologist*, **52**(5), 597-606.

Rantz M.J., Popejoy L., Petroski G.F., Madsen R.W., Mehr D.R., Zwygart-Stauffacher M., Hicks L.L., Grando V., Wipke-Tevis D.D., Bostick J., Porter R., Conn V.S. & Maas M. (2001) Randomized clinical trials of quality improvement intervention in nursing homes. *The Gerontologist* **41**(4), 525-538.

Rao S.S. & Go J.T. (2010) Update on the management of constipation in the elderly: new treatment options. *Clinical Interventions in Aging* **9**(5), 163-171.

Rey E., Barcelo M., Cebriàn M.J.J., Alvarez-Sachez A., Diaz-Rubio M. & Rocha A.L. (2014) A Nation-Wide Study of Preavlence oand Risk Factors for Fecal Impaction in Nursing Homes. *PLoS ONE* **9**(8): e105281.

Ringard Å., Sagan A., Saunes I.S. & Lindahl A.K. (2013) Norway: health system review. *Health Systems in Transition* **15**(8), 1-162.

Roe B., Flanegan L., Jack B., Barret J., Chung A., Shaw C. & Williams K. (2011) Systematic review of the management of incontinence and promotion of continence in older people in care homes: descriptive studies with urinary incontinence as primary focus. Journal of Advanced Nursing **67**(2), 228-250

Rosner B. (2006) Fundamentals of Biostatistics. Belmont, Brooks/Cole.

Roque M.V. & Bouras E.P. (2015) Epidemiology and management of chronic constipation in elderly patients. *Clinical Interventions in Aging* **10**, 919-930.

Sackett D.L., Rosenberg W.M.C., Gray J.A.M., Haynes R.B. & Richardson W.S. (1996) Evidence based medicine: what it is and what it isn't. *BMJ,* 312:71

Saga, S., Vinsnes, A. G., Mørkved, S., Norton, C., & Seim, A. (2015) What Characteristics Predispose to Continence in Nursing Home Residents?: A Population-Based Cross-Sectional Study. *Neurourology and Urodynamics*, **34**(4), 362–367.

Saga S., Seim A., Mørkved S., Norton C. & Vinsnes A. (2014) Bowel problem management among nursing home residents: a mixed methods study. *BMC Nursing* **13**(1):35.

Saga S. (2014) *Understanding faecal incontinence in nursing home patients. Epidemiology and nurses' management.* Doctoral thesis at Norwegian University of Science and Technology, Trondheim.

Saga S., Vinsnes A.G., Mørkved S., Norton C. & Seim A. (2013) Prevalence and correlates of fecal incontinence among nursing home residents: a population-based cross-sectional study. *BMC Geriatrics* **30**(13): 87.

SAK (2014) The Norwegian Registration Authoroty for Health Personell (SAK) Retrieved from http://www.nokut.no/Documents/INVIA/Infoark/Vernepleier_EN_23.pdf; on 5 May 2014.

Sandelowski M. (2000) Whatever Happened to Qualitative Description? Research in Nursing and Health **23**, 334-340.

Sansoni J., Hawthorne G., Fleming G. & Marosszeky N. (2013) The revised faecal incontinence scale: A clinical validation of a new, short measure for assessment and outcome evaluation. *Diseases of the Colon & Rectum* **56**(5), 652-659.

Scheffer B.K. & Rubenfeld M.G. (2000) A consensus statement on critical thinking in nursing. *Journal of Nursing Education* **39**(8), 352-360.

Schnelle J.F., Leung F.W., Rao S.S.C., Beuscher L., Keeler E., Clift J.W. & Simmons S. (2010) A controlled Trial of an Intervention to Improve Urinary and Fecal Incontinence and Constipation. *JAGS* **58**(8), 1504-1511.

Schnelle J.F., Simmons S.F., Beuscher L., Peterson E.N., Habermann R. & Leung F. (2009) Prevalence of constipation symptoms in fecally incontinent nursing home residents. *Journal of American Geriatric Society* **57**(4), 647-652.

Seago J.A. (2001) Nurse Staffing, Models of Care Delivery, and Interventions. Retrieved from http://archive.ahrq.gov/clinic/ptsafety/chap39.htm on 22 August 2015.

Shin J.H. & Scherer Y. (2009) Advantages and Disadvantages of Using MDS Data in Nursing Research. *Journal of Gerentological Nursing* **35**(1), 7-17.

Sirnes S.M. (2005) Flervalgsoppgaver – konstruksjon og analyse. Bergen, Fagbokforlaget.

Snow A.L., Cook K.F., Lin P.-S., Morgan R.O. & Magaziner J. (2005) Proxies and Other Raters: Methodological Considerations. *Health Services Research* **40**. doi: 10.1111/j.1475-6773.2005.00447.x.

Squires J.E., Estabrooks C.A., Gustavsson P. & Wallin L. (2011) Individual determinants of research utilization by nurses: a systematic review update. *Implementation Science*, **6**:1.

Statistics Norway (2014) Register of health care personell. Retrieved from http://www.ssb.no/en/forside;jsessionid=769CA19F4266D79878FCCCAB758EC4FD.kpld-as-prod11?hide-from-left-menu=true&language-code=en&menu-root-alternative-language=true on 13 May 2014.

Stokke K., Olsen N.R., Espehaug B. & Nordtvedt M. (2014). Evidence based practice beliefs and implementation among nurses: a cross-sectional study. *BMC Nursing* **13**:8.

Talley N.J., Fleming K.C., Evans J.M., O'Keefe E.A., Weaver A.L., Zinsmeister A.R. & Melton L.J. (1996) Constipation in an elderly community: a study of prevalence and potential risk factors. *American Journal of Gastroenterology* **91**(1), 19-25.

Thabane L., Ma J., Chu R., Cheng J., Ismaila A., Rios L.P., Robson R., Thabane M., Giangregorio L. & Goldsmith C.H. (2012) A tutorial on pilot studies: the what, how and why. *BMC Medical Research Methology* **10**:1.

Thekkinkattil D.K., Lim M., Finan P.J., Sagar P.M. & Burke D. (2008) Awareness of investigations and treatment of faecal incontinence among the general practitioners: a postal questionnaire survey. *Colorectal Disease* **10**, 263-267.

Titler M. (2008) The evidence for Evidence-Based Practice Implementation. In *Patient safety and Quality: An evidence-Baced Handbook for Nurses* (Hughes R.G. ed.,) Rockville, AHRQ Publications.

Tjora A.H. (2012) *Kvalitative forskningsmetoder i praksis.* Bergen, Gyldendal akademisk.

Twigg D.E., Myers H., Duffield C., Giles M. & Evans G. (2014) Is there an economic case for investing in nursing care – what does the literature tell us? *Journal of Advanced Nursing* **71**(5), 975-990.

Tøsse S. (2011) *Historie, praksis, teori og politikk: om kunnskapsgrunnlaget for voksnes læring*. Trondheim, Tapir Akademiske Forlag.

University Hospital of North Norway (2015). Norwegian registry for Anal Incontinence. St Marks Incontinence Score Retrieved from http://www.unn.no/getfile.php/UNN%20INTER/Enhet/Inkontinenssenter_web/Dokumenter/Anal%20inkontinens%201B_200214.pdf on 2 June 2015.

van Dijk K.N., de Vries C.S., van den Berg P.B., Dijkema A. M., Brouwers J.R.B.J & de Jong-van den Berg L.T.W. (1998) Constipation as an adverse effect of drug use in nursing home patients: an overestimated risk. *British Journal of Clinical Pharmacol*ogy **46**(3), 255-261.

Wagg A.S., Chen L.K., Kirschner-Hermanns R., Kuchel G.A., Johnson Y., Ostaszkiewicz J., Markland A., Palmer M. & Szonyi G. (2013) Incontinence in the Frail Elderly. In *Incontinence* (Abrams B., Cardozo L., Khoury S. & Wein A. ed.). 5th International Consultation on Incontinence 2013. Retrived from http://www.ics.org/Publications/ICI_5/INCONTINENCE.pdf on 9 September 2015.

Wald A., Scarpignato C., Kamm M.A., Mueller-Lissner S., Helfrich I., Schuijt C., Bubeck J., Limoni C. & Petrini O. (2007) The burden of constipation on quality of life: results of a multinational survey. *Alimentary Pharmacology and Therapeutics* **26**(2), 227-236.

Wang J., Kane R.L., Lynn E.E., Virnig B.A & Chang L-H. (2009) The effects of Resident and Nursing Home Characteristics on Activities of Daily Living. *Journal of Gerentology* **64**(4):473-480.

Wensing M., Wollersheim H. & Grol R. (2006) Organizational interventions to implement improvements in patient care. A structured review of reviews. *Implementation Science* **22**(1):2.

WHO (2015a) Collaborating Centre for Drug Statistic Methodology. ATC/DDD Index," Retrieved from http://www.whocc.no/atc_ddd_index/ on September 2015.

WHO (2015b) World report on ageing and health. WHO Library Cataloguing-in-Publication Data. Retrieved from http://apps.who.int/iris/bitstream/10665/186463/1/9789240694811_eng.pdf?ua=1 on 2. January 2016.

Zisberg A., Young H.M., Schepp K. & Zysberg L. (2007) A concept analysis of routine: relevance to nursing. *Journal of Advanced Nursing* 57(4), 442-453.

PAPER I

JAN
Informing Practice and Policy Worldwide through Research and Scholarship

ORIGINAL RESEARCH: EMPIRICAL RESEARCH – QUANTITATIVE

Exploring faecal incontinence in nursing home patients: a cross-sectional study of prevalence and associations derived from the Residents Assessment Instrument for Long-Term Care Facilities

Lene Elisabeth Blekken, Anne Guttormsen Vinsnes, Kari Hanne Gjeilo, Christine Norton, Siv Mørkved, Øyvind Salvesen & Sigrid Nakrem

Accepted for publication 9 December 2015

Correspondence to L.E. Blekken:
e-mail: lene.blekken@hist.no

Lene Elisabeth Blekken RN
PhD Student
Faculty of Health and Social Science, Faculty of Medicine, Norwegian University of Science and Technology, Trondheim, Norway

Anne Guttormsen Vinsnes PhD RN
Professor
Faculty of Health and Social Science, Norwegian University of Science and Technology, Trondheim, Norway

Kari Hanne Gjeilo PhD RN
Associate Professor
St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway and
Faculty of Medicine, Norwegian University of Science and Technology, Trondheim, Norway

Christine Norton PhD RN
Professor
Faculty of Nursing and Midwifery, King's College London, UK

Siv Mørkved PhD Physiotherapist
Professor
Medical Faculty, Norwegian University of Science and Technology, Trondheim, Norway and
St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway

Øyvind Salvesen PhD Statistician
Associate Professor
Medical Faculty, Norwegian University of Science and Technology, Trondheim, Norway

continued on page 2

BLEKKEN L.E., VINSNES A.G., GJEILO K.H., NORTON C., MØRKVED S., SALVESEN Ø. & NAKREM S. (2016) Exploring faecal incontinence in nursing home patients: a cross-sectional study of prevalence and associations derived from the Residents Assessment Instrument for Long Term Care Facilities. *Journal of Advanced Nursing* **00**(0), 000–000. **doi: 10.1111/jan.12932**

Abstract

Aim. To explore prevalence and associations of faecal incontinence among nursing home patients, to examine the effect of clustering of observations and to study the variation in faecal incontinence rates on both the level of nursing home units and individual patients.

Background. Faecal incontinence affects 40-55% of the patients in nursing homes and is associated with increased risk of morbidity and reduced quality of life. There is a lack of studies investigating faecal incontinence with validated instruments. More studies need to include models of analyses that allow for clustering of observations.

Design. Cross-sectional.

Methods. Data on 261 patients from 20 nursing home units were collected during September–October 2014. The Norwegian version of the Resident Assessment Instrument for Long-Term Care Facilities was used. Mixed effect models were conducted.

Results. Prevalence of faecal incontinence was 42·1% or 54% depending on the frequency labelling chosen. The effect of clustering by nursing home unit was not statistically significant. Most of the variation in faecal incontinence rates was explained by differences in patient characteristics, the most important being deficiencies in activities of daily living, cognitive impairment, diarrhoea and not participating in activities.

Conclusion. Nursing home patients should be offered individualized assessment and continence care matching their patient characteristics. The Resident Assessment Instrument for Long-Term Care Facilities is a useful instrument because of its' combination of a comprehensive range of individual items and scales allowing for comparison of immediate or long-term change in patients

Sigrid Nakrem PhD RN
Associate Professor
Faculty of Health and Social Science, Norwegian University of Science and Technology,
Trondheim, Norway

status. Studies evaluating interventions targeting faecal incontinence are warranted.

Keywords: associations, cross-sectional, faecal incontinence, interRAI LTCF, mixed effects models, nursing, nursing home, prevalence, protective factors, risk factors

Why is this research needed?

- Faecal incontinence has high prevalence in the nursing home setting, is associated with reduced quality of life and poor health perception, and entails a high indirect and direct economic burden to the health care system.
- There is a lack of studies exploring faecal incontinence with standardized and validated instruments in the nursing home population.
- Variation in faecal incontinence rates between patients and between nursing home units is poorly understood.

What are the key findings?

- It is the variation between the individual patients, not the nursing home units, which explains the variation in faecal incontinence rates.
- Risk factors are deficiencies in activities in daily living, cognitive impairment, diarrhoea and urinary incontinence, and being involved in activities and instability in health/frailty are protective factors.
- The Resident Assessment Instrument for Long-Term Care Facilities is a comprehensive, useful and feasible instrument for exploring prevalence and associations of faecal incontinence in nursing home patients.

How should the findings be used to influence policy/practice/research/education?

- We need more awareness of faecal incontinence as potentially preventable and treatable by offering nursing home patients individualized assessment and continence care matching their patient characteristics.
- There is a need for studies evaluating the effect of interventions targeting faecal incontinence in nursing home patients.
- The Resident Assessment Instrument for Long-Term Care Facilities is a comprehensive and validated instrument that might be useful both for clinicians as a tool for individualized care and for researchers in evaluating effects of interventions targeting multifactorial symptoms such as faecal incontinence, that also enables comparison of results between different setting and countries.

Introduction

Faecal incontinence (FI) is defined by the International Consultation on Incontinence as 'the involuntary loss of liquid or solid stool that is a social or hygienic problem' (Bliss *et al.* 2013). The reported prevalence of FI in nursing homes (NHs) varies between 10-67%, but it is most often reported to be between 40-55% (Saga 2014). FI is related to feelings of shame and embarrassment (Bliss *et al.* 2013, Taylor *et al.* 2014), and can lead to a downward spiral of psychological distress, dependency and poor health (Wagg *et al.* 2013). Furthermore, FI leads to a high direct and indirect economic burden to the healthcare system, and is an important cause of institutionalization of older people (Borrie M.J. & Davidson H.A. 1992, Wagg *et al.* 2013). Hence, exploring FI is a significant international issue due to the high prevalence, the consequences for the individual patient and for the healthcare system.

Background

Defecation involves a complex series of events and factors including diet, stool consistency, anorectal sensation, muscle strength and function and neurological integrity cognition, and motivation. Age-related anatomical changes in the anorectum lead to decreased squeeze pressures that impair the neuromotor mechanisms of continence in older people (Bannister *et al.* 1987, Fox *et al.* 2006, Wagg *et al.* 2013). However, the high prevalence of FI in the NH population compared with younger people cannot be explained by the anatomical and physiological changes of ageing alone (Wagg *et al.* 2013). Colonic function in general, and FI specifically, appears to be more influenced by factors associated with ageing than with ageing itself (Wagg *et al.* 2013).

Previous reviews have reported possible associations of FI such as functional incapacity, reduced cognitive function, diarrhoea, constipation/impaction, stroke, neurological diseases, diabetes and comorbidity in general (Wagg *et al.* 2013, Saga 2014). The level of knowledge among health personnel on the value of good bowel care, including appropriate assessment and treatment options, seems limited (Mangnall *et al.* 2006, Thekkinkattil *et al.* 2008,

Bliss *et al.* 2013, Saga *et al.* 2014), and use of incontinence pads is the most common management for FI in long-term care settings (Rodriguez *et al.* 2007, Roe *et al.* 2011, Saga *et al.* 2014). Harrington *et al.* (2011) found that only 3·7% of nursing home patients with FI were offered a bowel-training program (diet, fluid, regular schedules). Comparing results on prevalence of FI and associations in studies over the last 40 years are complicated due to different or absent definitions of FI, different and often poor description of the associations, and shortcomings in the reporting of methodology and the NH setting (Saga 2014).

There is a lack of studies investigating FI prevalence and associations with validated instruments in the NH setting (Norton *et al.* 2009). Over the years, there has been development of instruments designed to measure a single construct for a single purpose in NH patients, e.g. Barthel ADL Index, Mini Mental State Examination (MMSE) and Geriatric Depression Scale (GDS). Today, most of the NH patients have complex health problems and care needs (Harrington *et al.* 2011). This has created a need for assessment instruments that can capture a holistic picture of the patient. As a response to a demand to improve quality of care in NH in the USA, the Minimum Data Set-Resident Assessment Instrument (MDS-RAI) was implemented in all NHs in 1990-92 (Carpenter & Hirdes 2013). The international collaboration interRAI was founded in 1992. Ongoing development by interRAI has resulted in an updated suite of instruments, including a revised version of MDS: the Residents Assessment Instrument for Long-Term Care Facilities (interRAI LTCF) (Morris *et al.* 2012) which is a standardized, validated and comprehensive tool to assess patients' health status in the long-term care setting for use in care planning and research (Hirdes *et al.* 2008, Onder *et al.* 2012).

Another challenge in NH research is that unit of observations are clustered as patients are grouped in NHs, and there is a need to investigate how this might affect the results in this population (Rabe-Hesketh & Skrondal 2012a). In addition, we need more studies with a design that includes analyses that discriminate between variability due to individual patient factors and factors related to the NH (Wagg *et al.* 2013).

The study

Aim

The primary aim of this study was to explore the prevalence and associations of FI among NH patients using the Norwegian version of interRAI LTCF. Another aim was to investigate the effect of clustering of observations and to study variance on both the NH unit level and the patient level by analysing data using mixed effects models.

Design

A cross-sectional design was employed. Data were gathered during September and October 2014 as the baseline of a cluster-randomized controlled trial investigating the effect of an educational program for care staff about FI in NH patients (Blekken *et al.* 2015a). The trial is registered in the clinical trial registry (NCT02183740).

Setting

Most Norwegian NHs are owned and run by the municipalities. Usually NHs are managed by Registered Nurses (RNs) and have an agreement with a general practitioner (GP) who visits the NH once a week. There are no legal requirements for staff-to-patient ratios or specifications for qualifications required for care workers (Ringard *et al.* 2013). However, NHs have RNs on duty 24-hours a day, and according to Statistics Norway the staff comprises on average 31% RNs, 45% licenced practical nurses (care staff with high school education), and 24% healthcare aides (no formal healthcare education) (Statistics Norway 2014). For this study NHs units with 24 hour long-term residency, comparable staff-to-patient ratios on the day shift and similar GP coverage were eligible for inclusion. Specialized NH units or units with enhanced staff-to-patient ratios were excluded. In Norway, a majority of NH patients are above 67 years, have complex health problems, significant deficiencies in functioning related to activities of daily living (ADL), and about 80% have cognitive impairment (Nylenna 2014).

Patients

Of a total of 27 NHs available in the municipality, the sample of patients was recruited from 20 NHs units from 10 different NHs. The sample-size for the present cross-sectional study was not specifically calculated, but sample-size calculations for the trial are reported elsewhere (Blekken *et al.* 2015a). All long-term care patients with a stay of 1 month or more were eligible for inclusion.

Data collection

The project coordinator and a research assistant gave information and training to RNs (3 hours per NH) on completion on the interRAI LTCF and the St. Marks incontinence score (University Hospital of North Norway 2012). This

included training in using the interRAI LTCF standardized coding guidelines provided in the instrument's training manual (Morris *et al.* 2012). Two RNs were recruited per NH, a total of 20 RNs. The RNs in the same NHs were advised to preferably work together to enhance the clinical judgment when filling in the forms. In addition, RNs used information from the electronic patient's record, co-workers and the patients when completing the questionnaires.

Measurements

Response variable

FI is measured by interRAI LTCF, section H3: Bowel continence, on a scale where 0 = continent, 1 = continent with a stoma, 2 = seldom incontinent (not incontinent during the last 3 days, but has episodes of incontinence), 3 = occasionally incontinent (more seldom than daily), 4 = often incontinent (daily, but has some control), 5 = incontinent (no control), and 8 = did not occur (no bowel movement). For the multivariable analyses, patients assessed as occasionally incontinent (3), often incontinent (4) and incontinent (5) were defined as incontinent. The cut-off was informed by that considered clinically relevant in the trial involving the same NH population (Blekken *et al.* 2015a,b), and previous studies (Kinnunen 1991, Borrie & Davidson 1992, Harrington *et al.* 2011).

Explanatory variables

The choice of explanatory variables was guided by the results presented in two reviews (Norton *et al.* 2009, Saga 2014), and were as follows:

- Patient's cognitive status was measured by using the Cognitive Performance Scale (CPS) (Morris *et al.* 1994, interRAI 2015). Scores range from 0-6, where 0 represents being cognitively intact. Scores of 2 or greater indicate cognitive impairment (Büla & Wietlisbach 2009).
- Patient's functional status was measured by the Activity of Daily Living long form scale (ADLlf) (Morris *et al.* 1999). The items used in this study differ from Morris *et al.* (1999) due to revision in the ADL items in the interRAI LTCF. After communicating with a Norwegian member of the interRAI organization, the following seven items were included: personal hygiene, dressing upper body, dressing lower body, locomotion, toilet use, eating and bed mobility. The original ADL long form has five categories of response for each item. The Norwegian version has eight possible scores of response from 0 (total independence) to 6 (total dependence), and a score 8 for the activity did not occur. Thus, the score 0 (total independence) was collapsed with the score 1 (prepare for activity only); the score 5 (maximum assistance) and score 6 (total dependence) were collapsed with score 8 (activity did not occur), giving the new scoring categories: 0 = total independence/prepare only, 1 = supervision, 2 = limited assistance from staff, 3 = extensive assistance from staff, 4 = total dependence/activity did not occur. Total score ranges from 0-28 for the seven items, where 0 indicates no functional difficulty.
- The Depression Rating scale (DRS) (Burrows *et al.* 2000, InterRAI 2015) was used to measure symptoms of depression. Scores range from 0-14, where 0 indicates no depression symptoms. Scores of 3 or greater indicate depressive disorders (InterRAI 2015).
- Patient's instability in health/frailty was measured by the Changes in Health, End-Stage Disease, Signs, and Symptoms Scale (CHESS) (Hirdes *et al.* 2003, InterRAI 2015).
- The Aggressive Behavior Scale (ABS) (Perlman & Hirdes 2008, InterRAI 2015) was used to measure aggressive behaviour. Scores range from 0-12, where 0 indicates no aggressive behaviour.
- The Revised Social Engagement scale (RISE) was used to measure the degree of involvement in positive social activities (Gerritsen *et al.* 2008). Scores range from 0-6, where 0 indicates no involvement in positive activities, i.e., the scale is reversed and low score indicates a low degree of engagement.
- The Communication Scale (COMM) measures both expressive and receptive communication skills. Scores range from 0-8, where 0 indicates no communication problems (Wellens *et al.* 2012, interRAI 2013).
- The following individual interRAI LTCF variables were used: 'Diarrhoea', 'Constipation', 'Pressure ulcers', 'Urinary incontinence', 'Maximum walking distance', 'Activity level', 'Fatigue', 'Body mass index', 'Hearing', and 'Vision'.
- Patient's medical condition was recorded by section I of interRAI LTCF: 'Alzheimer's disease', 'Dementia other than Alzheimer's disease', 'Hemiplegia', 'Multiple sclerosis', 'Paraplegia', 'Parkinson's disease', 'Quadriplegia', 'Cerebrovascular accident (stroke)', Cardiovascular disease', 'Congestive heart failure', 'Chronic obstructive lung disease', 'Anxiety disorder', 'Bipolar disease', 'Depression', 'Schizophrenia', 'Pneumonia', 'Urinary tract infection', 'Cancer', 'Diabetes mellitus', 'Hypothyroidism'.

- All the patient's medications were recorded by section N of interRAI LTCF. The relevant medications were grouped according to the Anatomical-Therapeutic-Chemical Classification (ATC) system, primarily on level four since drugs at this level often have common adverse drug reactions (WHO 2015): 'laxatives' (A06A), 'enemas' (A06A G), 'antidiarrhoeal agents' (A07D), 'opiates' (N02A), 'antibacterials', 'diuretics' (C03), 'antidepressants' (N06A), 'antipsychotics' (N05A), 'iron supplements' (B03A) and 'calcium supplements' (A12A).
- The questionnaire included a section where RNs were offered a list of interventions relevant for bowel problems and asked to identify what is done for each individual patient. In this study, we have included the variables 'use of incontinent pads' and 'use of micro-enemas' (Microlax®, A06AG11 and bisacodyl, A06AG02).
- A Norwegian version of St. Mark's faecal incontinence score was used to get additional information on type of FI (gas, loose or solid stool), urgency (inability to defer defecation for 15 minutes), and impact on daily life. It gives a total score from 0 (complete continence) to 24 (complete FI).

Ethical considerations

The study was approved by the Regional Committee for Medical and Health Research Ethics (REK) (2013/1802/REK North) and by The Norwegian Social Science Data Services (36482/2/MB). An essential ethical consideration in this study was whether or not informed consent should be obtained from patients or their representatives. After evaluating the overall project, the REK authorized RNs with dispensations from the duty of confidentiality to gather relevant patient health information (proxy data). Since dispensation was given, patient consent was not obtained. All patient information was de-identified by care staff before transfer to the researcher. The study was performed in concordance with the Helsinki Declaration.

Analyses

Statistical analyses were performed using STATA version 13 (StataCorp LP, College Station, TX, USA). Statistical methods included estimating prevalence in percentages, and other descriptive statistics. InterRAI LTCF offers a large number of variables. Univariable logistic regression analysis was conducted on the variables identified under the section *data collection*. We used perceived clinical significance, Log likelihood, McFadden's R^2 and $P \leq 0{\cdot}05$ to assess degree of impact on the outcome variable to inform the choice of variables to include in the multivariable logistic regression model. To ensure sufficient events per explanatory variable in the multivariable model, the ratio was set at a maximum of 10:1 (Peduzzi 1996). Effect sizes are presented as odds ratios (OR) with 95% confidence interval (CI) and P values. Variables were considered significant if $P < 0{\cdot}05$, but P values between 0·01 and 0·05 were interpreted with caution due to multiple comparisons. Cronbach's alpha was used to investigate internal consistency of the summated scales, where each item contributes equally to the total score (Wellens *et al.* 2011).

To investigate the effect of clustering, the multivariable logistic regression model was tested against a mixed effects logistic regression model with the NH units treated as a random effect. The definition of NH unit in this study is comparable with the functional definition made by Estabrooks *et al.* (2011). STATA provides a likelihood-ratio test for the null hypotheses that the NH unit-level variance is significantly different from zero. Hence, the mixed effects logistic regression model makes it possible to investigate variance on two levels, the level of the individual patient vs. the level of the NH unit (Eikemo & Clausen 2012, Rabe-Hesketh & Skrondal 2012a). The Akaike information criterion (AIC) and the Bayesian information criterion (BIC) were used to compare model fit of the different models (Rabe-Hesketh & Skrondal 2012b).

We also tested other basic assumptions for logistic regression (Stoltzfus 2011, Freedland *et al.* (2009). One assumption is linearity in the logit for any continuous explanatory variable (Ottenbacher *et al.* 2004, Stoltzfus 2011). For this, we performed a linktest (Stata 2015, UCLA 2015). Multicollinearity was investigated by using the tolerance value that indicates the variables' uniqueness in explaining variation, where zero means perfect collinearity between variables. Perfect collinearity makes it impossible to obtain a unique estimate of regression coefficients for the involved variables (UCLA 2015). A definite cut-off criteria for 'too much' multicollinearity does not exist. However, it is suggested that a value below 0·1 is problematic (Midtbø 2012). No replacements were made for missing data, thus, the number of patients varies between the different analyses.

Validity and reliability

Studies investigating and comparing reliability of the different interRAI instruments and the interRAI LTCF have found the majority of the items to exceed standard cut-offs

for acceptable reliability (Hirdes *et al.* 2008, Poss *et al.* 2008, Onder *et al.* 2012), and the interRAI LTCF had the highest mean kappa (0·74) (Hirdes *et al.* 2008). Both Hirdes *et al.* (2008) and Onder *et al.* (2012) found incontinence among the items with the best kappa values. However, the different scales have shown various results related to validity and reliability (Landi *et al.* 2000, Gerritsen *et al.* 2008, Perlman & Hirdes 2008, Poss *et al.* 2008, Shin & Scherer 2009), with the CHESS and the DRS as the two scales with the most varying results (Shin & Scherer 2009, Hogan *et al.* 2012, Liang *et al.* 2014). The St Mark's incontinence score correlates moderately well with patients' subjective perception and is reliable regardless of type of FI, patients' age or gender (Maeda *et al.* 2008). However, the instrument has not been tested in the NH population.

Results

The study included all patients ($n = 261$) within eligibility criteria from 20 NH units. Demographic and medical characteristics are presented in Table 1. Mean number of patients in each unit was 13 (range 10-23).

Table 1 Demographic and medical characteristic of nursing home patients.

Characteristic	Value *n* (%) or mean (SD)
Age (years)	84·7 (8·3)
Gender (female)	173 (66·3)
Length of stay (years)	2·3 (2·5)
Body Mass Index	23·1 (5·1)
Instability in health, CHESS scale (0-5)	1·5 (1·2)
Communication, COMM scale (0-8)	2·5 (2·4)
Aggressive behaviour, ABS scale (0-12)	1·2 (1·8)
Activities of Daily Living, ADL scale (0-28)	12·6 (9·3)
Social involvement, RISE scale (0-6)	3·3 (2·0)
Urinary incontinence	182 (69·7)
Cognitive impairment, CPS scale (0-6) Score ≥2	177 (69·4)
Depression, DRS scale (0-14) Score ≥3	55 (21·2)
Average time involved in activities	
<1/3 of the day	130 (50·6)
≥1/3 of the day	127 (49·4)
Maximum distance walked last 3 days	
<5 m	110 (42·5)
≥5 m	149 (57·5)
Constipation	61 (23·5)
Diarrhoea	31 (11·9)
Pressure ulcer	44 (16·9)
Inability to defer defecation for 15 min	104 (40·6)
Daily use of bed rails	103 (39·5)

Faecal incontinence and univariable associations

The prevalence of FI as derived from interRAI LTCF was 42·1% (Table 2). If we had included patients with the score 2 (seldom incontinent), the prevalence would have been 54%. Mean St Marks incontinence score was 6·6 (SD 5·4). Using St Marks's score with the definition 'at least one episode in the last 4 weeks', prevalence rate would have been 70·1%. Results on type of FI (solid, liquid), is presented in Table 3. In 104 (40.6%) of the patients urgency was reported. A total of 209 (80·4%) of the patients used incontinence pads. Among patients reported as continent for both urine and faeces ($n = 73$), twenty-eight (38·4%) were using incontinence pads.

The univariable logistic regression analyses resulted in 17 covariates with significant association with FI (Tables 4–6). Because of the 10:1 ratio criteria, a maximum of 11 variables could be included in the multivariable model. The 11 variables with the highest impact on the outcome variable (Log likelihood and McFaddens R^2) in the univariable logistic regression models ordered from highest to lowest, were: urinary incontinence, ADL, cognitive impairment (CPS), inability to defer defecation for 15 minutes, inability to communicate (COMM), maximum distance walked, average time involved in activities, length of stay, social engagement (RISE), use of micro-enema and diarrhoea. The only medical diagnosis with a significant association with FI in the univariable analyses, was paraplegia ($P = 0·032$). However, the impact on FI was too small to be considered in the multivariable model.

Mixed effects logistic regression

Results from the mixed effects logistic regression are presented in Table 4. The likelihood-ratio statistic for the model was 0·89 ($P = 0·173$). This means that the variance between NH units did not have a significant influence on the results, and thereby a multilevel model was not required. The analyses resulted in an Intra-Cluster Correlation Coefficient (ICC) = 0·12 which means that 12% of the total variance in the data is on the NH unit level, while 88% of the total variance can be explained by differences between individual patients. The analyses comparing the multivariable logistic model with the mixed effects logistic model resulted in AIC and BIC values for the logistic model of 146·25 and 183·53 and for the mixed model 147·36 and 191·00. The slightly lower AIC and BIC values for the multivariable logistic regression model indicates a better fit to the data. Hence, below we will present

Table 2 Prevalence of faecal incontinence derived from interRAI LTCF* (n = 261).

Scores		n (%)	Prevalence n (%)
0	Continent; full control	115 (44·1%)	Continent
1	Control with a stoma	1 (0·4%)	151 (57·9%)
2	Seldom incontinent; not incontinent the last 3 days, but has episodes of incontinence	31 (11·9%)	
3	Occasionally incontinent; more seldom than daily	27 (10·3%)	Incontinent
4	Often incontinent; daily, but has a certain control	30 (11·5%)	110 (42·1%)
5	Incontinent; no control	53 (20·3%)	
8	Did not happen; no bowel movement in the last 3 days	4 (1·5%)	Continent

*Resident Assessment Instrument for Long-Term Care Facilities.

Table 3 Scores derived from St Mark's incontinence score* (n = 254).

	Continent for liquid faeces	Incontinent for liquid faeces	Total
Continent for solid faeces	76 (29·9)	45 (17·7)	121 (47·6)
Incontinent for solid faeces	13 (5·1)	120 (47·2)	133 (52·3)
Total	89 (35·0)	165 (64·9)	254 (100)

Numbers are given as n (%) for each column.
*When faecal incontinence defined as at least one episode in the past 4 weeks.

adjusted ORs from the multivariable logistic regression model (Table 4).

Results from the multivariable logistic regression

The results from the multivariable logistic regression shows that the risk of FI increases with OR 2·24 ($P < 0·001$) for each unit increase on the urinary incontinence scale, and with the OR of 1·12 ($P = 0·001$) for each unit worsening on the ADL scale. The risk for FI increased by 1·69 ($P = 0·006$) for each increase on the CPS scale. 'Diarrhoea' (OR 8·9, $P = 0·006$) was significantly more prevalent among patients with FI. Being involved in activities more than 1/3 of time during the day had a significantly protective effect on FI (OR 0·33, $P = 0·036$), compared with being involved in activities less than 1/3 of the time. 'Increased instability in health/frailty (CHESS) showed a significant protective effect' (OR 0·62, $P = 0·041$).

The use of interRAI LTCF

RNs managed to fill in the questionnaire on all patients (n = 261). Mean percentages of missing values in single items of the completed questionnaire was 0·8%. Cronbach's alpha for the summated scales were as follows: ADLlf = 0·93, COMM = 0·88, ABS = 0·73, RISE = 0·81, DRS = 0·69.

Results of the test for statistical assumptions

Linearity in the logit

The linktest was not significant ($P = 0·553$). This means that the model was properly specified, and that the assumption of linearity was fulfilled (Stata 2015).

Multicollinearity

The Tolerance-test revealed collinearity between 'ADL' and 'Maximum walking distance', and CPS and COMM. Hence, we excluded 'COMM' and 'Maximum walking distance' from the multivariable analyses. Instead, we found it clinically interesting to include CHESS. The variable 'Micro-enema' was excluded from the model as it lost its significance in the multivariable analyses and did not affect the outcome of the other variables. Age was included in the model as it is considered as clinically significant when investigating health problems in general. These alternations did not affect significance level of the variables, but the final model including CHESS resulted in an overall better fit when comparing McFadden's R^2, AIC and BIC.

Discussion

Our study confirms the previously reported high prevalence of FI among NH patients (Harrington *et al.* 2011, Saga *et al.* 2013, Jerez-Roig *et al.* 2015). However, the prevalence rate will vary due to different frequency labelling. Therefore, we underline the importance of reporting details on labelling FI to compare results. We found no other studies using interRAI LTCF with the primary aim to investigate prevalence and associations of FI, only one study using data from the MDS version 2.0 (Nelson *et al.* 1998) and one study using data from MDS version 3.0 (Jerez-Roig *et al.* 2015). Only MDS version 2.0 is an interRAI product. We found no other studies using the scales derived from interRAI LTCF/MDS to explore FI. Jerez-Roig *et al.* (2015) used Barthel ADL index for measuring ADL, and Pfeiffer's test to evaluate cognitive capacity. Nelson *et al.* (1998) used individual ADL items in the multivariable analyses.

Table 4 Exploring associations between faecal incontinence and demographic/clinical health problems.

Variables	Univariable logistic regression* OR (95% CI)	*P* value	Multivariable logistic regression† OR (95% CI)	*P* value	Mixed effects logistic regression‡ OR (95% CI)	*P* value
Age (years)	0·97 (0·94–1·00)	0·057	0·96 (0·91–1·01)	0·11	0·95 (0·9–1·01)	0·093
Gender (female)	1·66 (0·98–2·83)	0·06				
Body Mass Index (BMI)	0·97 (0·92-1·02)	0·26				
Length of stay (years)						
0-2	Reference		Reference		Reference	
>2-5	2·51 (1·34–4·72)	0·004	1·87 (0·59–5·87)	0·28	1·79 (0·53–6·09)	0·35
>5	6·10 (2·15–17·4)	0·001	1·34 (0·18–9·80)	0·77	1·00 (0·1–10. 03)	1·00
Urinary incontinence (Scale 0-4)	3·01 (2·32–3·90)	<0·001	2·24 (1·56–3·20)	<0·001	2·40 (1·58–3·65)	<0·001
Activities of daily living (ADL) (Scale 0-28)	1·18 (1·14–1·23)	<0·001	1·12 (1·05–1·19)	0·001	1·13 (1·05–1·21)	0·001
Cognitive performance (CPS) (Scale 0-6)	1·98 (1·64–2·4)	<0·001	1·96 (1·16–2·44)	0·006	1·68 (1·12–2·52)	0·012
Social Engagement (RISE) (Scale 0-6)	0·76 (0·69–0·87)	<0·001	0·90 (0·71–1·16)	0·430	0·88 (0·67–1·16)	0·37
Average time involved in activities 0 = <1/3 of the day 1 = ≥1/3 of the day	0·23 (0·51–0·44)	<0·001	0·33 (0·10–0·92)	0·036	0·30 (0·09–0·97)	0·045
Inability to defer defecation for 15 minutes (0 = no, 1 = yes)	1·61 (1·40–1·85)	<0·001	1·20 (0·93–1·54)	0·15	1·23 (0·93–1·62)	0·15
Maximum walking distance (0 = <5 m, 1 = ≥5 m)	0·20 (0·12–0·35)	<0·001				
Fatigue (Scale 0-4)	1·63 (1·25–2·13)	<0·001				
Communication (COMM) (Scale 0-8)	1·48 (1·31–1·67)	<0·001				
Vision impairment (Scale 0-4)	1·78 (1·30–2·40)	<0·001				
Hearing impairment (Scale 0-4)	1·58 (1·21–2·09)	0·001				
Aggressive Behaviour (Scale 0-12)	1·25 (1·08–1·43)	0·002				
Diarrhoea (0 = no, 1 = yes)	3·30 (1·49–7·34)	0·003	8·90 (1·87–42·5)	0·006	10·10 (1·85–55·01)	0·008
Pressure ulcer (0 = no, 1 = yes)	2·29 (1·18–4·43)	0·01				
Constipation (0 = no, 1 = yes)	1·87 (1·05–3·33)	0·034				
Instability in health (CHESS) (Scale 0-5)	1·22 (0·96–1·50)	0·07	0·62 (0·39–0·98)	0·041	0·62 (0·38–1·01)	0·053
Depression rating scale (Scale 0-14)	1·04 (0·92–1·17)	0·55				

*Univariable logistic regression performed with faecal incontinence as response variable and explored by a range of covariates.

†Multiple logistic regression, covariates selected by direct variable selection with $P \leq 0.05$ and/or the highest impact (Log likelihood, McFadden's R^2) on FI in the univariable logistic regression analyses, and perceived clinical significance.

‡Mixed effects logistic regression, NH units defined as grouping variable (cluster) to investigate the impact of NH units, and whether the grouping of data significantly affected the results. The estimated intra-cluster correlation coefficient (ICC) = 0.12. The likelihood-ratio test for testing if the data required a multilevel model resulted in $P = 0.173$ meaning that a multilevel model will not significantly improve the analyses of the data.

Other studies not based on MDS for investigating FI have seldom used validated instruments when investigating association. Exceptions are Akpan *et al.* (2007) using the Barthel ADL index and Mini Mental State Examination (MMSE), Aslan *et al.* 2009 using the Mini Mental Test and Ranking Scale, and Saga *et al.* (2013) using the Barthel

Table 5 Exploring association between faecal incontinence and medical diagnoses.

Variables	Univariable logistic regression OR (95% CI)	*P* value
Paraplegia	4·41 (1·17-16·69)	0·029
Cardivascular disease	0·59 (0·34-1·02)	0·058
Urinary tract infection	1·86 (0·91-3·82)	0·09
Dementia other than Alzheimer's	1·42 (0·86-2·34)	0·17
Hemiplegia	1·76 (0·70-4·40)	0·23
Depression	1·41 (0·80-2·51)	0·24
Diabetes mellitus	0·67 (0·31-1·45)	0·31
Alzheimer's disease	1·29 (0·78-2·24)	0·38
Hypothyroidea	1·69 (0·50-5·68)	0·40
Cerebrovascular accident (stroke)	1·32 (0·68-2·57)	0·41
Congestive heart failure	0·84 (0·40-1·76)	0·65
Anxiety disorder	0·89 (0·48-1·64)	0·70
Schizophrenia	1·39 (0·19-10·0)	0·74
Parkinson's disease	1·19 (0·39-3·65)	0·76
Chronic obstructive lung disease	1·12 (0·50-2·50)	0·78
Cancer	1·14 (0·43-2·99)	0·79
Rheumatoid arthritis/arthritis	0·94 (0·44-2·00)	0·87
Bipolar disease	0·92 (0·15-5·61)	0·93
Pneumonia	1·06 (0·23-4·84)	0·94

Table 6 Exploring associations between faecal incontinence and medications.

Variables*	Univariable logistic regression OR (95% CI)	*P* value
Micro-enemas*	3·17 (1·83-5·50)	<0·001
Laxatives†	1·60 (0·92-2·79)	0·10
Antibacterials	1·80 (0·68-4·69)	0·24
Opiats	1·30 (0·79-2·15)	0·30
Iron supplements	1·42 (0·63-3·20)	0·39
Antidepressants	0·82 (0·47-1·41)	0·47
Diuretics	0·87 (0·50-1·53)	0·64
Calcium supplements	0·88 (0·45-1·77)	0·72
Antipsychotics	1·13 (0·57-2·26)	0·73
Antidiarrhoeal agents	1·15 (0·34-3·90)	0·82

*Anatomical-Therapeutic-Chemical Classification System (ATC) (Microlax®, A06A G11, Bisacodyl, A06A G02).
†Regular and on demand; tablets, oral liquids and suppositories.

ADL index. These scales are standalone scales designed to measure a single construct for a single purpose. Attempts to use clusters of these instruments may result in cumbersome assessment approaches employing overlapping assessment items and conflicting assessment methods (Carpenter & Hirdes 2013). Compared with this, interRAI LTCF, which is found to be an overall reliable instrument (Hirdes *et al.* 2008, Onder *et al.* 2012), enables a multidimensjonal assessment that both contains a comprehensive amount of individual items, and data driven algorithms to generate scales. Hence, interRAI LTCF might replace the use of several standalone scales.

FI was significantly associated with urinary incontinence. This is consistent with findings reported in two reviews (Wagg *et al.* 2013, Saga 2014). However, it is well established that urinary incontinence is a co-morbid condition, rather than a risk factor (Nelson *et al.* 1998). Also consistent with other findings is the associations between FI and ADL deficiency and cognitive impairment (Wagg *et al.* 2013, Saga 2014). In contrast to what has been reported in reviews, no medical diagnosis had a sufficient impact on FI to be considered in the multivariable analyses. These findings support the assumption that NH patients develop functional incontinence due to incapacity to reach the toilet because of ADL deficiencies or cognitive impairment and that this is more important than the medical diagnoses in explaining FI (Saga *et al.* 2013, 2014). Also, 80·4% of the patients in this study used incontinence pads, and among them 38% of the patients were reported to be continent for both urine and faeces. This result is consistent with findings that use of incontinent pads is the most prevalent form of management among NH patients (Roe *et al.* 2011). The result support the assumption that the knowledge of appropriate assessment and treatment options is limited among care staff and that patients are often not offered best practice both related to FI specific nor elimination in general (Thekkinkattil *et al.* 2008, Wagg *et al.* 2013, Saga *et al.* 2014).

Diarrhoea was identified as an important risk factor for FI. At the same time, about 72% of the patients used laxatives. The high use of laxatives is consistent with findings in other studies (Gage *et al.* 2010, Fosnes *et al.* 2012), and so is diarrhoea as an important risk factor for FI (Wagg *et al.* 2013). An interpretation supported by Saga *et al.* (2014) is that care staff do not consider FI as a problem. The problem they identify and try to manage is constipation. The RNs may think that it is more important to secure a loose stool, than to carry out interventions that make the stool harder and more controllable, relieving FI but thereby risking constipation.

Health instability (CHESS) showed a significant protective effect for FI. Other studies have reported frailty as a risk factor for FI among community-dwelling adults (Nelson *et al.* 1995, Goode *et al.* 2005). In a NH setting, increased health instability may lead to care staff being more observant about the patient's healthcare needs in general, including bowel care. Care staff are less likely to be able offer this kind of care among patients living at home. Also, being involved in activities more than 1/3 of the time during the day had a protective effect. This might mean that patients with no FI are more likely to be involved in

activities, while the incontinent patients are not. This finding could also indicate that patients with FI do not want to participate, because they are socially affected by their FI. However, other research has found physical activity as protective against faecal and urinary incontinence among NH patients (Johanson *et al.* 1997, Schnelle *et al.* 2002, Vinsnes *et al.* 2012).

The mixed effects logistic regression analyses revealed that 88% of the total variance in the likelihood of having FI was associated with variance on the individual patient level. The variance between the NH units did not significantly affect the results. Estabrooks *et al.* 2011 found a significant NH unit variance, so did Wang *et al.* (2009). Our NH units were all from the same municipality, and might have more similarities than NHs from different municipalities. In other countries with more varied ownership or management of NHs there might be more variability. However, most of the variance in the data was explained by different patient characteristics/health deficiencies. Hence, it is important to stress that FI in many patients might be prevented and treated if care staff have knowledge of risk factors and undertake individualized assessment and care plans to target continence care to the needs of different patients.

We found interRAI LTCF feasible and useful for exploring FI among NH patients. RNs managed to complete interRAI LTCF in all included patients within a reasonable timeframe. This confirms the results from a pilot study performed by our group (Blekken *et al.* 2015b). In the pilot study, RNs reported completing interRAI LTCF as a time consuming but meaningful task as it allowed them to sit down, discuss and do a thorough assessment of the patients. Although testing interRAI LTCF was not an aim for this study, we calculated Cronbach's alpha for the scales suitable for this measure. Acceptable values of alpha are reported to range from 0·70-0·95. A maximum alpha value of 0·90 has been recommended (Tavakol & Dennick 2011). The Cronbach's alphas in this study confirm that the scales have an acceptable reliability, but seen together with other studies caution is needed in using the DRS as a reliable measure for depression among NH patients (Shin & Scherer 2009, Liang *et al.* 2014).

Limitations

Our study comprised a relatively small sample which might have limited the investigation of association of some conditions and FI e.g. urinary tract infection, cardiovascular disease and stroke. This might threaten the external validity of the study concerning these conditions. RNs who filled in the questionnaires received training based on pragmatic considerations of acceptable time use and we did not use any agreement test among RNs after training. This might affect generalizability of the results. Another limitation is the use of proxy data, since the RNs scored the questionnaires, and not the patients themselves. The reliability and validity of proxy data is found to be high for tasks of daily living and health conditions that are easily observed and relatively low for conditions that are private and less likely to be reported (Snow *et al.* 2005). In NHs, most of the patients have a cognitive impairment, which makes it difficult for them to answer questions or fill in questionnaires. Hence, to get a representative sample and comprehensive data on the NH population, the forms were completed by RNs.

Conclusion

Mixed effects logistic regression revealed that most of the variance of FI was explained by variation in patient characteristics. The characteristics most strongly associated with FI were ADL deficiencies, cognitive impairment, diarrhoea and not participating in activities, making these the main targets for interventions. The value of good bowel care needs to be emphasised since individualized continence care might be the key in preventing and treating the condition. We found InterRAI LTCF a feasible and useful instrument, which enabled a comprehensive exploration of FI prevalence and associations. We need studies to evaluate the effect of individualized continence care in NH patients. InterRAI LTCF might be a very useful instrument because of its combination of a comprehensive range of individual items and scales giving a holistic picture of the patients, allowing for comparisons of immediate or long-term change in patient status across settings.

Acknowledgements

The authors wish to thank the nurses and the rest of the care staff from the participating nursing homes for making this study possible.

Funding

The study was financed by grants from Sør-Trøndelag University College. The Norwegian Nurses Organization contributed to the funding of this study.

Conflict of interest

No conflict of interest has been declared by the authors.

Author contributions

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/recommendations/)]:

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

References

Akpan A., Gosney M.A. & Barrett J. (2007) Factors contributing to fecal incontinence in older people and outcome of routine management in home, hospital and nursing home setting. *Clinical Intervention in Aging* **2**(1), 139–145.

Aslan E., Beji N.K., Erkan H.A., Yalcin O. & Gungor F. (2009) The prevalence of and the related factors for urinary and fecal incontinence among older residing in nursing homes. *Journal of Clinical Nursing* **18**(23), 3290–3298.

Bannister J.J., Abouzekry L. & Read N.W. (1987) Effect of aging on anorectal function. *International Journal of Gastroenterology and Hepatology* **28**(3), 353–357.

Blekken L.E., Vinsnes A.G., Gjeilo K.H., Salvesen Ø., Norton C. & Nakrem S. (2015a) Effect of a multifaceted educational program for care staff concerning fecal incontinence in nursing home patients: study protocol of a cluster randomized controlled trial. *Trials* **16**, doi:10.1186/s13063-015-0595-3.

Blekken L.E., Nakrem S., Gjeilo K.H., Norton C. & Vinsnes A.G. (2015b) Feasibility, acceptability, and adherence of two educational programs for care staff concerning nursing home patients' fecal incontinence: a pilot study preceding a cluster-randomized controlled trial. *Implementation Science* **10**(1), 72.

Bliss D.Z., Mellgren A., Whitehead W.E., Chiarioni G., Emmanuel A., Santoro G.A., Zbar A., Peden-McAlpibe C., Northwood M., Slieker-Ten Hove M., Berghmans B. & Mimura T. (2013) Assessment and conservative management of faecal incontinence and quality of life in adults. In *Incontinence* (Abrams B., Cardozo L., Khoury S. & Wein A., eds) 5th International Consultation on Incontinence 2013. Retrieved from http://www.ics.org/Publications/ICI_5/INCONTINENCE.pdf on 09 September 2015.

Borrie M.J. & Davidson H.A. (1992) Incontinence in institutions: cost and contributing factors. *Canadian Medical Association Journal* **147**(3), 322–328.

Büla C.J. & Wietlisbach V. (2009) Use of the Cognitive Performance Scale (CPS) to detect cognitive impairment in the acute care setting: concurrent and predictive validity. *Brain Research Bulletin* **80**(4–5), 173–178.

Burrows A.B., Morris J.N., Simon S.E., Hirdes J.P. & Phillips C. (2000) Development of a minimum data set-based depression rating scale for use in nursing homes. *Age and Ageing* **29**, 165–172. doi:10.1093/ageing/29.2.165.

Carpenter I. & Hirdes J.P. (2013) Using interRAI assessment systems to measure and maintain quality of long-term care. In *A Good Life in Old Age? Monitoring and Improving Quality in Long-Term Care*. OECD Health Policy Studies. Retrieved from http://www.uems.eu/__data/assets/pdf_file/0003/1497/A_Good_Life_in_Old_Age_2013_OECD-EC_EN.pdf on 03 November 2015.

Eikemo T.A. & Clausen T.H. (2012) *Kvantitativ Analyse med SPSS. En Praktisk Innføring i Kvantitativ Analyseteknikker*. Tapir Akademiske Forlag, Trondheim.

Estabrooks C.A., Morgan D.G., Squires J.E., Boström A.-M., Slaughter S.E., Cummings G.G. & Norton P.G. (2011) The care unit in nursing home research: evidence in support of a definition. *Medical Research Methodology* **11**, 46, doi:10.1186/1471-2288-11-46.

Fosnes G.S., Lydersen S. & Farup P.G. (2012) Drugs and constipation in elderly in nursing homes: what is the relation? *Gastroenterology Research and Practice* **2012**, ID 290231, doi:10.1155/2012/290231.

Fox J.C., Fletcher J.G., Zinsmeister A.R., Seide B., Riederer S.J. & Bharucha A.E. (2006) Effect of aging on anorectal and pelvic floor functions in females. *Diseases of the Colon and Rectum* **49** (11), 1726–1735.

Freedland K.E., Reese R.L. & Steinmeyer B.C. (2009) Multivariable models in biobehavioral research. *Psychosomatic Medicine* **71**(2), 205–216.

Gage H., Goodman C., Davies S.L., Norton C., Fader M., Wells M., Morris J. & Williams P. (2010) Laxative use in care homes. *Journal of Advanced Nursing* **66**(6), 1266–1272.

Gerritsen D.L., Steverink N., Frijters D.H., Hirdes J.P., Ooms M.E. & Ribbe M.W. (2008) A revised index for social engagement for long-term care. *Journal of Gerontological Nursing* **34**(4), 40–48.

Goode P.S., Burgio K.L., Halli A.D., Jones R.W., Richter H.E., Redden D.T., Baker P.S. & Allman R.M. (2005) Prevalence and correlates of fecal incontinence in community-dwelling older adults. *Journal of the American Geriatrics Society* **53**(4),629–635.

Harrington C., Carillo H. Dowall M., Tang P.P. & Blank B.W. (2011) Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2005 Through 2010. University of California, Department of Social and Behavioral Sciences, San Francisco. Retrieved from http://thenewsoutlet.org/media/documents/Nursing-Homes/Funding/Harrington-nursing-home-staffing-report.pdf on 02 June 2015.

Hirdes J.P., Frijters D.H. & Teare G.F. (2003) The MDS-Chess Scale: A New Measure to Predict Mortality in Institutionalized Older People. *Journal of the American Geriatrics Society* **51**, 96–100.

Hirdes J.P., Ljunggren G., Morris J.N., Frijters H.H., Soveri H.F., Gray L., Björkgren M. & Gilgen R. (2008) Reliability of the interRAI suite of assessment instrument: a 12-country study of an integrated health information system. *BMC Health Services Research* **8**, 277, doi:10.1186/1472-6963-8-277.

Hogan D.B., Freiheit E.A., Strain L.A., Patten S.B., Schmaltz H.N., Rolfson D. & Maxwell C.J. (2012) Comparing frailty measures in their ability to predict adverse outcome among older residents of assisted living. *BMC Geriatrics* **2012**, 56, doi:10.1186/1471-2318-12-56.

InterRAI (2013) An Introduction to InterRAI. Retrived from http://interrai.co.nz/LinkClick.aspx?fileticket=Un5NyQb9ud8%3d&tabid=259&mid=933 on 03 May 2015.

InterRAI (2015) Scales: Status and Outcome Measures. Retrieved from http://interrai.org/scales.html 24 September 2015.

Jerez-Roig J., Souza D.B.D., Amaral F.L.J.S. & Lima K.C. (2015) Prevalence of fecal incontinence (FI) and associated factors in institutionalized older adults. *Archives of Gerontology and Geriatrics* **60**, 425–430.

Johanson J.F., Irizarry F. & Doughty A. (1997) Risk factors for fecal incontinence in a nursing home population. *Journal of Clinical Gastroenterology* **24**(3), 156–160.

Kinnunen O. (1991) Study of constipation in a geriatric hospital, day hospital, old people's home and at home. *Aging* **3**(2), 161–170.

Landi F., Tua E., Onder G., Carrara B., Sgadari A., Rinaldi C., Gambassi G., Lattancio F. & Barnebei R. (2000) Minimum data set for home care: a valid instrument to assess frail older people living in the community. *Medical Care* **38**(12), 1184–1190.

Liang C.-K., Chen L.-K., Tsai C.-F., Su T.-P., Lo Y.-K., Lan C.-F. & Hwang S.-J. (2014) Screening depression among institutionalized older Chinese men by minimum data set: we need a new instrument. *Journal of Geriatric Psychiatry* **24**(4), 79–83.

Maeda Y., Parés D., Norton C., Vaizey C.J. & Kamm M.A. (2008) Does the St. Mark's Incontinence Score Reflect Patients' Perception? A review of 390 patients. *Diseases of the Colon & Rectum* **51**, 436–442.

Mangnall J., Tyler P., Thomas S. & Watterson L. (2006) Continence problems in care homes: auditing assessment and treatment. *Nursing Older People* **18**, 20–22.

Midtbø T. (2012) *Stata. En Entusiastisk Innføring*. Universitetsforlaget, Oslo.

Morris J.N., Fries B.E., Mehr D.R., Hawes C., Philops C., Mor V. & Lipsitz L. (1994) MDS cognitive performance scale. *Journal of Gerontology* **49**(4), M174–M182.

Morris J.N., Fries B.E. & Morris S.A. (1999) Scaling ADLs Within the MDS. *Journal of Gerontology* **54**(11), 546–553.

Morris J.N., Belleville-Taylor P., Fries B.E., Hawes C., Murphy K., Mor V., Nonemaker S., Phillips C.D., Berg K., Björkgren M., Frijters D., Gilgen R., Gray L., Henrard J.C., Hirdes J.P., Ljunggren G., Steel K. & Zimmerman D. (2012) *InterRAI Long-Term Care Facilities (LTCF) Assessment Form and User's Manual*. Verson 9.1 Norwegian version. interRAI, Washington, DC.

Nelson R., Norton N., Cautley E. & Furner S. (1995) Community-based prevalence of anal incontinence. *Journal of the American Medical Association* **274**(79), 559–561.

Nelson R., Furner S. & Jesudason V. (1998) Fecal incontinence in Wisconsin nursing homes. Prevalence and associations. *Diseases of the Colon & Rectum* **41**(10), 1226–1229.

Norton C., Whitehead W., Bliss D. Z., Harai D. & Lang J. (2009) Conservative and Pharmacological Management of Faecal Incontinence in Adults. In *Incontinence* (Abrams B., Cardozo L., Khoury S. & Wein A., eds), 4th International Consultation on Incontinence 2009. Retrieved from http://www.icud.info/PDFs/Incontinence.pdf on 02 June 2015.

Nylenna M. (2014) *Helsetjenesten i Norge: Et Overblikk*. Gyldendal akademisk, Oslo.

Onder G., Carpenter I., Finne-Soveri H., Gindin J., Frijters D., Henrared J.C., Nikolaus T., Topinkova E., Tosato M., Liperoti R., Landi F. & Barnabei R. (2012) Assessment of nursing home residents in Europa: the Services and Health for Elderly in Long TERm care (SHELTER) study. *BMC Health Services Research* **12**, doi:10.1186/1472-6963-12-5.

Ottenbacher K.J., Ottenbacher H.R., Tooth L. & Ostir G.V. (2004) A review of two journals found that articles using multivariable logistic regression frequently did not report commonly recommended assumptions. *Journal of Clinical Epidemiology* **57**(11), 1147–1152.

Peduzzi P. (1996) A simulation study of number of events per variable in logistic regression analysis. *Journal of Clinical Epidemiology* **49**(12), 1373–1379.

Perlman C.M. & Hirdes J.P. (2008) The aggressive behavior scale: a new scale to measure aggression based on the minimum data set. *Journal of the American Geriatrics Society* **56**(12), 2298–2303.

Poss J.W., Jutan N.M., Hirdes J.P., Fries B.E., Morris J.N., Teare J.F. & Reidel K. (2008) A Review of Evidence on the Reliability and Validity of Minimum Data Set Data. Healthcare Management FORUM. Retrieved from http://hmf.sagepub.com/content/21/1/33.long on 03 November 2015.

Rabe-Hesketh S. & Skrondal A. (2012a) *Multilevel and Longitudinal Modeling Using Stata. Volum II: Categorical Responses, Counts and Survival*. Stata Press Publication, Texas.

Rabe-Hesketh S. & Skrondal A. (2012b) *Multilevel and Longitudinal Modeling Using Stata. Volume I: Continious Responses*. Stata Press Publication, Texas.

Ringard Å., Sagan A., Saunes I.S. & Lindahl A.K. (2013) Norway: health system review. *Health Systems in Transition* **15**(8), 1–162.

Rodriguez N., Sackley C. & Badger F. (2007) Exploring the facets of continence care: a continence survey of care homes for older people in Birmingham. *Journal of Clinical Nursing* **16**, 954–962.

Roe B., Flanagan L., Jack B., Barrett J., Chung A., Shaw C. & Williams K. (2011) Systematic review of the management of incontinence and promotion of continence in older people in care homes: descriptive studies with urinary incontinence as primary focus. *Journal of Advanced Nursing* **67**, 228–250.

Saga S. (2014)*Understanding Faecal Incontinence in Nursing Home Patients. Epidemiology and Nurses' Management*. Doctoral thesis at Norwegian University of Science and Technology, Trondheim.

Saga S., Vinsnes A.G., Mørkved S., Norton C. & Seim A. (2013) Prevalence and correlates of fecal incontinence among nursing home residents: a population-based cross-sectional study. *BMC Geriatrics* **13**, 87, doi:10.1186/1471-2318-13-87.

Saga S., Seim A., Mørkved S., Norton C. & Vinsnes A.G. (2014) Bowel problem management among nursing home residents: a mixed methodes study. *BMC Nursing* **13**(1), 35, doi:10.1186/s12912-014-0035-9.

Schnelle J.F., Alessi C., Simmons S.F., Beck J.G., Al-Samarrai N.R., Beck M.D. & Ouslander J.G. (2002) Translating clinical research into practice: a randomized controlled trial of exercise and incontinence care with nursing home residents. *Journal of the American Geriatrics Society* **50**, 1476–1483.

Shin J.H. & Scherer Y. (2009) Advantages and Disadvantages of Using MDS Data in Nursing Research. *Journal of Gerentological Nursing* **35**(1), 7–17.

Snow A.L., Cook K.F., Lin P.-S., Morgan R.O. & Magaziner J. (2005) Proxies and other raters: methodological considerations. *Health Services Research* **40** (5 Pt 2), 1676–1693.

Stata (2015) Linktest – Specification Link Test for Single-Equation Models. Retrieved from http://www.stata.com/manuals13/rlinktest.pdf on 01 September 2015.

Statistics Norway (2014) Register of Health Care Personell. Retrieved from http://www.ssb.no/en/forside;jsessionid=769CA19F4266D79878FCCCAB758EC4FD.kpld-as-prod11?hide-from-left-menu=true&language-code=en&menu-root-alternative-language=true on 13 May 2014.

Stoltzfus J.C. (2011) Logistic regression: a brief primer. *Academic Emergency Medicine* **18**, 1099–1104.

Tavakol M. & Dennick R. (2011) Making sense of Cronbach's alpha. *International Journal of Medical Education* **18**, 1099–1104. doi:10.5116/ijme/4dfb.8dfb.

Taylor D.W., Cahill J.J. & Rizk D.E.E. (2014) Denial, shame and acceptance: generating base-line knowledge and understanding of fecal incontinence amongst long-term care residents and care providers. *Public Health Research* **4**, 13–18.

Thekkinkattil D.K., Lim M., Finan P.J., Sagar P.M. & Burke D. (2008) Awareness of investigations and treatment of faecal incontinence among the general practitioners: a postal questionnaire survey. *Colorectal Disease* **10**, 263–267.

UCLA (2015) Statistical Consulting Group, "Logistic Regression Diagnostics". Retrieved from http://www.ats.ucla.edu/stat/stata/webbooks/logistic/chapter3/statalog3.htm on 01 September 2015.

University Hospital of North Norway (2012) Norwegian Registry for Anal Incontinence. St Marks Incontinence Score. Retrieved from http://www.unn.no/getfile.php/UNN%20INTER/Enhet/Inkontinenssenter_web/Dokumenter/Anal%20inkontinens%201B_200214.pdf on 02 June 2015.

Vinsnes A.G., Helbostad J.L., Nyrønning S., Harkless G.E., Granbo R. & Seim A. (2012) Effect of physical training on urinary incontinence: a randomized parallel group trial in nursing homes. *Clinical Interventions in Aging* **7**, 45–50.

Wagg A.S., Chen L.K., Kirschner-Hermanns R., Kuchel G.A., Johnson Y., Ostaszkiewicz J., Markland A., Palmer M. & Szonyi G. (2013) Incontinence in the Frail Elderly. In *Incontinence* (Abrams B., Cardozo L., Khoury S. & Wein A., eds), 5th International Consultation on Incontinence 2013. Retrieved from http://www.ics.org/Publications/ICI_5/INCONTINENCE.pdf on 09 September 2015.

Wang J., Kane R.L., Lynn E.E., Virnig B.A. & Chang L.-H. (2009) The effects of Resident and Nursing Home Characteristics on Activities of Daily Living. *Journal of Gerentology* **64**(4), 473–480.

Wellens N.I.H., Milisen K., Flaming J. & Moons P. (2012) Methods to assess the reliability of the interRAI Acute Care: a framework to guide clinimetric testing. Part II. *Journal of Evaluation in Clinical Practice* **18**, 822–827.

WHO (2015) WHO Collaborating Centre for Drug Statistics Methodology. Retrieved from http://www.whocc.no/atc/structure_and_principles/ on 02 August 2015.

PAPER II

Hindawi Publishing Corporation
Gastroenterology Research and Practice
Volume 2016, Article ID 1215746, 12 pages
http://dx.doi.org/10.1155/2016/1215746

Research Article

Constipation and Laxative Use among Nursing Home Patients: Prevalence and Associations Derived from the Residents Assessment Instrument for Long-Term Care Facilities (interRAI LTCF)

Lene Elisabeth Blekken,[1,2] Sigrid Nakrem,[1] Anne Guttormsen Vinsnes,[1] Christine Norton,[3] Siv Mørkved,[2,4] Øyvind Salvesen,[2] and Kari Hanne Gjeilo[5,6]

[1] *Faculty of Health and Social Science, Department of Nursing Science, University College of Sør-Trøndelag, Postboks 2320, 7004 Trondheim, Norway*
[2] *Faculty of Medicine, Department of Public Health and General Practice, Norwegian University of Science and Technology (NTNU), Postboks 8905, MTFS, 7491 Trondheim, Norway*
[3] *King's College London, Florence Nightingale School of Nursing and Midwifery, 57 Waterloo Road, London SE1 8WA, UK*
[4] *St. Olavs Hospital, Trondheim University Hospital, Clinical Service, Postboks 3250 Sluppen, 7006 Trondheim, Norway*
[5] *St. Olavs Hospital, Trondheim University Hospital, Department of Cardiology and Department of Cardiothoracic Surgery, Postboks 3250 Sluppen, 7006 Trondheim, Norway*
[6] *Faculty of Medicine, Department of Circulation and Medical Imaging, Norwegian University of Science and Technology (NTNU), Postboks 8905, 7491 Trondheim, Norway*

Correspondence should be addressed to Lene Elisabeth Blekken; lene.blekken@hist.no

Received 4 September 2015; Accepted 2 November 2015

Academic Editor: Paul Enck

Introduction. Constipation is a common, bothersome, and potentially dangerous condition among nursing home (NH) patients. Between 50 and 74% of NH patients use laxatives. *Objective.* To study prevalence and associations of laxative use and constipation using the comprehensive Norwegian version of the Resident Assessment Instrument for Long-Term Care Facilities. *Methods.* Cross-sectional study. Patients from 20 NH units were included. Logistic regression was used to analyze the results. Data collected in NHs might be clustered. Consequently, the multivariable models were tested against a mixed effects regression model to investigate variance both on the level of patients and on the level of NH units. *Results.* In all, 261 patients were included. The prevalence of constipation was 23.4%, and 67.1% used laxatives regularly. Balance problems, urinary incontinence, hypothyroidism, and Parkinson's disease were associated with constipation. Reduced ability to communicate and number of drugs were associated with laxative use. Antidementia-drugs and being involved in activities 1/3 to 2/3 of daytime were protective factors for laxative use. Mixed effects analyses identified variance on the level of NH units as nonsignificant. *Conclusion.* Constipation and laxative use are common. Variance is mainly explained by different patient characteristics/health deficiencies. Hence, patients might benefit from individualized care to compensate for deficiencies.

1. Introduction

The management of constipation among patients in nursing homes (NHs) is challenging for both patients and health care staff [1]. Constipation is not a well-defined disease, but a general term describing the difficulties a person experiences with their bowel movements [2]; thus epidemiological studies show great disparity in the reporting of prevalence. The prevalence of constipation increases with age, with the largest increase in prevalence after the age of 70 years [3, 4]. Women are 2-3 times more likely to have constipation than men [3, 4]. Between 17 and 40% of the community-dwelling older

adults [5–7] and between 10 and 72% [8–11] of NH patients experience constipation.

Constipation can be classified as primary (idiopathic or functional) or secondary (iatrogenic or because of organic disease), the latter being more common in older people [12]. Diseases associated with constipation are endocrine or metabolic disorders; gastrointestinal disorders; neurological disorders; and psychological comorbidities [4]. Other contributory factors to the higher prevalence of constipation among older people include poor dietary fibre, fluid and calorie intake, immobility, weak abdominal and pelvic muscles, and cognitive impairment and medication side effects [12]. Among NH patients constipation is associated with impaired health-related quality of life [13–16], physical aggression [17], and psychological distress [16]. Chronic constipation can lead to faecal impaction [4, 6], and in severe cases, faecal impaction can cause stercolar ulcerations, intestinal obstruction, or bowel perforation [1]. Other complications of constipation are related to excessive straining that can contribute to haemorrhoids, anal fissures and rectal prolapse. Excessive straining can affect the cerebral and coronary circulation with resultant syncope or cardiac ischemia [12]. Some age-related changes in anorectal physiology have been described [2]. However, constipation should not be regarded as a physiological consequence of normal aging, since most healthy older people have normal bowel function [2]. Nurses working in NHs report constipation as hard to manage due to busy working days with many tasks, so that good bowel routines have low priority [18]. Further, staff discontinuity and a high proportion of unskilled nursing aides among the staff hinder good management of the patients' bowels [18, 19].

In addition to conservative interventions such as dietary fibre, physical activity, and fluids, laxatives are the cornerstone in the treatment of constipation. Between 50 and 74% of NH patients are reported to use laxatives regularly [4, 8]. All groups of laxatives are superior to placebo [20]. However, in contrast to the overall good results in clinical trials, patients' satisfaction with everyday use of laxatives is rather low [21]. Laxatives may serve as a marker for constipation because they are rarely used for other indications. Indeed, several NH studies have used laxatives as a proxy marker for constipation [8, 22–24]. In addition, constipation is a significant driver of health care costs including laxative use and time resources for health care personnel dealing with the problem in hospitals and NHs [25, 26]. In Norway, with a population of approximately 5.2 million, 18.9 million € was spent on laxatives in 2014 [27]. Constipation is a multifactorial condition with huge variability in reported prevalence in the NH population. There is therefore a need to investigate the condition with validated instruments. The Resident Assessment Instrument for Long-Term Care Facilities (interRAI LTCF) [28] is a standardized, validated and comprehensive tool to assess patients' health condition in the long-term care setting, which allow for international comparability. In addition, it is poorly understood whether clustering of observations in NHs affects the results [29, 30], and whether variability in prevalence found is due to differences between patients or differences between NH units [31].

The aim of this study was to study prevalence and associations of constipation and laxative use among NH patients using the Norwegian version of the interRAI LTCF [28]. A secondary aim was to investigate the effect of clustering of observations and whether living in different NH units had an impact on the prevalence of constipation and laxative use by analysing data using mixed effects models.

2. Materials and Methods

2.1. Design. A cross-sectional design was employed. The study was performed in NHs in one urban municipality in Norway, during September and October 2014. Data were collected at baseline in an ongoing cluster-randomized controlled trial investigating the effect of an educational program for care staff about faecal incontinence in NH patients [32]. Sample-size calculations for the trial are reported elsewhere [32]. The trial is registered in the clinical trial registry (NCT02183740).

2.2. Setting. Most Norwegian NHs are owned and run by the municipalities, are oftentimes managed by Registered Nurses (RNs), and have an agreement with a general practitioner (GP) who visits the NH once a week. There are no legal requirements for staff-to-patient ratios or specifications for qualifications required for care workers [33]. However, NHs have RNs on duty 24 hours a day, and according to Statistics Norway the staff comprises on average 31% RNs, 45% licenced practical nurses who are care staff with high school education, and 24% healthcare aides with no formal health care education [34]. In Norway, a majority of NH patients are above 67 years and have complex health problems, significant deficiencies in functioning related to activities of daily living (ADL), and about 80% have cognitive impairment [35].

2.3. Patients. Patients were recruited from NHs. Out of a total of 27 NHs available in the municipality, 20 NH units from 10 different NHs were recruited. All NHs had 24 hour long-term residency, comparable staff-to-patient ratios on the day shift and similar GP coverage. Specialized NH units or units with enhanced staff-to-patient ratios were excluded. All long-term care patients with a stay of four weeks or more were eligible for inclusion.

2.4. Variables. The interRAI LTCF is a standardized, validated, and comprehensive tool to assess patients' health status in the long-term care setting [28, 36–38]. In this study interRAI LTCF sections C to O were included, and the following variables were used.

Constipation was measured by interRAI LTCF, section J: Constipation, defined as no bowel movements for three days or problems with hard stools. Based on this definition, the RNs coded 0 for not constipated, 1 for problems with constipation, but no symptoms the last three days, 2 for symptoms of constipation present 1 of the last 3 days, 3 for symptoms of constipation present for 2 of the last 3 days, and 4 for symptoms of constipation present daily for the last 3

days. For this study, all patients with the scores 1 to 4 were defined as constipated.

Laxative use prescribed as regularly used in the patient record and recorded in interRAI, section N: Medications, and grouped according to the Anatomical-Therapeutic-Chemical Classification System (ATC) [39] (see (xi) below).

Informed by other studies [4, 6] the following variables from interRAI were used to investigate possible associations:

(i) Patients' cognitive status was measured by the Cognitive Performance Scale (CPS) [40]. Scores range from 0 to 6, where 0 represents being cognitively intact. To define presence of cognitive impairment, the usual cutoff of 2 points or more was used [41].

(ii) Patients' functional status was measured by the Activities of Daily Living long form scale (ADLlf) [42]. The items in this study differ from the original scale due to differences in ADL items in the Norwegian version of the interRAI LTCF. After communicating with a Norwegian member of the interRAI organization, the following 7 items were included: personal hygiene, dressing upper body, dressing lower body, locomotion, toilet use, eating, and bed mobility. Scores range from 0 to 28, where 0 indicates no functional difficulty.

(iii) The Depression Rating Scale (DRS) [43] was used to measure depression symptoms. Scores range from 0 to 14, where 0 indicates no depression symptoms.

(iv) Patients' instability in health/frailty was measured by the Changes in Health, End-Stage Disease, Signs, and Symptoms Scale (CHESS) [44]. Scores range from 0 to 5, where 0 indicates stability in health.

(v) The Aggressive Behavior Scale (ABS) [45] was used to measure aggressive behavior. Scores range from 0 to 12, where 0 indicates no aggressive behavior.

(vi) The Revised Index for Social Engagement (RISE) was used to measure the degree of involvement in positive social activities [46]. Scores range from 0 to 6, where 0 indicates no involvement in positive activities. Compared to the other scales derived from interRAI LTCF, this is the only scale where low score is worst rather than best.

(vii) The communication scale (COMM) was constructed by summing the scores for the variables "expressive communication skills" and "receptive communication skills," each with a score range of 0 to 4. This resulted in a score range for COMM from 0 to 8, where 0 indicates no communication problems [47].

(viii) Four variables measuring Balance in section J3 were used to construct a scale to measure balance: the four variables were: "Has difficulties or is unable to move to the standing position without help", "Has difficulties or is unable to turn to the opposite direction when standing", "Dizziness", and "Walking instability". The individual variables were dichotomized and the scores then summed giving a score range from 0 to 4, where 0 indicates no balance problems.

(ix) The following individual interRAI LTCF variables were used: "Faecal incontinence", "Urinary incontinence", "Pressure ulcers", "Maximum walking distance", "Locomotion", "Activity level", "Fatigue", "Body mass index", " Dehydration", Type of food (Regular or soft/liquid diet).

(x) The patients' medical condition was measured by section I of interRAI LTCF: "Alzheimer's disease", "Dementia other than Alzheimer's disease", "Hemiplegia", "Multiple sclerosis", "Paraplegia", "Parkinson's disease", "Quadriplegia", "Cerebrovascular accident (stroke)", "Cardiovascular disease", "Congestive heart failure", "Chronic obstructive lung disease", "Anxiety disorder", "Bipolar disease", "Depression", "Schizophrenia", "Pneumonia", "Urinary tract infection", "Cancer", "Diabetes mellitus", "Hypothyroidism". Comorbidity is measured by summing the above diagnoses giving one point per diagnosis.

(xi) Medications were measured by section N of interRAI LTCF and grouped according to the ATC-System, primarily on level four since drugs at this level often have common adverse drug reactions [48]: "opiates (N02A)", "antiepileptics (N03A)", "antipsychotics (N05A)", "anxiolytics (N05A)", "hypnotics and sedatives (N05C)", "diuretics (C03)", "antidepressants (N06A)", "anti-dementia drugs (N06D)" "iron supplements (B03A)", "calcium supplements (A12A)" "antidiarrheal agents (A07D)" and "laxatives (A06A)". Groups of laxatives were defined at ATC-level 5: softening laxatives (A06A A), stimulant laxatives (A06A B), bulk laxatives (A06A C), osmotic laxatives (A06A D), and enemas (A06A G).

In addition, the questionnaire included a section where RNs were offered a list of interventions relevant for constipation and asked to identify what is done for each individual patient. This list included questions about administration of laxatives (tablets, oral liquid, and suppositories) and enemas.

2.5. Data Collection. The project coordinator and a research assistant gave information and training to RNs (2-3 hours per NH) on completion of all the measures listed above. RNs were trained to use the interRAI LTCF standardized coding guidelines provided in the instrument's training manual. RNs used clinical judgment together with information from the electronic patient record, coworkers, and the patients when filling in the questionnaire.

2.6. Statistics. Statistical methods included estimating prevalence in percentages and other descriptive statistics. InterRAI LTCF offers a large number of variables. Univariable logistic regression analysis was conducted on the variables identified under *data collection*. We used perceived clinical significance, log likelihood, McFadden's R^2, and $p \leq 0.05$ to assess degree of impact on the outcome variable to inform the choice of variables to include in the multivariable logistic regression model [49]. To ensure sufficient events per independent variable in the multivariable models, the ratio was set at

a maximum of 10 : 1 [49–51]. Effect sizes are presented as odds ratios (OR) with 95% CI and p values. Variables were considered significant if $p < 0.05$, but p values between 0.01 and 0.05 were interpreted with caution due to multiple comparisons. The McKelvey and Zavoina R^2 was used to examine explained variability in the multivariable models. Its calculations are based on predicting a continuous latent variable underlying the observed 0-1 outcomes of data but need to be interpreted with caution compared to the adjusted R^2 in the Ordinary Least Squares regression [52, 53].

2.7. Tests of Statistical Assumption. Basic assumptions for logistic regression must be tested and reported [29, 49, 54]. One assumption is linearity in the logit for any continuous independent variables [49, 51]. For this we performed a link-test [55, 56]. The independent variables were also investigated for multicollinearity by means of the tolerance value that indicates the variables' uniqueness in explaining variation, where zero means perfect collinearity between variables. Perfect collinearity makes it impossible to obtain a unique estimate of regression coefficients for the involved variables [49, 56]. A definite cut-off criteria for "too much" multicollinearity do not exist. However, it is suggested that a value below 0.1 is problematic [57]. Assessments of the overall model fit were conducted by using the Hosmer-Lemeshow test [49, 51, 58]. Another assumption is independence between the observations. Patient observations collected in NHs might be described as clustered data and thereby correlated [59]. Consequently, the multivariable logistic regression models were tested against a mixed effects logistic regression model with the NH units treated as a random effect to investigate whether this further improved the model. STATA and the xtlogit command provide a likelihood-ratio test for the null hypotheses that the NH unit-level variance is significantly different from zero. In addition, the mixed effects logistic regression model makes it possible to investigate variance on two levels, the level of the individual patient versus the level of the NH unit [29, 60]. The Akaike information criterion (AIC) and the Bayesian information criterion (BIC) were used to compare model fit of the multivariable models and the mixed-effect models [30].

No replacements were made for missing data; thus, the number of patients varies between the different analyses. Statistical analyses were performed using STATA version 13 (StataCorp LP, Texas, USA).

2.8. Ethical Considerations. The study was approved by the Regional Committee for Medical and Health Research Ethics (REK) (2013/1802/REK North) and by The Norwegian Social Science Data Services (36482/2/MB). An essential ethical consideration in this study was whether or not informed consent should be obtained from patients or their representatives. After evaluating the overall project, REK authorized RNs with dispensations from the duty of confidentiality to gather relevant patient health information (proxy data). Since dispensation was given, patient consent was not obtained. The study was performed in accordance with the Helsinki Declaration.

Table 1: Patients characteristics[1], $n = 261$.

Age, years	84.7 (8.3)
Gender, female	173 (66.3)
CPS[2] ≥ 2	177 (69)
BMI[2]	23.1 (5.1)
ADL[2] long form	12.6 (9.3)
Locomotion	
(i) Walks without aid	52 (20.0)
(ii) Walks with aid (e.g., cane, crutches, rollator)	140 (53.8)
(iii) Wheelchair	56 (21.5)
(iv) Bed-ridden	12 (4.6)
Length of stay, years	2.3 (2.5)
Number of medical diagnoses	2.6 (1.5)
Number of drugs	7.0 (3.5)

[1]The results are given as mean (standard deviation (SD)) and number (proportion (%)).
[2]CPS = Cognitive Performance Scale, BMI = body mass index, ADL = activities of daily living.

3. Results

3.1. Characteristics of the Patients. The study included all patients ($n = 261$) within eligibility criteria from 20 NH units. Patient characteristics are presented in Table 1.

3.2. Constipation. There were 61 (23.4%) patients with constipation. Table 2 shows the result from the univariable logistic regression analyses. Because of the 10 : 1 ratio criteria, only six of the variables were included in the multivariable model. The variables with the highest impact (log likelihood and McFadden's R^2) on the dependent variable in the univariable analyses and/or variables considered as clinical significant were included in the multivariable logistic regression model (Table 2).

3.2.1. Mixed Effect Logistic Regression: The Constipation Model. The results are presented in Table 2. The likelihood-ratio statistic for the constipation model was 1.97 giving $p = 0.08$. Thus, the variance between NH units did not have a significant influence on the results, and thereby a multilevel model was not required. The analyses resulted in an intracluster correlation coefficient (ICC) = 0.097, indicating 90.3% of the variance in the data being on the individual patient level. The analyses comparing the multivariable logistic model with the mixed effect logistic model resulted in AIC and BIC values for the logistic model of 198.47 and 222.29 and for the mixed model 198.50 and 225.72, respectively. Lower AIC and BIC values indicate the better fit. This means that the result indicates a slightly better fit for the multivariable logistic regression model compared to the mixed effects model [30]. Hence, below we will present adjusted ORs from the multivariable logistic regression model (Table 2).

3.2.2. Adjusted Results. The results show that the odds of constipation increase with an OR of 1.69 for each unit increase on the Balance scale, and OR of 1.34 for each unit increase on the

Table 2: Associations between constipation and clinical health problems, medical diagnoses, and medications.

Variables	Univariable logistic regression[1] OR (95% CI)[4]	p value	Multivariable logistic regression[2] OR (95% CI)	p value	Mixed effects logistic regression[3] OR (95% CI)	p value
Age (years)	1.00 (0.97–1.04)	0.906				
Gender (female)	1.06 (0.58–1.96)	0.842				
BMI	0.95 (0.89–1.01)	0.112				
Length of stay, years	1.07 (0.96–1.19)	0.255				
CPS[5] (scale 0–6)	1.16 (0.99–1.37)	0.069				
Balance (scale 0–4)	1.69 (1.33–2.13)	<0.001	1.68 (1.25–2.27)	0.001	1.69 (1.23–2.32)	0.001
Urinary incontinence (scale 0–4)	1.44 (1.18–1.75)	<0.001	1.35 (1.06–1.71)	0.015	1.38 (1.07–1.78)	0.013
ADL[5] long form (scale 0–28)	1.06 (1.03–1.09)	<0.001				
CHESS[5] (scale 0–5)	1.41 (1.10–1.81)	0.007	1.23 (0.90–1.68)	0.187	1.29 (0.92–1.81)	0.142
Maximum walking distance						
0 = <5 m 1 = ≥5 m	0.44 (0.24–0.78)	0.006				
Bed rails	2.54 (1.41–4.57)	0.002				
COMM[5] (scale 0–8)	1.17 (1.04–1.31)	0.007				
Sleep during daytime	2.28 (1.21–4.30)	0.011				
Fatigue (scale 0–4)	1.37 (1.05–1.79)	0.021				
Time involved in activities						
No time	Reference					
<1/3 of daytime	0.69 (0.30–1.60)	0.392				
≥1/3 to 2/3 of daytime	0.64 (0.27–1.50)	0.306				
>2/3 of daytime	0.22 (0.06–0.76)	0.016				
Dehydrated	2.11 (1.10–4.05)	0.025				
Type of food						
0 = regular 1 = soft/liquid	2.27 (1.16–4.44)	0.017				
Pressure ulcer	2.17 (1.08–4.36)	0.029				
Hypothyroidism	4.29 (1.26–14.59)	0.029	7.63 (1.86–31.34)	0.005	8.59 (1.79–41.21)	0.007
Fecal incontinence	1.87 (1.05–3.33)	0.034				
Parkinson's disease	3.03 (0.98–9.49)	0.055	5.96 (1.36–26.18)	0.018	7.03 (1.49–33.30)	0.014
Stroke	1.87 (0.89–3.77)	0.098	2.34 (0.94–5.80)	0.073	2.14 (0.79–5.74)	0.133

[1] Univariable logistic regression performed with constipation as dependent variable and explored by a range of covariates.
[2] Multiple logistic regression, covariates selected by direct variable selection with $p \leq 0.05$ and/or the highest impact (Log likelihood, McFadden's R^2) on constipation in the univariable logistic regression analyses.
[3] Mixed effect logistic regression, NH units defined as grouping variable (cluster) to investigate the impact of NH units, and whether the grouping of data significantly affected the results. The estimated intracluster correlation coefficient, ICC = 0.097. The likelihood ratio test for testing if the data required a multilevel model resulted in $p = 0.08$ meaning that a multilevel model will not significantly improve the analyses of the data.
[4] Results are presented as odds ratios (OR), 95% confidence intervals (CI), and p values.
[5] CPS = Cognitive Performance Scale, ADL = activity of daily living, CHESS = Changes in Health, End-Stage Disease, Signs, and Symptom Scale, COMM = Communication Scale.

Table 3: Use of laxatives among patients, $n = 261$.

Laxative type	Patients using laxatives, n (%)
Use of laxatives as prescribed in the patients record	
Laxatives regularly[1] and on demand[1]	187 (71.7)
Laxatives regularly only	175 (67.1)
(i) Stimulant laxative (A06A B)[2]	87 (33.3)
(ii) Osmotic laxatives (A06A D)	143 (54.8)
(iii) Softening laxatives (A06A A)	1 (0.4)
(iv) Microenema (A06AG02 or A06AG11)	4 (1.5)
(v) Bulk laxatives (A06A C)	0 (0)
(vi) Oil enema (A06AG04)	0 (0)
(vii) Minienema (A06AG10)	0 (0)
Use of enemas as reported by nurses	
(i) Microenema (A06AG02 or A06AG11)	78 (30.0)
(ii) Oil enema (A06AG04)	10 (3.9)
(iii) Minienema (A06AG10)	6 (2.3)
Number of laxatives per patient[3]	
0	76 (29.1)
1	88 (33.7)
2	58 (22.2)
3	35 (13.4)
4	4 (1.5)

[1]Regular use and on demand as prescribed in the patient record.
[2]Laxatives are grouped according to the Anatomical-Therapeutic-Chemical Classification System (ATC).
[3]Reported as regular use in the patient record together with the use of microenemas, oil enemas, and minienemas as reported by nurses.

urinary incontinence scale. Patients who were diagnosed with hypothyroidism had a higher risk of constipation (OR 8.59) compared with patients not diagnosed with hypothyroidism. Being diagnosed with Parkinson's disease resulted in an OR of 7.03 compared to patients not diagnosed with Parkinson's disease. This final model resulted in a McKelvey and Zavoina's R^2 of 0.312. This means that 31.2% of the total variability of constipation among patients can be explained by the variables in the model.

3.3. Use of Laxatives. The use of laxatives is reported in Table 3. There were 175 (67.1%) patients using laxatives regularly as reported on the drug charts. Forty-six (75.4%) of the patients defined by the nurses as constipated used laxatives regularly. As shown in Table 3, we found a rather huge difference in the use of enemas as prescribed in the patient record compared to the use of enemas as reported by RNs. Table 4 shows the result from the univariable logistic regression analyses. Again, the variables with the highest impact (log likelihood and McFadden's R^2) on the dependent variable in the univariable analyses and/or variables considered as clinically significant were included in the multivariable logistic regression model (Table 4).

3.3.1. Mixed Effect Logistic Regression: The Laxative Use Model. The results are presented in Table 4. The likelihood-ratio statistic was 0.21 giving $p = 0.325$, indicating also here that the variance between NH units did not have a significant influence on the results, and thereby a multilevel model was not required. The analyses resulted in an ICC = 0.031, indicating 96.9% of the variance in the data being on the individual patient level. The analyses comparing the multivariable logistic model with the mixed effects logistic model resulted in AIC and BIC values for the logistic model of 292.62 and 356.15 and for the mixed model of 294.41 and 361.47, indicating best fit for the multivariable logistic regression model [30]. Hence, we will also here present adjusted ORs from the multivariable logistic regression model (Table 4).

3.3.2. Adjusted Results. The results shows that OR for laxative use increases by 1.22 for each unit increase on the COMM scale, and with an OR of 1.23 for each increase in number of medications other than laxatives. Being engaged in activities between 1/3 and 2/3 of daytime resulted in a protective effect (OR = 0.28) compared to the patients not engaged in activities at all. Taking antidementia medications gave a protective effect with an OR = 0.17 compared to patients not taking antidementia medications. This final model resulted in a McKelvey and Zavoina's R^2 of 0.369, explaining 36.9% of the total variability.

3.4. Results of the Test for Statistical Assumptions

Linearity in the Logit. For both regression models, the linktest was not significant with $p = 0.802$ for the constipation model, and $p = 0.245$ for the laxative use model. This means that the model was properly specified and that the assumption of linearity was fulfilled [55, 56].

Multicollinearity. For the model with "constipation" as the dependent variable no adjustment of the model was made as a result of the tolerance test. The variable with the lowest value was "CHESS" with the value 0.89. For the model with "Laxative use" as the dependent variable, ADLlf had a tolerance value of 0.27, which is rather low but not surprising since ADLlf includes a range of measures that might interfere with the uniqueness of the variable in the multivariable analyses. However, after investigating the fit of different alternatives with and without ADLlf, and the variables "Type of food", "Maximum walking distance", and "Locomotion", we chose to keep ADLlf in the model and exclude "Maximum walking distance". This maneuver changed the tolerance value for ADLlf from 0.27 to 0.33. Either way, the models were stable considering p values and confidence intervals in the different alternatives. The result from the *Hosmer-Lemeshow test* on the final models resulted in a goodness-of-fit $\chi^2 = 5.38$, $p = 0.716$, for the constipation model and goodness-of-fit $\chi^2 = 6.11$, $p = 0.635$, for the laxative use model. This means that both models fit the data well [58].

Table 4: Associations between laxative use and clinical health problems, medical diagnoses, and medications.

Variables	Univariable logistic regression[1] OR (95% CI)[4]	p value	Multivariable logistic regression OR[2] (95% CI)	p value	Mixed effects logistic regression[3] OR (95% CI)	p value
Age (years)	0.99 (0.96–1.03)	0.731	1.01 (0.97–1.05)	0.529	1.01 (0.97–1.05)	0.541
Gender (female)	1.36 (0.79–2.33)	0.265	1.42 (0.74–2.73)	0.288	1.38 (0.70–2.72)	0.346
BMI[5]	1.02 (0.97–1.08)	0.443				
Length of stay (years)	1.14 (1.00–1.29)	0.046	1.04 (0.89–1.22)	0.579	1.05 (0.89–1.23)	0.573
CPS (scale 0–6)	1.13 (0.98–1.32)	0.101				
Locomotion						
0 = walking with/without help 1 = wheelchair/bedridden	3.25 (1.60–6.60)	0.001	1.74 (0.65–4.68)	0.269	1.61 (0.56–4.65)	0.378
Urinary incontinence (scale 0–4)	1.21 (1.03–1.41)	0.020	1.06 (0.81–1.39)	0.646	1.05 (0.80–1.39)	0.711
ADL[5] long form (scale 0–28)	1.07 (1.03–1.10)	<0.001	1.03 (0.97–1.09)	0.325	1.03 (0.97–1.09)	0.310
Time involved in activities						
No time	Reference		Reference		Reference	
<1/3 of daytime	0.31 (0.11–0.88)	0.028	0.39 (0.12–1.26)	0.117	0.39 (0.12–1.29)	0.122
≥1/3 to 2/3 of daytime	0.23 (0.08–0.33)	0.006	0.28 (0.08–0.93)	0.037	0.28 (0.08–0.95)	0.042
>2/3 of daytime	0.25 (0.08–0.79)	0.017	0.38 (0.10–1.46)	0.159	0.36 (0.09–1.47)	0.155
Opiates	3.62 (1.69–7.76)	0.001	1.33 (0.55–3.24)	0.529	1.42 (0.55–3.66)	0.472
Antidementia drugs	0.22 (0.07–0.68)	0.008	0.17 (0.05–0.66)	0.010	0.17 (0.04–0.68)	0.012
Number of drugs	1.17 (1.07–1.28)	0.000	1.23 (1.09–1.39)	0.001	1.24 (1.09–1.41)	0.001
COMM[5] (Scale 0–8)	1.17 (1.04–1.31)	0.008	1.22 (1.03–1.45)	0.023	1.23 (1.03–1.48)	0.025
Stroke	2.77 (1.17–6.53)	0.020	2.00 (0.74–5.38)	0.170	2.10 (0.75–5.88)	0.158
Parkinson's disease	6.22 (0.79–48.67)	0.082	8.32 (0.72–95.76)	0.089	8.29 (0.69–99.58)	0.095
Type of food						
0 = regular 1 = soft/liquid	2.18 (1.03–4.61)	0.042	0.72 (0.28–1.85)	0.496	0.75 (0.28–1.97)	0.555
Fecal incontinence	1.69 (0.99–2.90)	0.054	0.55 (0.22–1.35)	0.191	0.56 (0.22–1.41)	0.219

[1] Univariable logistic regression performed with laxative use as dependent variable and explored by a range of covariates.
[2] Multiple logistic regression, covariates selected by direct variable selection with $p \leq 0.05$ and/or the highest impact (Log likelihood, McFadden's R^2) on laxative use in the univariable logistic regression analyses.
[3] Mixed effect logistic regression, NH units defined as grouping variable (cluster) to investigate the impact of NH units, and whether the grouping of data significantly affected the results. The estimated intracluster correlation coefficient, ICC = 0.031. The likelihood ratio test for testing if the data required a multilevel model resulted in $p = 0.325$ meaning that a multilevel model will not significantly improve the analyses of the data.
[4] Results are presented as odds ratios (OR), 95% confidence intervals (CI), and p values.
[5] CPS = Cognitive Performance Scale, ADL = activity of daily living, COMM = Communication Scale.

4. Discussion

4.1. Constipation. The prevalence of constipation was 23.4% among NH patients. Comparison of prevalence rates in general is difficult because the definitions of constipation vary. In the NH population, there is even larger variation amongst estimates of constipation, from 10% [11] up to 72% [6, 8]. In this study, there was no significant association between either age or gender and constipation among NH patients. This is different compared to the general population where constipation is more prevalent among women and where age is considered a risk factor [3, 4]. Since two reviews have identified the age of 65–70 years as when there is a particular increase in prevalence [4, 12], this study investigated age both as a continuous variable and as a categorical variable grouping patients on the bases of age with emphasis on age groups identified in the above-mentioned reviews. Either way, age was not significantly associated with constipation. This might mean that when living in a NH, factors other than age and gender are of importance.

Hypothyroidism and Parkinson's disease were significantly associated with constipation. This is consistent with findings in two reviews [4, 6]. These publications additionally identified stroke/cerebrovascular disease as a risk factor for constipation, which was not in this study. This might be explained by the rather small subgroup with these conditions and thereby a lack of power to explain associations between constipation and stroke. The same reviews [4, 6] identified reduced mobility and functional decline as risk factors for constipation. In our study, ADL lost its significance in the multivariable analyses. The rest of the variables available in interRAI LTCF measuring function and mobility were not significant in the univariable analyses or had too little impact on constipation to be considered for the multivariable analyses. On the other hand, the condition with the strongest impact on constipation was "balance." Together, these findings suggest that balance problems are of greater importance than ADL deficiencies and immobility in the understanding of constipation.

Type of food (regular, soft/liquid), body mass index (BMI), and dehydration also had too little impact to be considered for the multivariable analyses. It is often suggested that insufficient diet, hydration, fiber, and physical activity are associated with constipation, but the evidence behind these factors is inconsistent and of low to medium quality [4, 6]. If this is the case, our results confirm these factors having a weak impact on constipation. However, Leung et al. [4] conclude that increasing fiber, exercise, and fluids might benefit patients with actual deficiencies. Our study also identified urinary incontinence as a risk factor for constipation. The association between urinary incontinence and constipation can be linked to common muscular and neurological processes regulating continence, defecation, and urinating. It might also be a result of an adverse effect from drugs used for urinary incontinence.

4.2. Use of Laxatives. In this study 67.1% of the patients used laxatives regularly. Other studies have reported regular use of laxatives in NHs from 55.3% to 83.6% [7, 24, 31, 61, 62]. Only number of drugs and ability to communicate remained significant risk factors in the adjusted analyses. The number of drugs as a risk factor for laxative use is found in several other studies [7, 24, 31]. Opiates were the only drug significantly associated with laxative use in the univariable analyses but lost significance in the adjusted analyses. These findings are opposite to the findings by Fosnes et al. [8] among NH patients in another part of Norway. They did not find a significant association between number of drugs and laxative use but found some antidepressants and benzodiazepine derivates as independent predictors. van Dijk et al. [22] found the overall adverse effect of drugs on constipation to be an overestimated risk.

As far as we know the association between laxative use and ability to communicate has not been reported before. This is an interesting result indicating that patients having problems making themselves understood, and understanding others, are more likely to use laxatives. The bowel is a sensitive organ that gives signals when the rectum is full. If the patient has lost the ability to understand and to communicate their bowel habits or need to defecate, it might lead to bowel problems and a prescription for laxatives.

Being involved in activities from ≥1/3 to 2/3 of daytime and antidementia medications were protective factors. Antidementia medications have diarrhea as a known adverse effect, which may lead to a lower risk for laxative use. The covariate "time involved in activities" expresses the patient's involvement in activities either alone or in a group when the patient is awake and not receiving treatment or care related to activities of daily living. Hence, the result supports the hypothesis that active living is protective against constipation and the need for laxatives. It might also be that the most active patients are able to manage their bowel independently in terms of responding to the need to defecate. However, it is worth mentioning that none of the other covariates involving physical activity or ADL functioning were significantly associated with laxative use in the adjusted analyses. Immobility in general [23, 24] and loss of functional status have been found to be a significant risk factor for laxative use in other studies [8, 62].

Stroke was significantly associated with laxative use in the univariable analyses, but not in the adjusted analyses. Parkinson's disease did not reach the significance level. Other studies show varying results concerning the association between Parkinson's disease and use of laxatives, where Chen et al. [62], did not find a significant association with either diseases, but both Hosia-Randell et al. [24] and Harari et al. [23] found an association between Parkinson's disease and use of laxatives. When investigating the relationship with stroke and Parkinson's disease it is possible that the nonsignificant findings are due to the small number with these conditions in the sample.

An important finding is the differences in the reported prescriptions for microenemas, small enemas, and oil enemas in the patient record compared to what was reported as used by the RNs. This indicates that RNs give patients these drugs without prescription from the GP, which support the hypotheses that in NHs RNs handle bowel problems independently [61], including the administration of laxatives.

4.3. Constipation and Laxative Use. When investigating and comparing variance on the NH unit level and the patient level, our results show that the significant variability in constipation and laxative use among patients is largely explained by difference in patients characteristics/health deficiencies, for example, number of drugs, different medical diagnosis, or ability to communicate. Although interRAI LTCF offers a large number of variables, the results show a rather low explained variability of 31.2% (constipation) and 36.9% (laxative use). Hence, other variables should be considered. One possible variable to discuss is the overall care routines in the NH setting. Even though this study identified most of the variance at the patient level, most of the patients are dependent on care staff to compensate for the deficiencies that make them at risk for constipation and laxative use.

Constipation and laxative use might be considered a result of standardized routines where the patients have not received an individualized assessment or treatment for their bowel needs. This interpretation may be supported by the positive association between constipation and urine incontinence where care related to elimination in general is determined by care routines and not the patients' individual needs, possibly leading to a worsening in ability to maintain function. In spite of increased recognition of the importance of the application of individualized treatment and care in NHs, NHs with few nursing resources dedicated to the care of older persons might be based on standardization [63, 64] and routine [65]. Several studies have identified care culture, with standardized routines as a problem for individualized bowel care [18, 31].

4.4. Strengths and Limitations. A major strength is the use of interRAI LTCF with standardized and validated measures for investigating prevalence and associations. A study investigating and comparing reliability in the different interRAI instruments in 12 countries found the majority of the items to exceed standard cut-offs for acceptable reliability [36]. However, the different scales have shown varying results for validity and reliability [36, 45, 46, 66, 67], with the CHESS scale and the DRS scale as the two with the most variable results [67–69]. Another strength is that we have considered the effect of clustering and tested whether a mixed effect logistic regression model made a significantly better fit for the data.

A limitation is that we did not use ROME III criteria [70] when defining constipation among patients. InterRAI LTCF only considers two aspects of constipation: no bowel movements for three days, or problems with hard stools. On the other hand, the ROME III definition of constipation is problematic in this population because (1) many of the patients are treated with laxatives and (2) patients are cognitively impaired and might have a problem since ROME III uses a combination of subjective symptoms to define constipation which can be hard to verbalize for a cognitively impaired person. Another limitation in our study is that it did not include variables measuring the patients' fiber or calorie intake.

The use of a proxy, where the RNs filled in the interRAI LTCF based on their knowledge about the patients' health condition, and not the patients themselves, might be considered a limitation. The reliability and validity of proxy data is found to be high for tasks of daily living and health conditions that are easily observed and relatively low for conditions that are private and less likely to be reported [71]. In the NH setting, most of the patients have cognitive impairment, which make it difficult to answer questions or fill in questionnaires. However, in order to get a representative sample of the NH population, we chose to design a study with the use of proxy data.

Other limitations are that the relatively small sample might have impeded the investigation of association of some conditions, for example, Parkinson's disease, stroke, and multiple sclerosis, which were found significant in other studies. This might threaten the external validity of the study concerning the conditions in question. Only patients that according to their patient record used laxatives or other drugs regularly were defined as users in the analyses. Patients with an "on demand" prescription were defined as nonusers. Hence, patients defined as nonusers may have used laxatives or other drugs and thereby influenced the results.

5. Conclusion

The prevalence of constipation was 24.1%, and was associated with impaired balance, urinary incontinence, Parkinson's disease, and hypothyroidism. About 67% of the patients used laxatives regularly. Laxative use was associated with impaired ability to communicate and number of other drugs used. Antidementia drugs and being involved in activities were protective factors. Mixed-effects analyses of both the constipation model and the laxative use model identified variance between NH units as nonsignificant in explaining the total variance. Hence, variance in constipation and laxative use are mainly explained by different individual patient characteristics/health deficiencies. NH patients are dependent on care staff to compensate for health deficiencies. NHs with few nursing resources might perform care based on standardization and routines. Hence, standardized care might be an important factor in order to explain constipation and laxative use among patients.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

Acknowledgments

The authors wish to thank nurses and care staff in general from the participating nursing homes for making this study possible. The Norwegian Nurses Organization has contributed to the funding of this study.

References

[1] S. S. C. Rao and J. T. Go, "Update on the management of constipation in the elderly: new treatment options," *Clinical Interventions in Aging*, vol. 5, pp. 163–171, 2010.

[2] G. L. McCrea, C. Miaskowski, N. A. Stotts, L. Macera, and M. G. Varma, "Pathophysiology of constipation in the older adult," *World Journal of Gastroenterology*, vol. 14, no. 17, pp. 2631–2638, 2008.

[3] S. M. Mugie, M. A. Benninga, and C. Di Lorenzo, "Epidemiology of constipation in children and adults: a systematic review," *Best Practice & Research: Clinical Gastroenterology*, vol. 25, no. 1, pp. 3–18, 2011.

[4] L. Leung, T. Riutta, J. Kotecha, and W. Rosser, "Chronic constipation: an evidence-based review," *Journal of the American Board of Family Medicine*, vol. 24, no. 4, pp. 436–451, 2011.

[5] N. J. Talley, K. C. Fleming, J. M. Evans et al., "Constipation in an elderly community: a study of prevalence and potential risk factors," *The American Journal of Gastroenterology*, vol. 91, no. 1, pp. 19–25, 1996.

[6] P. F. Gallagher, D. O'Mahony, and E. M. M. Quigley, "Management of chronic constipation in the elderly," *Drugs and Aging*, vol. 25, no. 10, pp. 807–821, 2008.

[7] S. Cusack, M. R. Day, T. Wills, and A. Coffey, "Older people and laxative use: comparison between community and long-term care settings," *British Journal of Nursing*, vol. 21, no. 12, pp. 711–717, 2012.

[8] G. S. Fosnes, S. Lydersen, and P. G. Farup, "Drugs and constipation in elderly in nursing homes: what is the relation?" *Gastroenterology Research and Practice*, vol. 2012, Article ID 290231, 7 pages, 2012.

[9] O. Kinnunen, "Study of constipation in a geriatric hospital, day hospital, old people's home and at home," *Aging Clinical and Experimental Research*, vol. 3, no. 2, pp. 161–170, 1991.

[10] S. Saga, A. G. Vinsnes, S. Mørkved, C. Norton, and A. Seim, "Prevalence and correlates of fecal incontinence among nursing home residents: a population-based cross-sectional study," *BMC Geriatrics*, vol. 13, article 87, 2013.

[11] K. L. Moore, W. J. Boscardin, M. A. Steinman, and J. B. Schwartz, "Age and sex variation in prevalence of chronic medical conditions in older residents of U.S. Nursing homes," *Journal of the American Geriatrics Society*, vol. 60, no. 4, pp. 756–764, 2012.

[12] P. Gallagher and D. O'Mahony, "Constipation in old age," *Best Practice & Research: Clinical Gastroenterology*, vol. 23, no. 6, pp. 875–887, 2009.

[13] A. Glia and G. Lindberg, "Quality of life in patients with different types of functional constipation," *Scandinavian Journal of Gastroenterology*, vol. 32, no. 11, pp. 1083–1089, 1997.

[14] A. Wald, C. Scarpignato, M. A. Kamm et al., "The burden of constipation on quality of life: results of a multinational survey," *Alimentary Pharmacology and Therapeutics*, vol. 26, no. 2, pp. 227–236, 2007.

[15] E. A. O'Keefe, N. J. Talley, A. R. Zinsmeister, and S. J. Jacobsen, "Bowel disorders impair functional status and quality of life in the elderly: a population-based study," *The Journals of Gerontology, Series A: Biological Sciences and Medical Sciences*, vol. 50, no. 4, pp. M184–M189, 1995.

[16] C. Norton, "Constipation in older patients: effects on quality of life," *British Journal of Nursing*, vol. 15, no. 4, pp. 188–192, 2006.

[17] R. Leonard, M. E. Tinetti, H. G. Allore, and M. A. Drickamer, "Potentially modifiable resident characteristics that are associated with physical or verbal aggression among nursing home residents with dementia," *Archives of Internal Medicine*, vol. 166, no. 12, pp. 1295–1300, 2006.

[18] S. Saga, A. Seim, S. Mørkved, C. Norton, and A. G. Vinsnes, "Bowel problem management among nursing home residents: a mixed methods study," *BMC Nursing*, vol. 13, article 35, 2014.

[19] L. E. Blekken, S. Nakrem, K. H. Gjeilo, C. Norton, S. Mørkved, and A. G. Vinsnes, "Feasibility, acceptability, and adherence of two educational programs for care staff concerning nursing home patients' fecal incontinence: a pilot study preceding a cluster-randomized controlled trial," *Implementation Science*, vol. 10, article 72, 2015.

[20] A. C. Ford and N. C. Suares, "Effect of laxatives and pharmacological therapies in chronic idiopathic constipation: systematic review and meta-analysis," *Gut*, vol. 60, no. 2, pp. 209–218, 2011.

[21] J. F. Johanson and J. Kralstein, "Chronic constipation: a survey of the patient perspective," *Alimentary Pharmacology and Therapeutics*, vol. 25, no. 5, pp. 599–608, 2007.

[22] K. N. van Dijk, C. S. de Vries, P. B. van den Berg, A. M. Dijkema, J. R. B. J. Brouwers, and L. T. W. D. J.-V. den Berg, "Constipation as an adverse effect of drug use in nursing home patients: an overestimated risk," *British Journal of Clinical Pharmacology*, vol. 46, no. 3, pp. 255–261, 1998.

[23] D. Harari, J. H. Gurwitz, J. Avorn, I. Choodnovskiy, and K. L. Minaker, "Correlates of regular laxative use by frail elderly persons," *The American Journal of Medicine*, vol. 99, no. 5, pp. 513–518, 1995.

[24] H. Hosia-Randell, M. Suominen, S. Muurinen, and K. H. Pitkälä, "Use of laxatives among older nursing home residents in Helsinki, Finland," *Drugs and Aging*, vol. 24, no. 2, pp. 147–154, 2007.

[25] R. Pekmezaris, L. Aversa, G. Wolf-Klein, J. Cedarbaum, and M. Reid-Durant, "The cost of chronic constipation," *Journal of the American Medical Directors Association*, vol. 3, no. 4, pp. 224–228, 2002.

[26] L. Frank, J. Schmier, L. Kleinman et al., "Time and economic cost of constipation care in nursing homes," *Journal of the American Medical Directors Association*, vol. 3, no. 4, pp. 215–223, 2002.

[27] S. Sakshaug, *Drug Consumption in Norway 2010–2014*, Norwegian Institute of Public Health, Oslo, Norway, 2015.

[28] J. N. Morris, P. Bellville-Taylor, B. E. Fries et al., *interRAI Long-Term Care Facilities (LTCF) Assessment form and User's Manual. Verson 9.1 Norwegian Version*, interRAI, Washington, DC, USA, 2012.

[29] T. A. Eikemo and T. H. Clausen, *Kvantitativ Analyse med SPSS: En Praktisk Innføring i Kvantitative Analyseteknikker*, Tapir Akademisk Forlag, Trondheim, Norway, 2012.

[30] S. Rabe-Hasketh and A. Skrondal, *Multilevel and Longitudinal Modeling Using Stata. Volume I: Continious Responses*, Stata Press Publications, College Station, Tex, USA, 2012.

[31] H. Gage, C. Goodman, S. L. Davies et al., "Laxative use in care homes," *Journal of Advanced Nursing*, vol. 66, no. 6, pp. 1266–1272, 2010.

[32] L. E. Blekken, A. G. Vinsnes, K. H. Gjeilo et al., "Effect of a multifaceted educational program for care staff concerning fecal incontinence in nursing home patients: study protocol of a cluster randomized controlled trial," *Trials*, vol. 16, article 69, 2015.

[33] Å. Ringard, A. Sagan, I. Sperre Saunes, and A. K. Lindahl, "Norway: health system review," *Health systems in transition*, vol. 15, no. 8, pp. 1–162, 2013.

[34] Statistics Norway, "Register of health care personell," May 2014, http://www.ssb.no/en/forside;jsessionid=769CA19F4266D79878FCCCAB758EC4FD.kpld-as-prodl1?hide-from-left-menu=true&language-code=en&menu-root-alternative-language=true.

[35] M. Nylenna, *Helsetjenesten i Norge: et overblikk*, Gyldendal Akademisk, Oslo, Norway, 2014.

[36] J. P. Hirdes, G. Ljunggren, J. N. Morris et al., "Reliability of the interRAI suite of assessment instruments: a 12-country study of an integrated health information system," *BMC Health Services Research*, vol. 8, article 277, 2008.

[37] G. Onder, I. Carpenter, H. Finne-Soveri et al., "Assessment of nursing home residents in Europe: the Services and Health for Elderly in Long TERm care (SHELTER) study," *BMC Health Services Research*, vol. 12, article 51, 2012.

[38] V. Mor, J. Angelelli, R. Jones, J. Roy, T. Moore, and J. Morris, "Inter-rater reliability of nursing home quality indicators in the U.S," *BMC Health Services Research*, vol. 3, article 20, 2003.

[39] WHO Collaborating Centre for Drug Statistics Methodology, "ATC/DDD Index," September 2015, http://www.whocc.no/atc_ddd_index/.

[40] J. N. Morris, B. E. Fries, D. R. Mehr et al., "MDS cognitive performance scale," *Journals of Gerontology*, vol. 49, no. 4, pp. M174–M182, 1994.

[41] C. J. Büla and V. Wietlisbach, "Use of the Cognitive Performance Scale (CPS) to detect cognitive impairment in the acute care setting: concurrent and predictive validity," *Brain Research Bulletin*, vol. 80, no. 4-5, pp. 173–178, 2009.

[42] J. N. Morris, B. E. Fries, and S. A. Morris, "Scaling ADLs within the MDS," *The Journals of Gerontology, Series A: Biological Sciences and Medical Sciences*, vol. 54, no. 11, pp. M546–M553, 1999.

[43] A. B. Burrows, J. N. Morris, S. E. Simon, J. P. Hirdes, and C. Phillips, "Development of a minimum data set-based depression rating scale for use in nursing homes," *Age and Ageing*, vol. 29, no. 2, pp. 165–172, 2000.

[44] J. P. Hirdes, D. H. Frijters, and G. F. Teare, "The MDS-CHESS scale: a new measure to predict mortality in institutionalized older people," *Journal of the American Geriatrics Society*, vol. 51, no. 1, pp. 96–100, 2003.

[45] C. M. Perlman and J. P. Hirdes, "The aggressive behavior scale: a new scale to measure aggression based on the minimum data set," *Journal of the American Geriatrics Society*, vol. 56, no. 12, pp. 2298–2303, 2008.

[46] D. L. Gerritsen, N. Steverink, D. H. M. Frijters, J. P. Hirdes, M. E. Ooms, and M. W. Ribbe, "A revised index for social engagement for long-term care," *Journal of Gerontological Nursing*, vol. 34, no. 4, pp. 40–48, 2008.

[47] N. I. H. Wellens, K. Milisen, J. Flamaing, and P. Moons, "Methods to assess the reliability of the interRAI acute care: a framework to guide clinimetric testing. Part II," *Journal of Evaluation in Clinical Practice*, vol. 18, no. 4, pp. 822–827, 2012.

[48] WHO Collaborating Centre for Drug Statistics Methodology, October 2015, http://www.whocc.no/atc/structure_and_principles/.

[49] J. C. Stoltzfus, "Logistic regression: a brief primer," *Academic Emergency Medicine*, vol. 18, no. 10, pp. 1099–1104, 2011.

[50] P. Peduzzi, J. Concato, E. Kemper, T. R. Holford, and A. R. Feinstem, "A simulation study of the number of events per variable in logistic regression analysis," *Journal of Clinical Epidemiology*, vol. 49, no. 12, pp. 1373–1379, 1996.

[51] K. J. Ottenbacher, H. R. Ottenbacher, L. Tooth, and G. V. Ostir, "A review of two journals found that articles using multivariable logistic regression frequently did not report commonly recommended assumptions," *Journal of Clinical Epidemiology*, vol. 57, no. 11, pp. 1147–1152, 2004.

[52] UCLA and Statistical Consulting Group, "What are pseudo R-squareds?" September 2015, http://www.ats.ucla.edu/stat/mult_pkg/faq/general/Psuedo_RSquareds.htm.

[53] T. M. Hagle and G. E. Mitchell, "Goodness-of-fit measures for probit and logit," *American Journal of Political Science*, vol. 25, no. 3, pp. 762–784, 1992.

[54] K. E. Freedland, R. L. Reese, and B. C. Steinmeyer, "Multivariable models in biobehavioral research," *Psychosomatic Medicine*, vol. 71, no. 2, pp. 205–216, 2009.

[55] Stata, "Linktest—Specification link test for single-equation models," September 2015, http://www.stata.com/manuals13/rlinktest.pdf.

[56] UCLA. Statistical Consulting Group, "Logistic regression diagnostics," September 2015, http://www.ats.ucla.edu/stat/stata/webbooks/logistic/chapter3/statalog3.htm.

[57] T. Midtbø, *Stata. En Entusiastisk Innføring*, Universitetsforlaget, Oslo, Norway, 2012.

[58] Stata, "Pearson or Hosmer-Lemeshow goodness-of-fit test," September 2015, http://www.stata.com/manuals13/restatgof.pdf.

[59] S. Eldridge and S. M. Kerry, *A Practical Guide to Cluster Randomised Trials in Health Services Research*, John Wiley & Sons, Chichester, UK, 2012.

[60] S. Rabe-Hasketh and A. Skrondal, *Multilevel and Longitudinal Modeling Using Stata. Volume II: Categorical Responses, Counts and Survival*, Stata Press Publication, College Station, Tex, USA, 2012.

[61] G. S. Fosnes, S. Lydersen, and P. G. Farup, "Effectiveness of laxatives in elderly—a cross sectional study in nursing homes," *BMC Geriatrics*, vol. 11, article 76, 2011.

[62] I. C. Chen, H. J. Huang, S. F. Yang, C. C. Chen, Y. C. Chou, and T. M. Kuo, "Prevalence and effectiveness of laxative use among elderly residents in a regional hospital affiliated nursing home in hsinchu county," *Nursing and Midwifery Studies*, vol. 3, no. 1, Article ID e13962, 2014.

[63] A. Palese, D. Granzotto, M. G. Broll, and N. Carlesso, "From health organization-centred standardization work process to a personhood-centred care process in an Italian nursing home: effectiveness on bowel elimination model," *International Journal of Older People Nursing*, vol. 5, no. 2, pp. 179–187, 2010.

[64] A. Harris and L. Hall, *Evidence to Inform Staff Mix Decision-Making: A Focused Literature Review*, Canadian Nurses Association, Ottawa, Canada, 2012.

[65] A. Zisberg, H. M. Young, K. Schepp, and L. Zysberg, "A concept analysis of routine: relevance to nursing," *Journal of Advanced Nursing*, vol. 57, no. 4, pp. 442–453, 2007.

[66] F. Landi, E. Tua, G. Onder et al., "Minimum data set for home care: a valid instrument to assess frail older people living in the community," *Medical Care*, vol. 38, no. 12, pp. 1184–1190, 2000.

[67] J. H. Shin and Y. Sherer, "Advantages and disadvantages of using MDS data in nursing research," *Journal of Gerontological Nursing*, vol. 35, no. 1, pp. 7–17, 2009.

[68] C.-K. Liang, L.-K. Chen, C.-F. Tsai et al., "Screening depression among institutionalized older chinese men by minimum data set: we need a new instrument," *Journal of Geriatric Psychiatry and Neurology*, vol. 24, no. 4, pp. 179–183, 2011.

[69] D. B. Hogan, E. A. Freiheit, L. A. Strain et al., "Comparing frailty measures in their ability to predict adverse outcome among older residents of assisted living," *BMC Geriatrics*, vol. 12, article 56, 2012.

[70] D. A. Drossman, "Rome III: the new criteria," *Chinese Journal of Digestive Diseases*, vol. 7, no. 4, pp. 181–185, 2006.

[71] A. L. Snow, K. F. Cook, P.-S. Lin, R. O. Morgan, and J. Magaziner, "Proxies and other external raters: methodological considerations," *Health Services Research*, vol. 40, no. 5, pp. 1676–1693, 2005.

PAPER III

Blekken et al. Implementation Science (2015) 10:72
DOI 10.1186/s13012-015-0263-8

IMPLEMENTATION SCIENCE

RESEARCH Open Access

Feasibility, acceptability, and adherence of two educational programs for care staff concerning nursing home patients' fecal incontinence: a pilot study preceding a cluster-randomized controlled trial

Lene Elisabeth Blekken[1*], Sigrid Nakrem[1], Kari Hanne Gjeilo[3,4], Christine Norton[5], Siv Mørkved[2,6] and Anne Guttormsen Vinsnes[1]

Abstract

Background: Fecal incontinence has a high prevalence in the nursing home population which cannot be explained by co-morbidity or anatomic and physiological changes of aging alone. Our hypothesis is that fecal incontinence can be prevented, cured, or ameliorated by offering care staff knowledge of best practice. However, it is not clear which educational model is most effective. To assess the effect of two educational programs for care staff, we planned a three armed cluster-randomized controlled trial. There is a lack of research reporting effects of interventions targeting improved continence care processes in older patients. Thus, to improve the quality of the planned trial, we decided to carry out a pilot study to investigate the feasibility of the planned design, the interventions (educational programs) and the outcome measures, and to enable a power calculation. This paper reports the results from the pilot study.

Methods: Three nursing homes, representing each arm of the planned trial, were recruited. Criteria for assessing success of feasibility were pre-specified. Methods, outcome measures, acceptability, and adherence of the components of the intervention were evaluated by descriptive statistical analyses and qualitative content analysis of one focus group interview ($n = 7$) and four individual interviews.

Results: The main study is feasible with one major and some minor modifications. Due to challenges with recruitment and indications supporting the assumption that a single intervention with one workshop is not sufficient as an implementation strategy, the main study will be reduced to two arms: a multifaceted education intervention and control. The components of the multifaceted intervention seemed to work well together and need only minor modification. Important barriers to consider were sub-optimal use of skill-mix, problems of communicating important assessments and care plans, and isolated nurses with an indistinct nurse identity.

Conclusions: Overall, the main study is feasible. The pedagogical approach needs to consider the identified barriers. Thus, it is essential to empower nurses in their professional role, to facilitate clinical reasoning and critical thinking among care staff, and to facilitate processes to enable care staff to find, report, and utilize information in the electronic patient record.

Trial registration: ClinicalTrials.gov: NCT01939821

Keywords: Fecal incontinence, Nursing homes, Long-term care, Older patients, Implementation study, Pilot study, Feasibility study, Care processes, Nursing

* Correspondence: lene.blekken@hist.no
[1]Faculty of Nursing, Sør-Trøndelag University College, Trondheim, Norway
Full list of author information is available at the end of the article

Background

Fecal incontinence (FI) is defined by the International Consultation on Incontinence as "the involuntary loss of liquid or solid stool that is a social or hygienic problem" [1]. FI has a higher prevalence in the nursing home (NH) population than in younger people, which cannot be explained by co-morbidity or anatomic and physiological changes of aging alone [2]. In the NH population, previous studies suggest prevalence between 10 and 69 % [3–5], most often reported to be between 40 and 55 % [5–8]. FI is associated with shame, social isolation, and reduced quality of life [1, 9, 10]. FI leads to a high direct and indirect economic burden to the health-care system and is an important cause of institutionalization of elderly patients [2, 7].

Among older patients, FI has a more complex etiology compared to the younger population [2]. Examples of reversible risk factors are loose stool, impaction, medication, inappropriate laxative use, toilet access, and quality of continence care [1, 8, 11]. Use of incontinence pads and toileting programs comprise the most common management in long-term care settings [12–14]. The level of awareness among health-care personnel regarding appropriate assessment and treatment options seems limited [1, 15, 16]. The hypothesis of this study is that FI among NH patients can be prevented, cured, or ameliorated by offering care staff knowledge of best practice.

There is a substantial evidence base to guide choice of implementation activities targeting health-care professionals in general [17–20]. However, relatively little of the implementation research has focused on care processes among older patients in NHs [21]. Specifically, there are few trials on either treatment of FI in NH patients nor on continence education programs for care staff [1]. Thus, we planned a three armed cluster-randomized controlled trial (C-RCT), with the aim to evaluate the effect of two educational programs with different degrees of complexity for care staff. Implementation research recommends multifaceted strategies to promote change of practice. In addition, it is important to investigate potential barriers [17, 19, 22]. Our rationale for choosing an interactive educational program was based on recommendations from the International Continence Society on the need to educate health-care providers to heighten awareness of FI, plus methods of identification, assessment, and management in older people [1]. The researchers' competence in educational theory and delivery competence was also an important rationale. To improve the quality of the planned C-RCT, we decided to carry out a pilot study to investigate the feasibility of the planned design, the interventions (educational programs), and the outcome measures.

The specific aims of the pilot study were to evaluate feasibility, acceptability, and adherence to the educational interventions and methods used. The UK Medical Research Council (MRC) [23] defines an educational intervention as a complex intervention; hence, an essential purpose was to investigate whether all the components could work together. Even though the pilot is a small study, the results will be used to inform an estimate of the intra-cluster correlation coefficient (ICC) and inform estimation of sample size for the main study.

Methods

The pilot study was designed as an external pilot which is a small-scale version of the main study which is not intended to be a part of the main study [24]. The pilot intervention period was 3 months. The study design was based on published guidance for developing and testing complex interventions [23–25].

Setting

In Norway, most NHs are owned and run by the municipalities and financed by taxes and patient payment. A majority of the patients are above 67 years, have complex health problems, significant deficiencies in functioning related to activities of daily living (ADL), and about 80 % suffer from cognitive impairment [26]. There are no legal requirements for staff-to-patient ratios or specifications of qualifications required for workers [27]. However, NHs have RNs on duty 24 h a day. In addition, NH staff may comprise some authorized social educators (ASE) who have a bachelor's degree in care related to people with intellectual disability, including dementia. ASEs have a defined health-care and pharmacological competence. According to Statistics Norway, the staff comprises on average 31 % RNs, 45 % licensed practical nurses (care education on a high school level most often leaving before the age 18), and 24 % health-care aides (no vocational health education). Statistics Norway has overall responsibility for official statistics in Norway.

Participants

The sample was recruited from the same urban municipality in Norway as intended for the C-RCT. The municipality has a total of 27 NHs. All NHs are under the administration of the director for health and social affairs in the municipality. NHs are typically managed by registered nurses (RNs) and have an agreement with a general practitioner (GP) who visits the NH once a week. Under the manager, a NH may have one or several care managers. The care managers are most often not involved in the everyday care of patients. We recruited three NHs for the pilot, representing each arm in the planned C-RCT. These NHs have 24-h long-term residency, were recruited based on the same eligibility criteria as for the planned C-RCT and allocated as a cluster to single intervention (SI), a multifaceted intervention (MI), or control (C). NHs with similar staff-to-patient ratios on the day shift and GP coverage were eligible for

selection. NHs designated with a specialty or with enhanced staff-to-patient ratio were excluded. RNs/ASEs working half time or more were eligible for participation in the workshop (see below) and to be recruited as an opinion leader (see below) in the intervention group. RNs/ASEs working less than half time or only night shifts were excluded. For the pilot, only RNs were involved in the study, and for the rest of the text we will use the term RN only. All care staff members in the NH were invited to the educational outreach meetings (see below) throughout the intervention period. All long-term care patients (who had stayed one month or more) were eligible for inclusion.

Intervention

The educational programs were developed according to recommendations from implementation research, pedagogic theory, and experience from members in the project group [17–22, 28–32]. To ensure a realistic intervention, one of the researchers had two meetings with experienced NH nurses to collect their comments on content and intensity of the educational programs and on the FI guideline.

The FI guideline

The project group developed a FI guideline for nurse-led assessment and treatment of FI based on international best practice recommendations [1, 33–35]. The FI guideline facilitates a systematic assessment and includes questions related to bowel symptom history and bowel patterns. As FI among NH patients is considered to have a complex etiology, the guideline facilitates the RNs to consider a range of possible causes. Examples are loose stools, immobility, cognitive impairment, impaction, and use of laxatives. Based on this assessment, the RN defines a nursing diagnosis, for example: FI related to loose stools, possibly due to incorrect doses of Laxoberal® (sodium picosulfate), urgency, and reduced mobility. This leads to FI episodes with loose stool and red perineal skin. The guideline then offers a range of possible interventions. An important intention is to empower the RNs' clinical reasoning [36] and critical thinking [37, 38]. Individualization of the nurses' diagnoses and the interventions for each patient is important. Both NHs receiving the SI and MI were introduced to the FI guideline during the workshop.

The SI comprised: one educational meeting (7 h), defined by the Cochrane Effective Practice and Organization of Care (EPOC) as "participation of health-care providers in conference, lectures, workshops, or traineeships" [19]. The educational meeting was organized as an interactive workshop that targeted knowledge, attitudes, and skills. The workshop was conducted in a meeting room in the NH. The workshop started with the RNs completing a knowledge test and was a part of the data collection and one of the outcome measures. However, by organizing it as a part of the workshop, the pedagogical intention was to make it a trigger for learning as answers were given in the following educational session. Part two of the workshop was case-based discussions concerning the FI guideline. How to integrate the use of the guideline to the electronic documentation system was an important issue. This was addressed by having access to a "learning module" in their local electronic patient record (EPR). Real patient cases were discussed, and the result was input into the EPR during the workshop. This gave the RNs and the care leaders the opportunity to experience how it could best be done. The topics of the workshop, including the guideline, were made available for the RNs as printed educational material.

In addition, MI comprised of two more elements: 1) recruitment of a local opinion leader, defined by EPOC as "use of providers nominated by their colleges as educationally influential" [19], and 2) educational outreach visits defined by EPOC as "use of a trained person who meets with providers in their practice setting to give information with the intent of changing the providers' practice" [19]. The local opinion leader was recruited after the educational meeting based on the informant method [39]. This was done by discussing with the care manager which of the RNs was considered to be able to influence and motivate the staff in general. The care manager had the responsibility for facilitating adherence to the program and the guidelines in cooperation with the opinion leader. The local opinion leader and care manager received a 1.5-h additional educational meeting on how to fulfill their roles in the study. The opinion leader and the care manager received contact information for the researcher for support during the intervention period.

The educational outreach visits were carried out in the NHs, facilitated by the project coordinator, and consisted of six sessions, lasting 1.5 h each. The opinion leader prepared cases for discussion together with the project coordinator. The project coordinator is the first author of this article and is a RN with additional educational theory and delivery competence. All of the care staff were the target group for the educational outreach and were invited to participate in the educational meetings throughout the intervention period. Facilitating and empowering care staffs' clinical reasoning and critical thinking were the main pedagogical approach.

Control group

The control group did not receive any educational program and continued with ordinary practice. The main reason for including a control group in the pilot study was to investigate their motivation to fill in questionnaires without getting the educational intervention in return.

Measures

The overall aim for the C-RCT is to study the effect of offering NH care staff an educational program on diagnosing and treating FI on reduction in FI for NH patients. The C-RCT primary outcome is frequency of FI among patients, and secondary outcomes are: remission of FI among patients identified with FI at baseline; incidence of FI among patients identified as continent at baseline; change in related concerns among patients; change in knowledge among RNs; and change in behavior among care staff. We also want to investigate correlates of FI among patients.

The following measures and data collection procedures were piloted for the main study:

The main unit of analysis for the planned C-RCT will be nursing home patients, and the same unit was used in the pilot study. The primary outcome measure was frequency of FI, measured by the Norwegian interRAI Long-Term Care Facilities Assessment System (interRAI LTCF) [40], section H3: Bowel continence. Bowel continence has the categories 0–5 where 0 = continent, 1 = continent with a stoma, 2 = seldom incontinent (not incontinent during the last three days, but has episodes of incontinence), 3 = occasionally incontinent (more seldom than daily), 4 = often incontinent (daily, but has some control), 5 = incontinent (no control), and 8 = did not occur (no bowel movement). The interRAI is a standardized, validated and comprehensive tool to assess patients' health status. It measures patients' functional, medical, cognitive, and psychosocial status [40]. In order to get some additional information on type of FI (gas, loose, or solid stool), urgency, and impact on daily life, a Norwegian version of the St. Marks anal incontinence score [41] was used. It gives a total score from 0 (complete continence) to 24 (complete incontinence).

Secondary outcome measures:

1. Both remission and incidence of FI measured by interRAI LTCF, section H3: Bowel continence.
2. Change in related factors measured by interRAI LTCF, section E: Mood and behavior, section F: Psychosocial well-being, section H1: Urinary continence, section J: State of health—Constipation and diarrhea, section L: Skin condition, and section M: Participation in activities.
3. Change in knowledge among RNs measured by a multiple choice test developed by the researchers according to established guidelines [42].
4. Change in care as reported in the EPR by care staff as measured by N-Catch. N-Catch is a validated audit instrument for care staff reports in the EPR [43–46]. N-Catch measures the quality of the content in the EPR on a scale from 0 to 32 where 0 is low quality and 32 is high quality. The instrument includes criteria for both quantity and quality of content. In order to get a score on quantity, the different parts only need to be present in the EPR (health status and a nursing care plan including nursing diagnoses, outcome, interventions, and evaluations). To get a high quality score, the content is assessed according to criteria reflecting clinical reasoning and critical thinking: does the assessment of health status seem sufficient, do the nurses' diagnoses have a logical focus and etiology, and are the outcomes and interventions individualized, relevant, and realistic [34–38, 43–46]. Change in care will also be measured by the Fecal Incontinence in Nursing Home questionnaire [8] where RNs are offered a list of interventions relevant for FI and asked to identify what is done for each individual patient.

In addition, correlates of FI were measured by interRAI LTCF, section C: Cognitive functioning, section D: Communication and vision, section G: Functionality and mobility, section I: Medical diagnosis, section J: Health condition, section K: Mouth and nutrition status, section N: Medications, and section O: Treatment, examinations/procedures.

In the pilot study, the project coordinator gave information and training on completion of the interRAI [40], the St. Mark's anal incontinence questionnaire [41], and the Fecal Incontinence in Nursing Home Patients questionnaire [8]. In addition, the project coordinator gave information and training on the procedure of printing data from the EPR in accordance with the audit instrument N-Catch. RNs with good knowledge of the patients completed questionnaires regarding patients' health.

Criteria for feasibility, adherence and acceptability

Feasibility, adherence, and acceptability of the educational programs were evaluated according to the following criteria:

Feasibility criteria:

1. Acceptable recruitment process.
2. >80% completed questionnaires returned
3. <10% missing data in each completed questionnaire
4. >0.5 mean change on the frequency scale on the primary outcome measure
5. Acceptable time use for RN's involved in the data collection

Adherence criteria:

6. >95 % of the recruited RNs participated in the workshop
7. >70 % of the health personnel participated in the educational outreach on each actual day
8. >90 of the patients assessed by the FI-guideline
9. >80% of the assessment specified by the FI-guideline reported in the EPR

Acceptability criteria:

10. Acceptable performance of the knowledge test according to sensitivity to change in knowledge
11. Satisfaction from RNs regarding the educational intervention
12. Satisfaction and acceptability from RNs regarding the FI guideline
13. Acceptable level of barriers versus facilitators for change in the NHs

Quantitative data was collected at baseline (t_0) and after 3 months (t_1 = end of intervention). In order to obtain data concerning criteria 11–13, qualitative data was collected by one focus group interview [47, 48] performed 1 month after the end of the intervention. To receive additional information, four focused individual interviews [49] were performed 4 months after the end of the intervention. Informants were recruited from the two intervention NHs. The focus group interview was moderated by one of the researchers not involved in the intervention. The project coordinator was present and could ask questions to explore a theme. The individual interviews were performed by the project coordinator. All NHs were offered economic compensation linked to the data collection in order to pay for the process of hiring extra staff to make it possible for the RNs to be absent from daily care to undertake data collection.

Analyses

Descriptive statistical analyses were performed using IBM SPSS version 21. Data from the interviews was digitally recorded, transcribed, and then analyzed by qualitative content analysis in accordance with Graneheim and Lundman [50].

All interviews were audiotaped and transcribed verbatim. First, the researcher reviewed the text several times to receive a general impression of the content. Second, the parts of the text addressing criteria 11, 12, and 13 were defined as content areas. Third, words, sentences, or paragraphs related to the content areas were identified and defined as meaning units. The meaning units were then condensed and labeled with a code. Fourth, the codes with similar meanings were grouped into categories. Related categories were then abstracted to themes with the intention to reveal the underlying meaning on an interpretive level [50]. The process from meaning units to themes went back and forth as members of the project group gave their feedback in the process of analysis.

Ethical aspects

The study was conducted with the approval of the Regional Committee for Medical and Health Research Ethics (REK) (2013/755 REK Nord) and by The Norwegian Social Science Data Services (35020). NH managers were informed and gave permission to perform the study in the individual NH. Informed consent was obtained from RNs for the knowledge test. After evaluating the overall project, the REK authorized RNs recruited to be involved in the data collection procedure with dispensations from the duty of confidentiality to gather relevant patient health information (proxy data) in order to measure effect of the educational intervention. The patients were given written information about the study and had the opportunity to withdraw themselves from data being gathered. In cases where RNs assessed a patient as not cognitively competent to read and understand the information, the letter was sent to the patients' representative. All patient information was de-identified by care staff before transfer to the researcher. The study was performed in concordance with the Helsinki Declaration. The project is registered in the clinical trial registry (NCT01939821).

Results

The aims of the pilot study were to evaluate feasibility, acceptability, and adherence to the educational intervention and methods used.

Recruitment

After obtaining approval from the director for health and social affairs in the municipality, an invitation letter was sent by email to the managers of 27 NHs. None of the managers responded positively to the first invitation. The project coordinator then telephoned the NH managers and asked if they were interested in participating. Three NHs were recruited (Table 1). The main reasons for declining were lack of time, that the NH was already

Table 1 Description of the nursing homes

	SI	MI	Control
Patient beds, long-term care	24	24	25
FTE[a], RNs/ASEs, *n* (%)	6 (33)	5.6 (36)	7.95 (43)
Number of RNs employed	6	8	8
Number of ASEs employed	0	0	1
FTE[a], licensed practical nurses, *n* (%)	7.21 (40)	8.5 (54)	9 (48)
Number of licensed practical nurses employed	11	13	15
FTE[a], health-care aides, *n* (%)	4.81 (26)	1.4 (9)	1.7 (9)
Number of health-care aides employed	16	5	10
Number of formalized meetings with general practitioner, per week	1	1	1

SI nursing home receiving single intervention, *MI* nursing home receiving multifaceted intervention, *RN* registered nurses, *ASE* authorized social educators
[a]Full-time equivalent

involved in other time-demanding projects, and/or that the NH recently had major staff turnover. The process of recruiting NHs was challenging (criterion 1). For recruited NHs, all RNs with positions ≥50 % in the NHs were automatically recruited to participate in the workshop. Seven RNs were recruited to participate in MI (4) or the SI (3) (Table 2). Sixty-two patients participated in the baseline data collection, and 57 patients participated in the follow-up data collection (Fig. 1).

Data collection procedure

Two information meetings were arranged: one 1-h meeting regarding general information and the procedure for information distribution to patients or their representatives, and one 3-h meeting regarding the data collection procedure. Time spent on filling in the questionnaire at baseline was initially approximately 2 h per patient but reduced to approximately 1 h 15 min when RNs became familiar with the questionnaire. At follow-up, it was 45–60 min per patient. The interRAI questionnaire was the most time consuming. All RNs and care leaders involved in the data collection procedure reported the information process regarding data collection to be satisfactory and data collection to be time consuming. The project coordinator did not experience any challenges in the process of training RNs to collect data. The care leaders reported that the economic compensation provided was used to cover extra hired staff, so that the RNs responsible for the collection could withdraw from daily patient work. Even so, the RNs and the research team evaluated the use of time involved in the data collection procedure as unacceptable (criterion 5).

Time between delivering the questionnaires and completion was 18–28 days at baseline and 22–26 days at follow-up. Time frames included giving or sending out information letters to patients or their representatives. This time frame was evaluated as acceptable by the research team. Although time consuming, the project coordinator experienced NHs to be motivated to undertake the data collection at both baseline and follow-up, including the control NH. Research staff time for recruitment and follow-up was evaluated as acceptable (criterion 1).

Table 2 Demographics of the included nurses[a]

n = 7	SI	MI
Age, mean (range)	42 (36–48)	38.25 (23–52)
Sex	All female	All female
Years since graduated, mean (range)	12 (10–15)	9.8 (1–25)
Employed in this nursing home Years, mean (range)	2.4 (0,2–4)	5 (1–9)

SI nursing home receiving single intervention, *MI* nursing home receiving multifaceted intervention
[a]One of the included nurses in each nursing home had the position of care manager

The RNs filled in questionnaires for all of the patients who met the eligibility criteria and did not decline to participate. The proportion of missing data in each completed questionnaire was less than 10 %. The result is in concordance with criteria 2 and 3. Table 3 shows the characteristics of the included patients. The characteristics were similar to NH patients in other studies [8].

Attendance at the workshop

After baseline data gathering, one NH was randomly allocated as a control. The other two NHs received the workshop as part of SI or MI. At both intervention NHs, the attendance was 100 % of the RNs, a total of seven RNs. The result is in concordance with criterion 6.

The knowledge test

All the included RNs completed the knowledge test both at baseline and at follow-up. Results from the knowledge test are presented in Table 4. The knowledge test was defined as acceptable according to criterion 10. This conclusion was based on an evaluation after feedback from the included RNs. Overall, the RNs found the questions relevant and meaningful. The project coordinator investigated whether the RNs answered correctly or incorrectly on the same questions that could indicate that the question was too hard or easy or not relevant. Overall, incorrect/correct answers varied between RNs. However, there were more incorrect answers among anatomy/physiology questions, than among questions related to continence care.

Local opinion leader and attendance at the educational outreach

One NH, consisting of 2 units with 12 patients per unit, was allocated to MI. Investigations revealed that units in NHs in the municipality were comparable with the functional definition made by Norton et al. [51]: a geographical area in a facility, serving a population of patients while they reside there, with dedicated management, which is characterized by: 1) a regular group of care personnel who deliver the direct care and who work most of their shifts on one unit, 2) a care manager who is in charge of the whole unit but whose supervision may stretch over several units, and 3) a RN who oversees the unit on a shift-by-shift basis but whose supervision may stretch over several units. We agreed with the care manager on recruiting one local opinion leader with responsibility for both units. The mean number of care staff on a day shift was 5.5 (per 24 patients). Of the seven planned meetings, five meetings were completed. Due to organizational issues, the period of the pilot was 2.5 months instead of the planned 3 months. The NH could not find time for more than five meetings during the 2.5 months. A mean of 29 % of the staff participated in the educational outreach. Participants

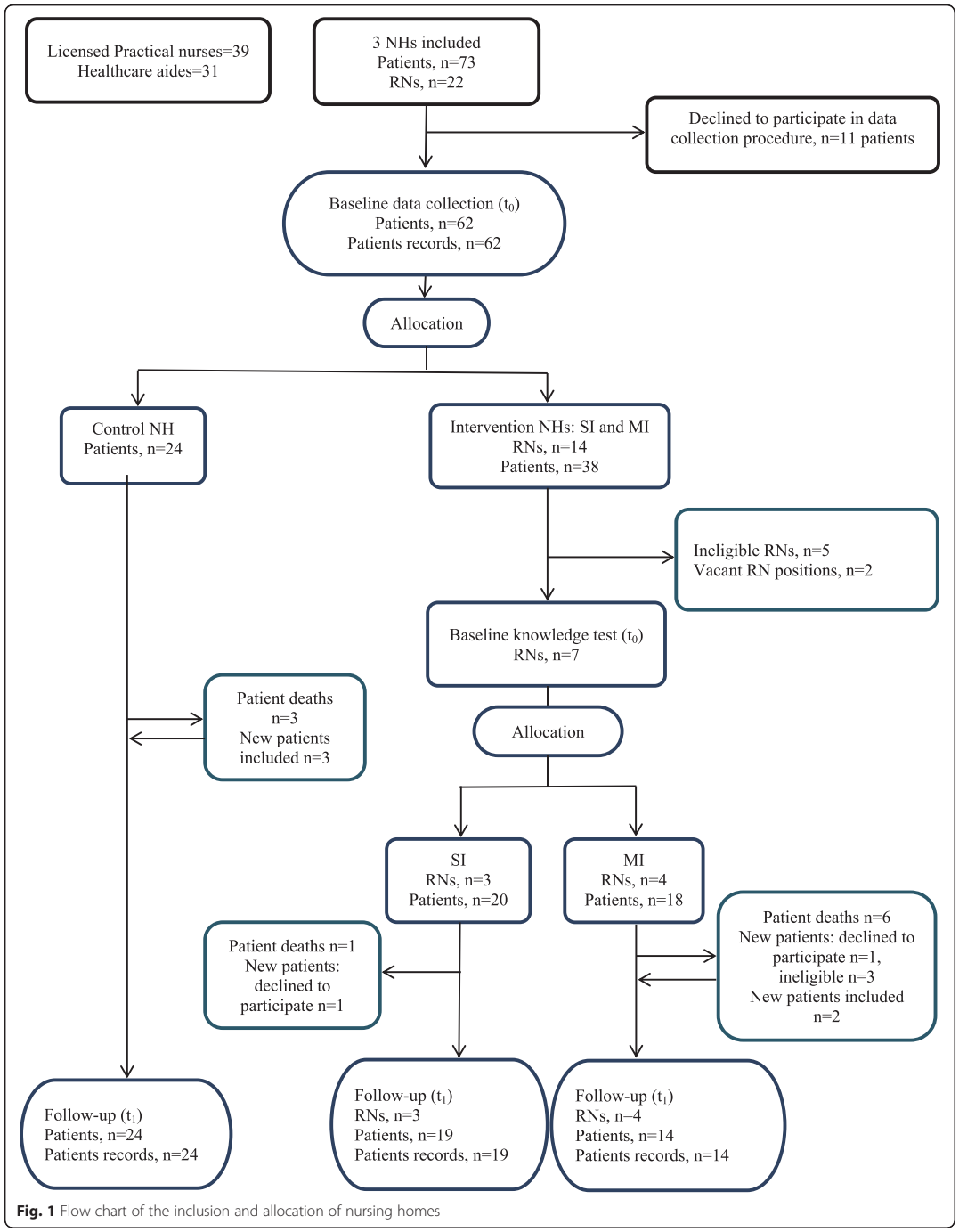


Fig. 1 Flow chart of the inclusion and allocation of nursing homes

Table 3 Selected baseline patients' characteristics

$n = 62$	Baseline values
Age, mean years (SD)	86 (10.14)
Gender, female, *n* (%)	48 (77.4)
Sum Barthel ADL score[a], $n = 57$[b], mean (SD)	10.07 (5.5)
Cognitive impairment	
Yes, *n* (%)	37 (59.7)
Partly, *n* (%)	13 (21)

[a]Barthels scoring form for functioning in activities of daily living, scoring range 0–20 where 0 = independent
[b]Missing data from one or more of the individual ADL score

Table 5 Distribution of continence scores among patients with FI

	Baseline			Follow-up			
	Prevalence[a], % (*n*)	Mean[a]	SD	Prevalence[a], % (*n*)	Mean[a]	SD	Mean change
SI	60 (12)	3.83	0.84	(53) 10	3.80	1.32	−0.03
MI	50 (9)	3.00	1.23	(57) 8	2.63	0.92	−0.37
Control	58 (14)	3.77	1.37	(67) 16	4.38	1.15	+0.57

SI nursing home receiving single intervention, *MI* nursing home receiving multifaceted intervention
[a]interRAI, H3 bowel continence (scores 2–5) 2 = seldom (have episodes, but not the last 3 days), 3 = occasionally (more seldom than daily), 4 = often (daily, have a curtain control), 5 = incontinent (no control). Patients with the scores 0 = continent, and 1 = continent with a stoma, are excluded

were the local opinion leader (all meetings), the care manager (two meetings), and one other RN (one meeting). The result is not in concordance with criterion 7.

Assessment with FI guideline and documentation in EPR

The NH receiving SI managed to assess 50 % of the patients with the FI guideline, and 26 % of the assessments were reported as a health status/individualized care plan in the EPR. NH receiving MI managed to assess 96 % of the patients, and 93 % of the assessments were reported in the EPR as a health status/individualized care plan. Only the NH receiving MI managed to assess and document in concordance with criteria 8 and 9. Researchers found N-Catch to be a useful audit instrument.

Primary outcome measure

Table 5 shows prevalence of FI in the different NHs and mean change on the frequency scale among patients with FI. Both intervention NHs show a tendency to reduced frequency of FI among patients. However, the reduction was smaller than specified in criterion 4.

Satisfaction and acceptability regarding the educational intervention

All RNs (seven) in the intervention NHs participated in the focus group interview. Four RNs, two from each intervention NH, participated in focused individual interviews. The results are presented in Table 6. The RNs found the workshop inspiring. It gave them the opportunity for professional discussions and raised consciousness of bowel problems in general and FI in particular in the NH population. The professional discussions about best practice for the individual patient were considered motivating for their nursing practice. The FI guideline was reported as a tool that made them stop and think in a systematic and critical way. RNs representing the NH receiving the MI reported the educational outreach as essential for a change in practice. Even though the NH receiving the SI did report some change in care for patients with FI, they did not manage to keep up the focus over time. Examples of barriers to change reported by RNs were sub-optimal use of skill-mix and many different care staff members resulting in problems spreading the information about assessments and care decisions to all care staff. These barriers were reported as the main reason why the patient did not get the care as intended.

Table 4 Results of the knowledge test[a] for nurses

	Baseline, $n = 7$	Follow-up, $n = 7$	Difference, points (%)
SI			
Mean points (range), $n = 3$	14.7 (11.5–18.5)	16 (10–21)	1.3 (5.0)
MI			
Mean points (range), $n = 4$	17.1 (17–17.5)	21.6 (19–26)	4.5 (17.3)

SI nursing home receiving single intervention, *MI* nursing home receiving multifaceted intervention
[a]Scoring range 0–26 points. Twenty-six multiple choice questions: all question, except one, actuated 1 point per correct answer. One question actuated 0.5 or 1 point

An important intention with the EPR is to make it possible for care staff to communicate their assessments and care plans as a means to secure continuity in care. RNs reported frustration with finding time to do the tasks involved in patient assessments and development of care plans, and if developed, that "nobody" read and followed the directions. Possible explanations described by all informants were lack of time and uncertainty on how to communicate and report care in the EPR, inefficient software, too few computers in the units, and a reluctance to use computers. RNs also described the nursing role as unclear based on the tendency to distribute tasks equally between staff irrespective of their level of qualification. This includes non-nursing tasks such as preparing food, washing patients' clothes, and cleaning beds. The results from the interviews indicate that the intervention facilitated a stronger nurse identity and raised consciousness on the importance of assessments and individual care. According to the RNs, the input of knowledge and the use of the FI guideline led to demonstrable results; the patients experienced fewer episodes of FI, which worked as an important motivation for adherence to the care plan. RNs also reported the FI guideline as a tool which helped them structure bowel assessments, identify FI-

Table 6 Results from qualitative content analysis of interviews

Content area	Categories	Themes
Workshop	Professional discussions	Professional discussions as inspiration for best practice
	Motivating	
	Sharing	
Local opinion leader	Collaboration	Valued and empowering role, but significant allies are essential
	Mastering	
Educational outreach	Enabling	Change require guidance over time, feedback and a sense of ownership
	Maintained focus	
	Monitoring	
FI guideline	Organizes knowledge	The FI guideline facilitates clinical and critical thinking
	Decision support	
	Comprehensive	
	Concrete and goal oriented	
	Made nurses think	
Barriers	Staff discontinuity	Hard to communicate important information to all
	Insufficient time	
	Large care staff	
	Few RNs	Isolated nurses and vague nurse identity in a fragmented care community
	Unclear nursing role	
	Sub-optimal use of skill-mix	
	Reluctance to use computers	Insecurity in how to find, report and utilize assessments and care plans in EPR
	EPR is difficult to navigate	
	Too few computers	
Facilitators	Demonstrable results	Raised consciousness on bowel problems and concrete results motivates
	Heightened awareness	
	Distinct nurse identity	Strong nurse identity in a positive care community
	Sense of community	

etiology and intervention, and was used as a decision support in the process of documenting a care plan in the EPR. All informants considered a positive care community as essential for change. The results are in concordance with criteria 11 and 12. Results related to criterion 13 will be used to tailor the intervention to overcome the identified barriers.

Discussion

The aims of the pilot study were to evaluate feasibility, acceptability, and adherence to the educational intervention and methods used. Overall, the pilot study showed a reasonable result, which will guide the main study. However, some modifications are needed.

As the main study plans to recruit from the same municipality, the recruitment problem experienced needs thorough consideration. The recruitment problem for the pilot might reflect a lack of motivation to participate in a pilot study where the presented aim was not considered clinical relevant. The RNs participating in the pilot recommended a recruitment strategy involving a clearer focus on FI and bowel problems as this is something considered clinically relevant. For the main study, we also plan to include personal meetings with the director of health and social affairs and the care managers of the NHs. We will also invite one of the RNs from the pilot study to share her experience and to answer questions about participating.

RNs did manage to fill in questionnaires for all included patients with less than 10 % missing data and to print and de-identify the information from the EPR within a reasonable time frame. This was also the case for the NH in the control group. The economic compensation and the recommendation of releasing the responsible RNs from daily work were reported as essential. Even so, the RNs recommended the research team to make the data gathering less time demanding. Completing interRAI was reported to be most time demanding, but as it is the instrument that has gone through the most thorough validation process and is in worldwide use, the project group considered it as essential, leading to the removal of the Fecal Incontinence in Nursing Home Patients questionnaire instead. In addition, RNs found the work of completing interRAI meaningful as the task included a time resource to sit down, discuss, and do a thorough assessment of the patients.

The work of printing data from the EPR was not considered time consuming, but the process of de-identifying the content was. After testing N-Catch on the pilot data, we considered daily evaluations over a period of 4 weeks as sufficient to audit the content. Therefore, the printing of daily evaluations will be reduced from the previous 12 to 4 weeks. The process of reporting complete health status, identifying accurate nurses' diagnoses, outcomes, and interventions is considered to reflect RNs' ability to use clinical reasoning and critical thinking [34–38]. Therefore, a systematic analysis of the nursing reports based on the N-Catch criteria can be used as a measure of clinical reasoning and critical thinking in the main study.

Overall, the components of the intervention seemed to work well together. The workshop was judged as feasible when all eligible RNs participated. The result is in concordance with other studies [17, 19], which reported workshops as feasible in most settings.

The local opinion leader worked with the rest of the staff on her own unit as recommended by Flodgren et al. [39]. However, both care manager and opinion leader reported that it was important to recruit one opinion leader per unit for the main study. The units have separate staff with different cultures, and it was challenging to fulfill the role as intended in two units. For the main study, the functional definitions of a unit made by Norton et al. [51] will be used as guide for recruitment of a local opinion leader and to inform the definition of cluster in the trial where one unit will be defined as one cluster. In addition, using the unit as a cluster will improve study feasibility by increasing the number of potential clusters, which impacts power more than increasing individuals enrolled [24].

For the educational outreach meetings, the intention was to include as many of the total care staff on duty as possible. Another intention was for the local opinion leader to prepare cases for discussion for the outreach meeting. This did not work as intended. The problem of involving more of the staff may be due to the practical issues on how to organize care staff between work tasks in the unit and the educational outreach meetings as it is impossible for all of the staff to leave the unit at the same time. Another reason might be that the project had decided that only RNs were to assess the patient with the FI guideline, and that the rest of the care staff was too little involved. There are few RNs, and to implement a new routine, it is important that as many as possible of the staff have ownership of the routine to be implemented [22, 28, 31]. For the main study, the RNs will maintain responsibility for FI assessment in order to reinforce the empowerment of the RNs to take the leading role in patient care but in closer cooperation with the licensed practical nurse with primary care responsibility for the patient. To accomplish this, the researcher should motivate the care staff present at the educational outreach meeting to make a reasonable work plan until the next meeting, including who of the licensed practical nurses is to be included in the work. This will also ease the local opinion leader's responsibility to prepare cases for discussion between meetings. This procedure was piloted, and the RNs involved reported this to work better than the original plan. The care leader and the opinion leader reported most of the licensed practical nurses and health-care aides to be positive and engaged, especially when they experienced a change among some of the patients. However, they experienced a challenge reaching all care staff, especially those working for few hours. An important strategy for implementing use of the FI guideline was to integrate the intervention with the existing EPR system [52]. The study identified insecurity in how to report and utilize assessment and care plans in the EPR as an essential barrier to change. Therefore, it is important to facilitate NH unit-specific strategies to ensure continuity in FI care for the individual patient.

Only the NH receiving MI managed to fulfill criteria 8 and 9. Results from the interviews support the assumption that RNs were motivated by the educational outreach meetings where they, together with the researcher, agreed upon how to continue the work. An issue for the researcher was to empower the RNs' critical thinking and highlight that making assessments is an important care task. These results are supported by studies indicating that a workshop alone is not sufficient [17, 19, 22], and that educational outreach meetings might be essential to improve the care delivered [18].

The interviews identified a culture where the role of the RN was unclear and that RNs were doing many non-nursing tasks. Ausserhofer et al. [53] found the same tendency among RNs in hospitals all over Europe. They also found that nursing care activities most left undone were developing or updating nursing care plans, adequately documenting nursing care and adequate patient surveillance. Together with a discontinuity among staff, this may lead to a tendency of "private practice" where the individual care staff member does what they find best on their individual shift. For the main study, empowering RNs in the nursing role and helping them find ways to best organize the work on their own unit and give feedback to the rest of the care staff will be important.

Concerning the small change in the chosen primary outcome measure of FI episodes, the result needs to be interpreted with caution due to the small sample size and high drop-out rate of patients in the NH receiving MI. However, the main purpose was to get information for the planned C-RCT to inform the estimation of sample size and decide a model of analyses. Results from the pilot study showed that the primary outcome was skewed to the right with most of the patients defined as continent with a score of 0. As a consequence, we found it reasonable to dichotomize the variable in order to investigate the proportion of patients moving from one category to another. After discussing the results, the cut-off was set between the scores 2 and 3 on the interRAI scale with the categories *seldom incontinent* with the scores 0–2, and *often incontinent* with the scores 3–5 (see Table 7). We hypothesized that a reasonable and clinically important effect size in the intervention group compared to the control group would be 15 % between the two groups in proportions with FI (score of 3–5). A thorough discussion of the sample size calculations and model of analyses are published elsewhere [54].

Table 7 Distribution of scores after dichotomization of the primary outcome variable

interRAI[a]	Baseline		Follow-up	
	Seldom Incontinent	Often Incontinent	Seldom Incontinent	Often Incontinent
SI, *n* (%)	8 (40)	12 (60)	10 (55.6)	8 (44.4)
MI, *n* (%)	13 (72.2)	5 (27.8)	11 (78.6)	3 (21.4)
Control, *n* (%)	14 (58.3)	10 (41.7)	10 (41.7)	14 (58.3)

SI nursing home receiving single intervention, *MI* nursing home receiving multifaceted intervention
[a]interRAI: 0 = continent, 1 = continent with stoma, 2 = seldom (have episodes, but not the last 3 days), 3 = occasionally (more seldom than daily), 4 = often (daily, has a curtain control), 5 = incontinent (no control); dichotomized scale: 0–2 = seldom incontinent, 3–5 = often incontinent

Results from the interviews stated that RNs and care staff in general did not manage to keep up the focus on FI assessment and management after a single intervention with a workshop. Together with the recruitment problem experienced and methodological considerations related to the complexity and cost of doing a study with three arms [24], the main study will be reduced to two arms: MI and a control group.

The generalizability and transferability of the results may be biased by the fact that recruiting NHs was challenging, and that NHs recruited may be higher functioning than the NHs rejecting participation for reasons outside the scope of the eligibility criteria, for example: personal characteristics of RNs and care leaders, care staff attitudes toward research and organizational change. As a consequence for the main study, the different components of the MI will be the same for all included NHs, while pedagogical strategies may vary in order to target needs in the individual NH, for example, to facilitate NH unit-specific strategies to ensure continuity in FI care and empower RNs in the nursing role.

In the main study, we will also include measures of adherence. These are: 1) proportion of RNs within eligibility criteria participating in the workshop, 2) how many and who of the care staff participated in the outreach meetings, 3) proportion of intended outreach meetings held, 4) proportion of patients assessed with the FI guideline, and 5) proportion of assessments reported in the EPR as health status and nursing care plan. In addition, researchers will record their reflections from the educational meetings.

Conclusions

The aims of the pilot study were to evaluate feasibility, acceptability, and adherence to the educational intervention and methods used. The components of the intervention seemed to work well together. The results of the pilot study shows that the main study is feasible with one major change and some minor changes. An essential pedagogical approach is to facilitate clinical reasoning and critical thinking among care staff and to empower the RNs in their professional role. Another important pedagogical approach is to facilitate processes among care staff on how to find, report, and utilize assessments and care plans in the EPR. If the result of the main study shows an effect, an interesting question for later studies is whether it is possible to achieve significant effect with less effort.

Abbreviations

FI: fecal incontinence; NH: nursing home; RN: registered nurse; ASE: authorized social educator; C-RCT: cluster-randomized controlled trial; EPR: electronic patient record; MRC: Medical Research Council; ICC: intra-cluster correlation coefficient; ADL: activities of daily living; MI: multifaceted intervention; SI: single intervention; C: control; EPOC: Cochrane Effective Practice and Organization of Care; interRAI LTCF: The interRAI Long-Term Care Facilities Assessment System; GP: general practitioner.

Competing interests

The authors declare they have no competing interests.

Authors' contributions

AGV is the principal investigator; LEB and AGV are responsible for the conception and design of the study; LEB, SN, and AGV are responsible for recruitment and acquisition of data; LEB, SN, KHG, CN, SM, and AGV are responsible for the analyses; LEB, AGV, KHG, CN, SM, and SN are responsible for critically revising the article for important intellectual content. All authors read and approved the final manuscript.

Authors' information

LEB is a RN and a PhD student; SN is a RN, a PhD, and an associate professor; KHG is a RN, a PhD, and an associate professor; CN is a RN, a PhD, and a professor; SM is a physiotherapist, a PhD, and a professor; AGV is a RN, a PhD, and a professor.

Acknowledgements

The authors wish to thank the Norwegian Nurses Organization for contributing funds for this study. We also wish to thank the Søbstad community hospital and teaching nursing home for participating in the planning of the educational intervention and the three nursing homes in Trondheim municipality participating in the pilot study.

Author details

[1]Faculty of Nursing, Sør-Trøndelag University College, Trondheim, Norway. [2]Department of Public Health and General Practice, Norwegian University of Science and Technology, Trondheim, Norway. [3]Department of Cardiothoracic Surgery, Department of Cardiology and National Competence Centre for Complex Symptom Disorders, St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway. [4]Department of Circulation and Medical Imaging, Faculty of Medicine, Norwegian University of Science and Technology, Trondheim, Norway. [5]Faculty of Nursing and Midwifery, King's College London, 57 Waterloo Road, London SE1 8WA, UK. [6]Clinical Service, St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway.

Received: 19 December 2014 Accepted: 15 May 2015
Published online: 23 May 2015

References

1. Norton C, Whitehead W, Bliss D, Z., Harai D, Lang J. Conservative and pharmacological management of faecal incontinence in adults. In Incontinence. Edited by Abrams B, Cardozo L, Khoury S, Wein A. 4th International Consultation on Incontinence. 2009. [http://www.icud.info/PDFs/Incontinence.pdf]. Accessed 17 Nov 2010.
2. Shah BJ, Chokhavatia S, Rose S. Fecal incontinence in the elderly: FAQ. Am J Gastroenterol. 2012;107:1635–46.
3. Aslan E, Beji NK, Erkan HA, Yalcin O, Gungor F. The prevalence of and the related factors for urinary and fecal incontinence among older residing in nursing homes. J Clin Nurs. 2009;18:3290–8.

4. Schnelle JF, Kapur K, Alessi C, Osterweil D, Beck JG, Al-Samarrai NR, et al. Does an exercise and incontinence intervention save healthcare costs in a nursing home population? J Am Geriatr Soc. 2003;51:161–8.
5. Saga S. Understanding faecal incontinence in nursing home patients, Epidemiology and nurses' management. Trondheim: Doctoral thesis at Norwegian University of Science and Technology; 2014. p. 282.
6. Bliss DZ, Harms S, Garrard JM, Cunanan K, Savik K, Gurvich O, et al. Prevalence of incontinence by race and ethnicity of older people admitted to nursing homes. J Am Med Dir Assoc. 2013;14:451.
7. Milsom I, Altman D, Lapitan MC, Nelson R, Sillèn U, Thom D. Epidemiology of urinary (UI) and faecal (FI) incontinence and pelvic organ prolapse (POP). In Incontinence. Edited by Abrams B, Cardozo L, Khoury S, Wein A. 4th International Consultation on Incontinence. 4th International Consultation on Incontinence. 2009. [http://www.icud.info/PDFs/Incontinence.pdf]. Accessed 17 Nov 2010.
8. Saga S, Vinsnes AG, Mørkved S, Norton C, Seim A. Prevalence and correlates of fecal incontinence among nursing home residents: a population-based cross-sectional study. BMC Geriatr. 2013;13:87.
9. Taylor DW, Cahill JJ, Rizk DEE. Denial, shame and acceptance: generating base-line knowledge and understanding of fecal incontinence amongst long-term care residents and care providers. Public Health Res. 2014;4:13–8.
10. Kenefick N. The epidemiology of faecal incontinence. In: Norton C, Chelvanayagam S, editors. Bowel continence nursing. Beaconsfield: Beaconsfield Publishers Ltd; 2004. p. 14–20.
11. O' Connell B, Ostaszkiewicz J, Day K. The challange of managing continence care in residential aged care settings: recommendations for research and practice. Geriaction. 2005;23:5–18.
12. Roe B, Flanagan L, Jack B, Barrett J, Chung A, Shaw C, et al. Systematic review of the management of incontinence and promotion of continence in older people in care homes: descriptive studies with urinary incontinence as primary focus. J Adv Nurs. 2011;67:228–50.
13. Rodriguez N, Sackley C, Badger F. Exploring the facets of continence care: a continence survey of care homes for older people in Birmingham. J Clin Nurs. 2007;16:954–62.
14. Saga S, Seim A, Mørkved S, Norton C, Vinsnes AG. Bowel problem management among nursing home residents: a mixed methodes study. BMC Nursing. 2014;13:35.
15. Mangnall J, Tyler P, Thomas S, Watterson L. Continence problems in care homes: auditing assessment and treatment. Nurs Older People. 2006;18:20–2.
16. Thekkinkattil DK, Lim M, Finan PJ, Sagar PM, Burke D. Awareness of investigations and treatment of faecal incontinence among the general practitioners: a postal questionnaire survey. Colorectal Dis. 2008;10:263–7.
17. Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. Health Technol Assess. 2004;8:1–72.
18. O'Brien MA, Rogers S, Jamtvedt G, Oxman AD, Odgaard-Jensen J, Kristoffersen DT, et al. Educational outreach visits: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2007; 4. doi:10.1002/14651858.CD000409.pub2.
19. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. Implementation Sci. 2012;7:3–17.
20. Cheater F, Baker R, Gillies C, Hearnshaw H, Flottorp S, Robertson N, et al. Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2010; 3. doi:10.1002/14651858.CD005470.
21. Boström AM, Slaughter SE, Chojecki D, Estabrooks CA. What do we know about knowledge translation in the care of older adults? A scoping review. J Am Med Dir Assoc. 2012;13:210–9.
22. Titler M. The evidence for Evidence-Based Practice Implementation. In: Hughes HG, editor. Patient safety and quality. An evidence-based handbook for nurses. Rockville: AHRQ Publications; 2008.
23. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;50:587–92.
24. Eldridge S, Kerry S. A practical guide to cluster randomised trials in health services research. Chichester: John Wiley & Sons; 2012.
25. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, how and why. BMC Med Res Methol. 2010;10:1.
26. Nylenna M. Helsetjenesten i Norge: et overblikk. Gyldendal akademisk: Oslo; 2014.
27. Ringard Å, Sagan A, Saunes IS, Lindahl AK. Norway: health system review. Health Syst Transit. 2013;15:1–162.
28. Rogers EM. Diffusion of innovations. New York: Free Press; 2003.
29. Eccles M, Grimshaw J, Walker A, Johnston M, Pitts N. Changing the behavior of healthcare professionals: the use of theory in promoting the uptake of research findings. J Clin Epidemiol. 2005;58:107–12.
30. Mezirow J. Transformative learning as discourse. J Transorm Educ. 2003; doi:10.1177/1541344603252172.
31. Argyris C. Organisatorisk læring - singel - og double loop. In: Illeris K, editor. Tekster om læring. Fredriksberg: Roskilde Universitets Forlag; 2000.
32. Kvalsund R. Organisering av kompetanseutvikling i arbeidslivet. In: Aarsand L, Håland E, Tønseth C, Tøsse S, editors. Voksne, læring og kompetanse. Oslo: Gyldendal Akademiske; 2011.
33. National Institute for Health and Clinical Exellence. Faecal incontinence: management of faecal incontinence in adults. NICE Clin Guidel 49. 2007. https://nice.org.uk/guidence/cg49/resources/guidance-faecal-incontinence-pdf. Accessed 18 Feb 2015.
34. Herdman T. Nursing diagnoses. Definition and classification (2012–2014). North America Nursing Diagnosis Associations (NANDA). Chichester: Wiley-Blackwell/NANDA International; 2012.
35. Bulechec G. Nursing interventions classification (NIC). St Louis: Mosby Elsevier; 2013.
36. Banning M. Clinical reasoning and its application to nursing: concepts and research strategies. Nurse Educ Pract. 2008;8:177–83.
37. Lunney M. Critical thinking to achive positive health outcomes. Nursing care studies and analyses. Wiley-Blackwell: Ames; 2009.
38. Fesler-Birch DN. Critical thinking and patient outcomes: a review. Nurs Outlook. 2005;53:59–65.
39. Flodgren G, Parmelli E, Doumit G, Gattellari M, O'Brien MA, Grimshaw J, et al. Local opinion leaders: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2011, 8. doi:10.1002/14651858.CD000125.pub4.
40. Morris JN B-TP, Fries BE, Hawes C, Murphy K, Mor V, Nonemaker S, et al. InterRAI Long-Term Care Facilities (LTCF) Assessment Form and User's Manual. Verson 9.1 Norwegian version. Washington DC: interRAI; 2012.
41. University Hospital of North Norway. Norwegian registry for anal incontinence. St. Marks skår. [http://www.unn.no/getfile.php/UNN%20INTER/Enhet/Inkontinenssenter_web/Dokumenter/Anal%20inkontinens%201B_200214.pdf]. Accessed 12 April 2013.
42. Sirnes SM. Flervalgsoppgaver - konstruksjon og analyse. Fagbokforlaget: Bergen; 2005.
43. Paans W, Sermeus W, Nieweg RM, van der Schans CP. D-Catch instrument: development and psychometric testing of a measurement instrument for nursing documentation in hospitals. J Adv Nurs. 2010;66:1388–400.
44. Björvell C, Wredling R, Thorell-Ekstrand I. Long-term increase in quality of nursing documentation: effects of a comprehensive intervention. Scand J Caring Sci. 2002;16:34–42.
45. Johnsen KMG, Ehrenberg A, Fossum M. Dokumentasjon av sykepleie i sykehjem. En Vurdering av innhold og kvalitet på sykepleiedokumentasjon og vurdering av reliabiliteten til instrumentet N-Catch. Vard Nord Utveckl Forsk. 2014;34:27–32.
46. Nøst TH, Tettum BI, Frigstad SA, Woldstad K, Haugan B, Oppheim AE, et al. N-Catch II – et gransknings instrument for vurdering av sykepleiedokumentasjon. Sykepleien (In press).
47. Krueger RA, Casey MA. Focus groups: a practical guide for applied research. Los Angeles: Sage; 2009.
48. Malterud K. Kvalitative metoder i medisinsk forskning: en innføring. Oslo: Universitetsforl; 2011.
49. Tjora AH. Kvalitative forskningsmetoder i praksis. Gyldendal akademisk: Oslo; 2012.
50. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. Nurse Educ Today. 2004;24:105–12.
51. Norton PG, Murray M, Doupe MB, Cummings GG, Poss JW, Squires JE, Teare GF, Estabrooks CA. Facility versus unit level reporting of quality indicators in nursing homes when performance monitoring is the goal. BMJ Open 2014, 4. doi:10.1136/bmjopen-2013-004488.
52. O'Connell B, Ostaszkiewicz J, Hawkins M. A suite of evidence-based continence assessment tools for residential aged care. Australas J Ageing. 2011;30:27–32.

53. Ausserhofer D, Zander B, Busse R, Schubert M, De Geest S, Rafferty AM, et al. Prevalence, patterns and predictors of nursing care left undone in European hospitals: results from the multicountry cross-sectional RN4CAST study. BMJ Qual Saf. 2014;23:126–35.
54. Blekken LE, Vinsnes AG, Gjeilo KH, Salvesen Ø, Norton C, Nakrem S. Effect of a multifaceted educational program for care staff concerning fecal incontinence in nursing home patients: study protocol of a cluster randomized controlled trial. Trials. 2015;16:69.

PAPER IV

Blekken et al. Trials (2015) 16:69
DOI 10.1186/s13063-015-0595-3

TRIALS

STUDY PROTOCOL Open Access

Effect of a multifaceted educational program for care staff concerning fecal incontinence in nursing home patients: study protocol of a cluster randomized controlled trial

Lene Elisabeth Blekken[1*], Anne Guttormsen Vinsnes[1], Kari Hanne Gjeilo[2,3], Siv Mørkved[4,7], Øyvind Salvesen[5], Christine Norton[6] and Sigrid Nakrem[1]

Abstract

Background: Fecal incontinence has a high prevalence in the older population, which cannot be explained by comorbidity or the anatomical or psychological changes of aging alone. Fecal incontinence leads to a high economic burden to the healthcare system and is an important cause of institutionalization. In addition, fecal incontinence is associated with shame, social isolation and reduced quality of life. The importance of identifying treatable causes in the frail elderly is strongly emphasized. It is recommended that an assessment of fecal incontinence should be implemented as part of an evaluation of older patients. Although there is a substantial evidence base to guide choice of implementation activities targeting healthcare professionals, little implementation research has focused on the care of older people nor involved care processes or care personnel. This study is based on the assumption that fecal incontinence among nursing home patients can be prevented, cured or ameliorated by offering care staff knowledge of best practice through a multifaceted educational program. The primary objective is to test the hypothesis that a multifaceted educational program for nursing home care staff on assessment and treatment of fecal incontinence reduces patients' frequency of fecal incontinence.

Methods/design: The study is a two-armed, parallel cluster-randomized controlled trial. Primary outcome is the frequency of fecal incontinence among patients. Sample size calculations resulted in a need for a total sample of 240 patients. Twenty nursing home units in one city in Norway will be recruited and allocated to intervention or control by an independent statistician using computer-generated tables. The intervention is a multifaceted educational program. Units in the control arm will provide care as usual. The intervention period is 3 months. Data will be collected at baseline, 3, and 6 months. Data will be analyzed using mixed effect models with the cluster treated as a random effect.

Discussion: This study is the first randomized controlled trial specifically focusing on this neglected area. The result of the study will give evidence for best practice for continence care in nursing homes, and organizational advice concerning implementation strategies.

Trial registration: ClinicalTrials.gov: NCT02183740, registered June 2014.

Keywords: Fecal incontinence, Nursing homes, Long-term care, Old patients, Care processes, Nursing, Protocol, Cluster-randomized trial

* Correspondence: lene.blekken@hist.no
[1]Faculty of Nursing, Sør-Trøndelag University College (HiST), Postbox 2320, 7004 Trondheim, Norway
Full list of author information is available at the end of the article

Background

Fecal incontinence (FI) is defined by the International Consultation on Incontinence as 'the involuntary loss of liquid or solid stool that is a social or hygienic problem' [1]. FI has a higher prevalence in the elderly population than in younger people, which cannot be explained by comorbidity or the anatomical and psychological changes of aging alone [2]. In the nursing home (NH) population, previous studies suggest a prevalence of FI between 10 and 69% [3-5], but it is most often reported to be between 40 and 55% [1,5,6]. The varying prevalence may be due to the lack of a consistent definition of FI, although differences in the quality of continence care in the NHs might also be an explanation [6,7].

FI leads to a high direct and indirect economic burden to the healthcare system, and is an important cause of institutionalization of older patients [1,2,7]. In addition, FI is associated with shame, social isolation and reduced quality of life [1,8,9]. FI among older patients has a more complex etiology compared to the younger population [2,6], and the importance of identifying treatable causes of FI in frail older people, rather than just managing symptoms passively, is strongly emphasized [1]. The level of awareness among health personnel regarding appropriate assessment and treatment options for FI seems limited [1,10-12]. Further, there are indications that both older patients themselves and health personnel consider FI to be a normal part of aging for which nothing can be done [9,11]. It is recommended that an assessment of FI should be implemented as part of an evaluation of older patients [1,2,13].

There is a substantial evidence base to guide choice of implementation activities targeting healthcare professionals in general [14-17]. However, relatively little of the implementation research has focused on the care of older people or involved care processes or care personnel [18]. Even though the evidence is not fully conclusive, implementation research suggests that the most effective method for changing the behavior of health personnel in long-term care settings involves multifaceted educational efforts such as written materials or toolkits combined with individual educational visits, small group training or feedback [14,17,19].

This study is based on the hypothesis that FI among NH patients can be prevented, cured or ameliorated by offering NH care staff knowledge of best practice through a multifaceted educational program on assessment and treatment of FI. The study has been developed according to guidelines for developing and testing complex interventions [20-23]. As there are very few trials either on the treatment of FI in NH patients or on continence education programs for care staff, it was considered necessary to investigate feasibility before evaluating the complex intervention with a randomized controlled trial [20]. Thus, a pilot study was conducted in autumn 2013. The results are not yet published, but the experiences and results have been used in the planning of this cluster-randomized controlled trial.

Aims and objectives

The overall aim of this study is to achieve a reduction in bowel leakage and accidents for NH patients by altering the quality of continence care among registered nurses (RNs), authorized social educators (ASEs, see below), and care staff in general. The primary objective is to test the hypothesis that a multifaceted educational program for NH care staff on assessment and treatment of FI reduces patients' frequency of FI.

Secondarily, the trial will investigate the effect of a multifaceted educational program for NH care staff on 1) remission of FI among patients with FI present at baseline or the incidence of new cases of FI among patients identified as continent at baseline; 2) change in NH patients' FI-related concerns such as mood, constipation, diarrhea and skin condition; 3) increased knowledge among RNs and ASEs; 4) change of practice among RNs, ASEs and care staff in general; 5) and reduction in costs related to FI management. The study also intends to investigate correlates of FI in the NH population.

Methods/design

The study is a parallel two-armed cluster randomized controlled trial (C-RCT) with a repeated cross-sectional design. As there will be considerable overlap between patients included at the different data-collection time points, some outcomes will be treated as if they come from a cohort design.

Setting

In Norway, the municipalities have a statuary obligation to provide NH care to those who need it. Most Norwegian NHs are owned and run by the municipalities, and financed by a combination of taxes and patient payment. NH size varies between 20 and 120 beds, divided into units most commonly with 15 beds. NHs are managed by RNs and have an agreement with a general practitioner (GP) who visits the NH once a week. There are no legal requirements for staff-to-patient ratios or specifications for qualifications required for workers [24]. However, NHs have RNs and/or ASEs on duty 24 hours a day, and according to unpublished information from Statistics Norway the staff comprises on average 31% RNs/ASEs, 45% licensed practical nurses (care education on high school level most often before age 18) , and 24% healthcare aides (no vocational health education). Statistics Norway has overall responsibility for official statistics in Norway. In Norway, an ASE has a bachelor's

degree and provides daily care to persons in need, particularly those with intellectual disability, including dementia. ASEs have a defined healthcare and pharmacological competence [25].

Intervention

The educational program has been developed according to recommendations from implementation research, pedagogic theory and experience from members of the project group [14,16,19,26-31]. A research group comprising four researchers will facilitate the educational program and will be trained as a unified team to enhance standardization of the intervention. Educational content, pedagogical methods and a paper-based guideline for nurse-led assessment and treatment of FI (the FI-guideline, see below) were developed for this study by expert consensus and were evaluated in the pilot study.

Content of the multifaceted intervention

The FI-guideline is based on best practice recommendations [1,13,32,33] and will be introduced to the RNs/ASEs in the intervention NHs during the workshop (see below). The FI-guideline facilitates a systematic assessment of bowel symptom history and bowel patterns. As FI among NH patients is considered to have a complex etiology, the guideline encourages the RN/ASE to consider a range of possible causes. Examples are loose stools, immobility, cognitive impairment, impaction and use of laxatives. Based on this assessment, the RN/ASE defines a nursing diagnosis, for example: 'FI related to loose stools, possibly due to excessive laxatives, urgency and reduced mobility. This leads to FI episodes with loose stool and red perineal skin'. The guideline then offers a range of possible interventions. The result of the paper-based assessment, the nursing diagnosis and interventions, is then documented in the patient's EPR as an individualized care plan.

One one-day educational meeting (7 hours) is defined by the Cochrane Effective Practice and Organization of Care (EPOC) as 'participation of healthcare providers in conference, lectures, workshops or traineeships' [14]. The educational meeting will be organized as an interactive workshop, which targets knowledge, attitudes, and skills. The workshop will be conducted in a local meeting room in each intervention NH. Part one of the workshop includes the RNs/ASEs filling in a knowledge test (which is part of the data collection). However, by organizing it as a part of the workshop, the pedagogical intention is to facilitate learning, as it is possible to find the answers in the following theoretical input. Part two of the workshop is case-based discussion concerning the FI-guideline. As individualization of the nurse's diagnoses and the interventions is essential, an important pedagogical intention is to empower the RNs/ASEs' clinical and critical thinking. Another important issue is how to integrate the use of the guideline with the electronic patient record (EPR) system. The topics for the educational meeting, including the FI-guideline, will be made available for the staff as printed educational material [14].

A local opinion leader is defined by EPOC as 'use of providers nominated by their colleges as educationally influential' [14]. The opinion leader will be recruited after the educational meeting by the informant method [34] by asking the care manager who is considered to be a principle source of influence. One opinion leader per unit will be recruited. The opinion leader will, together with the care manager, participate in an additional 1.5 hour educational meeting regarding the role of the opinion leader and care manager for this study. They will also receive contact information for the researcher for support during the intervention period. The care manager has responsibility for facilitating adherence to the program and the guidelines in cooperation with the opinion leader.

Educational outreach is defined by EPOC as 'use of a trained person who meets with providers in their practice setting to give information with the intent of changing the providers' practice' [14]. The researcher will meet with the healthcare personnel in the practice setting six times for 1.5 hours each time during the 3-month intervention period. The opinion leader will make an agreement with the researcher on how to work and what to focus on between meetings. The NH care staff as a whole is the target group for the educational outreach and will be invited to participate in the educational meetings throughout the intervention period. Facilitating and empowering the staff's critical and clinical thinking is the main pedagogical approach. The pilot study identified a culture of discontinuity among staff in reporting important clinical observations and decisions in the EPR as an essential barrier to change. In addition, even if decisions were reported in the EPR, it was a problem that staff did not check the patients' EPR for changes in the patients' care procedures, which resulted in the patients not receiving the correct interventions for his/her condition. Thus, it will be important to facilitate NH unit-specific strategies to ensure continuity in FI care for the individual patient.

Control group

The control group will not receive any educational program and will continue with usual care. Data on ordinary practice will be gathered as part of the data collection procedure in this study (health information on patients, ordinary practice as documented in the EPR, care for patients' FI, diarrhea and constipation as documented in The Fecal Incontinence in Nursing Home Patient questionnaire [6]).

Eligibility criteria

Results from the pilot study confirmed that units in Norwegian NHs are comparable with the definition by Norton and colleagues [35]. NH units with similar care staff/patient ratios on the day shift and GP coverage will be selected. NH units designated with a specialty or with an enhanced care staff/patient ratio will be excluded. RNs and ASEs working half time or more are eligible for participation in the workshop and to be recruited as opinion leaders in the intervention group. RNs/ASEs working less than half time or only night shifts are excluded. All care staff members in the NH will be invited to the educational outreach meetings throughout the intervention period. All long-term care patients (1 month or more) are eligible for inclusion.

Recruitment

Approval will be obtained from the director for health and social affairs in the municipality. The first and last authors will participate in a meeting where all managers for the NHs in the municipality will be gathered. The project will be presented and NHs invited to participate. NHs accepting the invitation will be eligible for selection. NH units will be enrolled until the target patient sample size is reached.

Randomization and allocation

One unit will be defined as one cluster. Two clusters per NH will be recruited. Allocation stages are as follows:

1. NHs will be identified and recruited;
2. Units will be identified and recruited;
3. Patients will be identified;
4. Baseline data collection will take place for units and patients;
5. Allocation will be done by an independent statistician to intervention or control; and
6. RNs/ASEs will be identified and recruited to the intervention (Figure 1).

The clusters will be allocated to the intervention or control arm using minimization [23]. Minimization factors are a) all units from the same NH will be allocated to the same arm and b) cluster size, where NHs will be sequenced in pairs according to size and then randomized to either intervention or control. The randomization method is simple randomization and is computer generated and performed by an independent statistician (Figure 1).

Outcome measures

The primary outcome measure is frequency of FI among patients 6 months after start of the intervention, as measured by The interRAI Long-Term Care Facilities Assessment System (interRAI LTCF) [36], section H3: Bowel continence with the categories 0 to 5 (0 = continent, 1 = continent with stoma, 2 = seldom incontinent, 3 = occasionally incontinent, 4 = often incontinent, 5 = incontinent). The interRAI LTCF is an internationally validated questionnaire regarding long-term care patients' health conditions. In order to get some additional information about the severity of FI and urgency, a Norwegian version of the St. Mark's anal incontinence score [37] will be used. The St. Marks grading system is based on the type and frequency of anal incontinence (gas, fluid, or solid) and the impact on daily life, the need to wear a pad/diaper and/or anal plug, the use of constipating medication and the presence of urgency. It gives a total score from 0 (complete continence) to 24 (complete incontinence).

The study has the following secondary outcome measures:

1. *Remission of FI* among patients identified with FI at baseline, or *incidence* of new cases of FI among patients identified as continent at baseline, measured by interRAI LTCF section H3 and the St Marks score.
2. *Change in FI related concerns* measured by interRAI LTCF: section E: Mood and behavior, section F: Psycho-social wellbeing, section H1: Urinary continence, section J: State of health - Constipation and diarrhea, section L: Skin condition, and section M: Participation in activities.
3. *Change in knowledge* among RNs/ASEs measured by multiple choice tests developed by the researchers according to established guidelines [38].
4. *Change in documented care for FI by health personnel as registered in the EPR*: RNs/ASEs will extract data from the EPR. The instrument N-Catch [39] will be used for this purpose. N-Catch is an audit instrument for nursing reports in the EPR. N-Catch is translated into Norwegian and developed based on the validated D-Catch [40] and Cat-ch-ing [41]. Change in care will also be measured by the Fecal Incontinence in Nursing Home Patients questionnaire [6] where RNs/ASEs are offered a list of interventions for FI, urinary incontinence, diarrhea and constipation and asked to identify what is done for each individual patient.
5. *Change in cost* of FI management measured by mapping the use of products (diapers, pads, plugs) and bowel medications measured by interRAI LTCF section H: Continence - remedies, section N: Medications, and the Fecal Incontinence in Nursing Home Patients questionnaire.
6. *Correlates of FI* among NH patients measured by interRAI LTCF: section C: Cognitive functioning, section D: Communication and vision, section G: Functionality and mobility, section I: Medical diagnoses, section J: Health condition, section K: Mouth- and nutrition status, section N: Medications, and section O: Treatment, examinations/procedures.

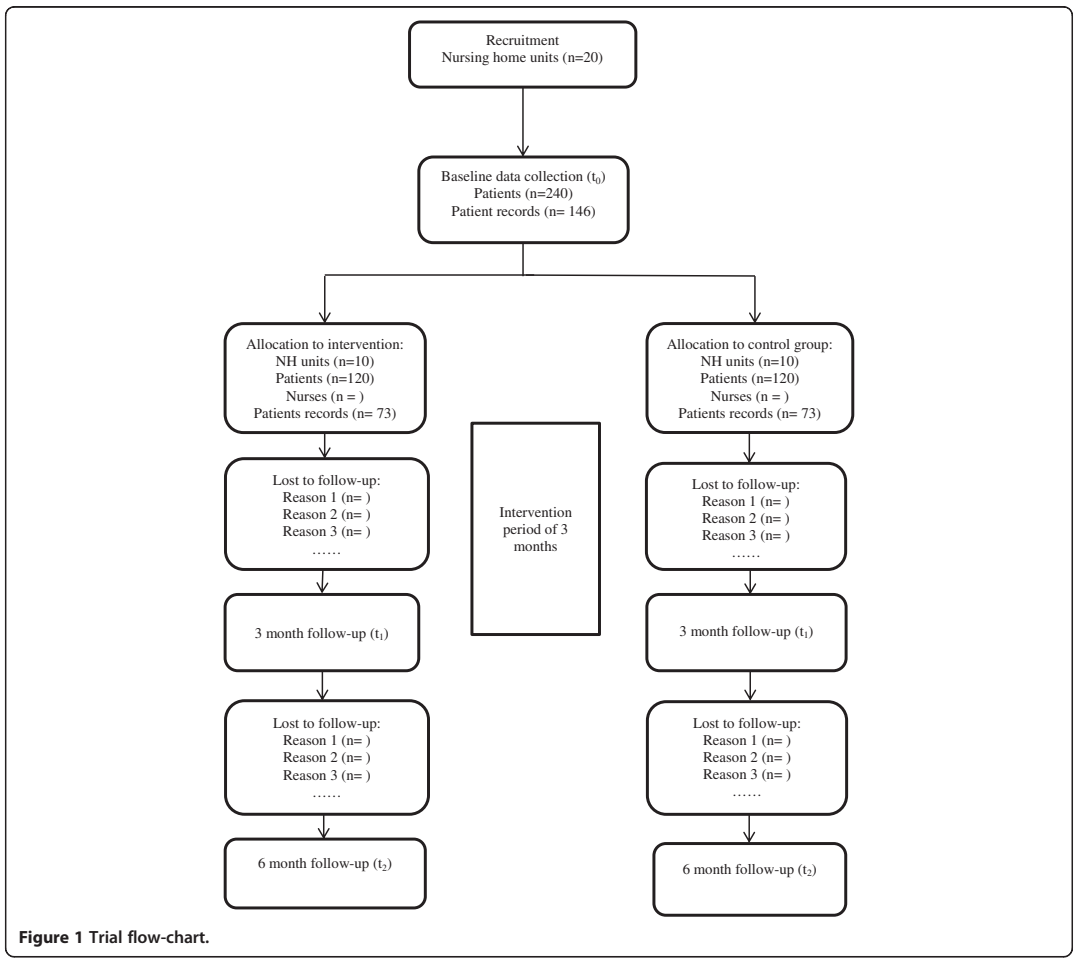


Figure 1 Trial flow-chart.

Process evaluation will include attendance at the pedagogical program and use of the FI-guideline. Evaluation will be conducted by using checklists administered by the researchers: proportion RNs/ASEs within eligibility criteria participating in the workshop, proportion of staff participating in the educational outreach meetings, proportion of patients assessed by the FI-guideline, and proportion of patient assessments resulting in an individualized care plan in the EPR.

Background variables

Organizational characteristics of the NHs and background information on patients' sex, medical status and length of stay in the NH will be obtained. Background variables for the RNs and ASEs are age, sex, educational level, years since registered/authorized and length of employment at the present site.

Sample size

Sample size calculations are based on the primary outcome: frequency of FI among patients. The power calculations have taken into account the results from the pilot study. The pilot study identified the primary outcome variable to be skewed to the right, and methodological consideration resulted in a dichotomization of the primary outcome variable with a cut off between 2 (continent, continent with a stoma and seldom incontinent) and 3 (occasionally incontinent, often incontinent and incontinent). Based on results from the pilot study, we hypothesized that a reasonable and clinically important effect size in the intervention group compared to the control group would be 15% between the two groups in proportions with FI (score of 3 to 5). As the design is a cluster randomized trial, we need to adjust for clustering. The intracluster correlation coefficient (ICC) is

estimated to be 0.04. The estimate is based on published patterns in ICCs [23,42-44], and results from the pilot study where the ICC was calculated to be 0.038. In addition, we had access to the FI variable with the categories 0 to 4 from an epidemiological study of 980 NH patients in Trondheim municipality [6] with an ICC calculated as 0.028. Based on the assumptions of the mixed logistic binominal model, 5% level of significance, test strength of 80%, an average cluster size of 15 patients, and an ICC of 0.04, a study population of 103 patients in each arm of the C-RCT is needed. The number of individuals in each cluster is set because each unit has a fixed number of beds. Assuming a 15% dropout, the sample needed is 120 patients in each arm. This means a total of 240 patients and about 20 NH units (Figure 1).

In addition, the number of patients records needed for data extractions, was calculated. N-Catch measures the quality of the content in the EPR on a scale from 0 to 32 where 0 is low quality and 32 is high quality [39-41]. Based on the assumption of a paired *t*-test, a 5% level of significance, test strength of 80%, an effect size of 3 points and an ICC of 0,04, records from 6 patients per cluster is needed for a total of 146 records (Figure 1).

Data collection methods

Data are collected at baseline (t_0), after 3 months (t_1 = end of intervention), and after 6 months (t_2=primary time of assessment). A research assistant will, together with the first author, give information and training on completion of the questionnaires and data extraction from EPR at baseline. RNs/ASEs will then be responsible for filling in the questionnaires about the patients' health condition (proxy) and extracting the data from the EPR. Organized alphabetically by last name on a list, the EPRs of the first six patients per cluster will be extracted. Time scheduled for the information meetings is 2 to 3 hours per NH. The ward manager will fill in a form on organizational characteristics. When completed, the first author and research assistant will collect the data forms. At both t_1 and t_2 the research assistant will deliver, give necessary additional information and collect the completed forms. NHs will be offered economic compensation for the data collection.

Blinding

Baseline measurements will be done before randomization. A research assistant who will be blinded to group allocation will inform, deliver and collect the questionnaires/data after 3 months (t_1) and 6 months (t_2).

Statistical analyses

Descriptive statistics will be used to present the population and the characteristics of the three groups (units, RNs/ASEs, and patients). As this is a C-RCT, the model of analysis needs to consider the effect of clustering. Analyses must also allow for inclusion of covariates at both the individual and cluster level. Relevant covariates at the individual level in a multiple logistic regression model are age, sex, length of stay in NH, cognitive performance, mobility, functionality, diarrhea, constipation. Hence, this study will use mixed effect models with the cluster treated as a random effect. Analyses will be computed using Stata 12.1.

Primary outcome

As a consequence of the dichotomization of the variable, the primary outcome will be analyzed according to a mixed logistic binominal model. The model will be fitted by maximum likelihood. Because of the relatively high risk of deaths and movement out of clusters, data will be treated as a cross-sectional time series, with the prevalence among all patients present in the cluster at baseline included as a covariate in the analyses.

Secondary outcomes

For remission of FI a cohort approach to data analyses with repeated measures with only those identified with FI at baseline and still present at 3 and 6 month follow-up will be included and analyzed according to a mixed logistic binominal model. For incidence of FI a cohort approach to data analyses with repeated measures with only those identified as continent at baseline and still present at 3 and 6 month follow-up will be included and analyzed according to mixed logistic binominal model. For change in FI-related concerns, change in knowledge among RNs/ASEs, change in care, and change in cost the outcomes, dependent on whether they are continuous, ordered or binary, will be treated as cross-sectional time-series and analyzed according to mixed effects models. Correlates of FI will, dependent on whether they are continuous, ordered or binary, be analyzed according to mixed effect models.

Ethics

The study was approved by the Regional Committee for Medical and Health Research Ethics (REK) (2013/1802/REK North) and by The Norwegian Social Science Data Services (36482/2/MB). NH leaders will be informed and give permission to perform the study in the individual NH. Informed consent will be obtained from RNs/ASEs concerning the knowledge test. An essential ethical consideration in this study is whether or not informed consent should be obtained from patients or their representatives. After evaluating the overall project, the REK authorized RNs/ASEs with dispensations from the duty of confidentiality to gather relevant patient health information in order to measure effect of the educational intervention. Since dispensation was given, consent will

not be obtained. The justifications of the conclusion are 1) the process of assessing the patients' cognitive ability to read and understand information, and the distribution of the information letter to the patients or their representatives, is considered as inconvenient for the patients and time consuming for care staff who would need to undertake this; 2) the gathering of patient data will not involve interviewing or examining patients, and the data in question is based on assessments made by RNs/ASEs who have good knowledge of the patients; and 3) the purpose of the study is to evaluate effect of an educational program for care staff. Patients are not the ones recruited to participate in the intervention. All patient information will be de-identified by care staff before transfer to the researcher. The codebook will be stored separate from the patient data according to storing routines by the responsible research institution, Sør-Trøndelag University College. The study will be performed in concordance with the Helsinki Declaration. The project is registered in the clinical trial registry (NCT02183740).

Discussion

The aim of this study is to achieve reduction in bowel leakage and accidents for NH patients. The primary objective is to test the hypothesis that a multifaceted educational program for NH care staff on assessment and treatment of FI, reduces patients' frequency of FI.

Major strengths of this study include thorough investigation of both what is considered best practice for assessment, care and treatment of FI among NH patients and what are considered to be the most effective implementation strategies. The study has a rigorous design with randomization, control and blinding where possible. The intervention is classified as a complex intervention, and the study has been designed according to published recommendations [20,21], where a thorough planning phase included an evaluation of the fit of the different components with a pilot study. In addition, a strength is that we will collect comprehensive information at three levels: NH units, RNs/ASEs and patients. It is of special interest that the educational intervention integrates the FI-guideline of best practice into the EPR as a mean to communicate the assessment and care plan to the staff as a whole. Because of this, we will have the opportunity to evaluate change of practice by investigating the EPR together with the use of the FI-guideline and patient's health information.

A weakness of the study is the complexity of the intervention with limited possibility to evaluate which of the components in the educational intervention is effective. The more complex the intervention, the harder it is to measure effect [14,20]. With an educational intervention, we also have the problem with the pedagogical ideal versus ideals for an RCT. An important pedagogic ideal is to individualize and adjust pedagogical methods according to the needs of the actual person/group in front of you [15,29-31]. On the other hand, an important ideal of an RCT is that the intervention is as similar as possible for all the participants [45]. In this study, we have agreed that some components will be the same, and some are allowed to vary. For instance, the format of the workshop will be the same, (total hours and themes to be covered), while empowerment strategies, guidance and timeframes for individual themes during the day may vary. During educational outreach, all participants will receive the same number of visits within the same time frame and main themes to be covered, whereas the when and how will vary.

As it is the RNs/ASEs who will fill in the questionnaires on the patients' health status, there is a risk for proxy bias. To counter for that, both the interRAI manual and the information meetings focus on how to include the patient when possible. However, since about 80% of the NH patients have some kind of cognitive impairment [46], the RNs/ASEs' clinical judgment of the patients' health status will be the main source of information. The RNs/ASEs involved in the data collection will also be part of the intervention, which means that they will not be blinded to care interventions. The RNs/ASEs will be informed about the importance of objectivity of observations and assessments at all data collection time points. There is also a risk for detection bias as those who have received education might recognize FI more frequently than before intervention.

This study is the first RCT specifically focusing on this neglected area. The results of the study will give evidence for best practice for FI care in NHs, and organizational advice concerning implementation strategies.

Trial status

Enrollment for the trial began in April 2014. Recruitment is still in progress. Data collection will continue until approximately June 2015.

Abbreviations

ASE: Authorized social educator; C-RCT: Cluster-randomized controlled trial; EPOC: Cochrane effective practice and organization of care; EPR: Electronic patient record; FI: Fecal incontinence; GP: General practitioner; ICC: Intra-cluster correlation coefficient; interRAI LTCF: The interRAI Long-Term Care Facilities Assessment System; NH: Nursing home; RN: Registered nurse.

Competing interests

The authors declare they have no competing interests.

Authors' contributions

AGV is the principal investigator; LEB, AGV, and SN are responsible for the conception and design of the study; LEB and SN are responsible for recruitment and data management; LEB is responsible for the acquisition of data; LEB, AGV, KHG, SM, ØS, CN, and SN are responsible for the analyses; LEB, AGV, KHG, SM, ØS, CN, and SN are responsible for critically revising the articles for important intellectual content; and OS is the trial statistician. All authors read and approved the final manuscript.

Authors' information
LEB, registered nurse, PhD student; AGV, Registered nurse, professor; KHG, registered nurse, associate professor; SM, physiotherapist, professor; ØS, statistician, associate professor, CN, registered nurse, professor.

Acknowledgements
The Norwegian Nurses Organization has contributed to the funding of this study.

Author details
[1]Faculty of Nursing, Sør-Trøndelag University College (HiST), Postbox 2320, 7004 Trondheim, Norway. [2]Department of Cardiothoracic Surgery, Department of Cardiology and National Competence Centre for Complex Symptom Disorders, St. Olavs Hospital, Trondheim University Hospital, Postbox 3250, 7006 Trondheim, Norway. [3]Department of Circulation and Medical Imaging, Norwegian University of Science and Technology (NTNU), 7491 Trondheim, Norway. [4]Department of Public Health and General Practice, Norwegian University of Science and Technology (NTNU), 7491 Trondheim, Norway. [5]Department of Cancer Research and molecular Medicine, Norwegian University of Science and Technology (NTNU), 7491 Trondheim, Norway. [6]Faculty of Nursing and Midwifery, King' College London, 57 Waterloo Road, London SE1 8WA, UK. [7]Clinical Service, St Olavs Hospital, Trondheim University Hospital, Postbox 3250, 7006 Trondheim, Norway.

Received: 19 September 2014 Accepted: 9 February 2015
Published online: 01 March 2015

References

1. Norton C, Whitehead W, Bliss DZ, Harari D, Lang J. Conservative and Pharmacological Management of Faecal Incontinence in Adults. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence 4th Edition 2009. http://www.icud.info/PDFs/Incontinence.pdf. Accessed 17 Nov 2010.
2. Shah BJ, Chokhavatia S, Rose S. Fecal incontinence in the elderly: FAQ. Am J Gastroenterol. 2012;107:1635–46.
3. Aslan E, Beji NK, Erkan HA, Yalcin O, Gungor F. The prevalence of and the related factors for urinary and fecal incontinence among older residing in nursing homes. J Clin Nurs. 2009;18:3290–8.
4. Schnelle JF, Kapur K, Alessi C, Osterweil D, Beck JG, Al-Samarrai NR, et al. Does an exercise and incontinence intervention save healthcare costs in a nursing home population? J Am Geriatr Soc. 2003;51:161–8.
5. Blekken LE, Saga S, Seim A. Faecal incontinence among elderly patients in nursing homes: A systematic review of prevalence and risk factors (abstract). In: 41st Annual Scientific Meeting of the International Continence Society Glasgow. 2015. http://www.ics.org/2011/programme/abstract/405. Accessed 18 Feb.
6. Saga S, Vinsnes AG, Mørkved S, Norton C, Seim A. Prevalence and correlates of fecal incontinence among nursing home residents: a population-based cross-sectional study. BMC Geriatr. 2013;13:87.
7. O'Connell B, Ostaszkiewicz J, Day K. The challenge of managing continence care in residential aged care settings: recommendations for research and practice. Geriaction. 2005;23:5–18.
8. Kenefick N. The epidemiology of Faecal Incontinence. In: Norton C, Chelvanayagam S, editors. Bowel continence nursing. Beaconfield: Beaconfield Publisher Ltd; 2004. p. 14–22.
9. Taylor DW, Cahill JJ, Rizk DEE. Denial, shame and acceptance: generating base-line knowledge and understanding of fecal incontinence amongst long-term care residents and care providers. Publ Health Res. 2014;4:13–8.
10. Harari D. Bowel care in old age. In: Norton C, Chelvanayagam S, editors. Bowel continence nursing. Beaconfield: Beaconfield Publisher Ltd; 2004. p. 132–49.
11. Mangnall J, Taylor P, Thomas S, Watterson L. Continence problems in care homes: auditing assessment and treatment. Nurs Older People. 2006;18:20–2.
12. Thekkinkattil DK, Lim M, Finan PJ, Sagar PM, Burke D. Awareness of investigations and treatment of faecal incontinence among the general practitioners: a postal questionnaire survey. Colorectal Dis J Assoc Coloproctol. 2008;10:263–7.
13. National Institute for Health and Clinical Exellence (NHS). Faecal incontinence: the management of faecal incontinence in adults. Nice Clin Guidel 49 2007. https://www.nice.org.uk/guidance/cg49/resources/guidance-faecal-incontinence-pdf . Accessed 18 Feb 2015.
14. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. Implement Sci. 2012;7:3–17.
15. Mezirow & Associates. Learning as transformation. San Fransisco: Jossey Bass; 2000.
16. Argyris C. Organisatorisk læring - singel - og double loop. In: Illeris K, editor. Tekster om læring. Fredriksberg: Roskilde Universitets Forlag; 2000.
17. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet. 2003;362:1225–30.
18. Boström A-M, Slaughter SE, Dagmara C, Estabrooks C. What do we know about knowledge translation in the care of older adults? A scoping review. J Am Med Dir Assoc. 2012;13:210–9.
19. Titler M. The evidence for evidence-based practice implementation. In: Hughes RG, editor. Patient safety and Quality: An evidence-Baced Handbook for Nurses. Rockville: AHRQ Publications; 2008.
20. Craig P, Petticrew M. Developing and evaluating complex interventions: reflections on the 2008 MRC guidance. Int J Nurs Stud. 2013;50:585–7.
21. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;50:587–92.
22. Lancaster GA, Campbell MJ, Eldridge S, Farrin A, Marchant M, Muller S. Trials in primary care: statistical issues in the design, conduct and evaluation of complex interventions. Stat Methods Med Res. 2010;19:349–77.
23. Eldridge S, Kerry SM. A practical guide to cluster randomised trials in health services research. Chichester, West Sussex: John Wiley & Sons; 2012.
24. Ringard Å, Sagan A, Saunes IS, Lindahl AK. Norway: Health system review. Health Sys Transitio. 2013;15:1–162.
25. The Norwegian Registration Authority for Health Personnel (SAK) http://www.nokut.no/Documents/INVIA/Infoark/Vernepleier_EN_23.pdf. Accessed 5 May 2014.
26. Rogers EM. Diffusion of innovations. New York: Free Press; 2003.
27. Eccles M, Grimshaw J, Walker A, Johnston M, Pitts N. Changing the behavior of healthcare professionals: the use of theory in promoting the uptake of research findings. J Clin Epidemiol. 2005;58:107–12.
28. Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L. Effectiveness and efficiency of guideline dissemination and implementation strategies. Health Technol Assess. 2004;8:1–72.
29. Mezirow J. Transformative learning as discourse. J Transform Educ 2003; doi:10. 1177/1541344603252172.
30. Kvalsund R. Organisering av kompetanseutvikling i arbeidslivet. In: Aarsand LHE, Tønseth C, Tøsse S, editors. Voksne, læring og kompetanse. Oslo: Gyldendal Akademiske; 2011.
31. Tøsse S. Historie, praksis, teori og politikk: om kunnskapsgrunnlaget for voksnes læring. Trondheim: Tapir Akademisk Forlag; 2011.
32. Bulechec G. Nursing Interventions classification (NIC). St Louis: Mosby Elsevier; 2013.
33. Herdman T. Nursing Diagnoses. Definition and Classification (2012–2014) North America Nursing Diagnosis Associations (NANDA). Chichester: Wiley-Blackwell/NANDA International; 2012.
34. Flodgren G, Parmelli E, Doumit G, Gattellari M, O'Brien MA, Grimshaw J, et al. Local opinion leaders: effects on professional practice and health care outcomes. Cochrane Database Syst Rev, 2011; doi:10. 1002/14651858. CD000125.pub4.
35. Norton PG, Murray M, Doupe MB, Cummings GG, Poss JW, Squires JE, et al. Facility versus unit level reporting of quality indicators in nursing homes when performance monitoring is the goal. BMJ Open 2014; doi:10. 1136/bmjopen-2013-004488.
36. Morris JN, Belleville-Taylor P, Fries BE, Hawes C, Murphy K, Mor V, et al. InterRAI Long-Term Care Facilities (LTCF) Assessment Form and User's Manual. Version 9.1 norwegian version. Washington, DC: interRAI; 2012.
37. University Hospital of North Norway. Norwegian registry forAnal Incontinence. St Marks skår. http://www.unn.no/getfile.php/UNN%20INTER/Enhet/Inkontinenssenter_web/Dokumenter/Anal%20inkontinens%201B_200214.pdf. Accessed 12 April 2013.
38. Sirnes SM. Flervalgsoppgaver - konstruksjon og analyse. Bergen: Fagbokforlaget; 2005.
39. Nøst TH, Tettum BI, Frigstad SA, Woldstad K, Haugan B, Oppheim AE, et al. N-Catch II – et granskningsinstrument for vurdering av sykepleiedokumentasjon. Sykepleien (In press).
40. Paans W, Sermeus W, Nieweg RMB. D-Catch instrument: development and psychometric testing of a measurement instrument for nursing documentation in hospitals. J Adv Nurs. 2010;66:1388–400.

41. Björvell C, Wredling R, Thorell-Ekstrand I. Long-term increase in quality of nursing documentation: effects of a comprehensive intervention. Scand J Caring Sci. 2002;16:34–42.
42. Eldridge SM, Ashby D, Feder GS, Rudnicka AR, Ukoumunne OC. Lessons for cluster randomized trials in the twenty-first century: a systematic review of trials in primary care. Clin Trials. 2004;1:80–90.
43. Health Services Research Unit in Aberdeen. http://www.abdn.ac.uk/hsru/research/research-tools/study-design/. Accessed 14 April 2013.
44. Smeeth L, Ng ES. Intraclass correlation coefficients for cluster randomized trials in primary care: data from the MRC Trial of the Assessment and Management of Older People in the Community. Control Clin Trials. 2002;23:409–21.
45. Fayers PM, Machin D. Randomized clinical trials: design, practice and reporting. Chichester: Wiley-Blackwell; 2010.
46. Nylenna M. Helsetjenesten i Norge: et overblikk. Oslo: Gyldendal Akademisk; 2014.

APPENDICES

(Løpenummer)

Kartlegging av helsetilstand blant pasienter på sykehjem

Gjelder pasienter med vedtak om langtidsopphold og som har bodd på institusjonen i minst 4 uker.

Bruk svart eller blå penn når du fyller ut

Dato for utfylling av skjema (dg.mnd.år):

☐☐.☐☐.☐☐☐☐

Pasientens innleggelsesdato v/sykehjemmet/helsehuset (dg.mnd.år):

☐☐.☐☐.☐☐☐☐

Pasientens fødselsår:

☐☐☐☐

Pasientens kjønn:

☐ Kvinne
☐ Mann

KODES FOR DE 3 SISTE DAGENE, MED MINDRE NOE ANNET ER SPESIFISERT

AVSNITT C. Kognitiv funksjon

1. KOGNITIV EVNE TIL Å TA BESLUTNINGER I DAGLIGLIVET ☐
Ta beslutninger om gjøremål i dagliglivet – f.eks. tidspunktet for å stå opp eller spise, hvilke klær å ta på seg eller aktiviteter

0 **Uavhengig** – Beslutninger er konsekvente, fornuftige og trygge
1 **Begrenset uavhengighet** – Visse vanskeligheter bare i nye situasjoner
2 **Minimalt svekket** – I spesielle, gjentatte situasjoner blir beslutningene uhensiktsmessige eller utrygge, og i disse tilfellene er det nødvendig med stikkord/veiledning
3 **Moderat svekket** – Beslutningene er gjennomgående uhensiktsmessige eller utrygge og stikkord/veiledning er nødvendig hele tiden
4 **Alvorlig svekket** – Tar aldri/sjelden beslutninger
5 **Ingen merkbar bevissthet, koma [Gå til avsnitt G]**

2. HUKOMMELSE/HUKOMMELSESEVNE
Kodes for minne om hva som er lært eller kjent

0 Ja, hukommelsen OK 1 Hukommelsesproblemer

a. **Korttidsminne OK** – Husker tilsynelatende etter 5 minutter ☐
b. **Langtidsminne OK** – Husker tilsynelatende fjern fortid ☐
c. **Prosedyrehukommelse OK** – Kan utføre alle eller nesten alle trinn i en flertrinnsoppgave uten veiledning ☐
d. **Situasjonshukommelse OK** – Både: Gjenkjenner navn/ansikter til omsorgspersoner som ofte er i kontakt OG vet hvor steder som ofte brukes er (soverom, spisestue, aktivitetsrom, behandlingsrom) ☐

3. PERIODER MED FORVIRRET TENKNING ELLER OPPMERKSOMHET
[Merk: Nøyaktig vurdering krever samtale med personalet, familien eller andre som har direkte kjennskap til vedkommendes oppførsel i dette tidsrommet]

0 Atferden ikke tilstede
1 Atferden tilstede, i overensstemmelse med vanlige fungering
2 Atferden tilstede, ser ut som den er forskjellig fra vanlige fungering (f.eks. ny eller forverret, annerledes enn for noen uker siden)

a. **Lett distrahert** – f.eks. perioder med konsentrasjonsproblemer; blir avsporet ☐
b. **Episoder med usammenhengende tale** – f.eks. meningsløs, irrelevant tale eller hopper fra emne til emne, mister tråden ☐
c. **Mental funksjon varierer i løpet av dagen** – f.eks. noen ganger bedre, noen ganger verre ☐

4. AKUTT ENDRING I MENTAL STATUS FRA PERSONENS NORMALE FUNGERING – *f.eks. rastløshet, døsighet, vanskelig å vekke, endret oppfatning av omgivelsene* ☐

0 Nei 1 Ja

5. ENDRING I EVNE TIL Å TA AVGJØRELSER SAMMENLIKNET MED FOR 90 DAGER SIDEN (ELLER SIDEN SISTE VURDERING) ☐

0 Forbedret 2 Svekket
1 Ingen endring 8 Usikkert

AVSNITT D. Kommunikasjon og syn

1. Å GJØRE SEG FORSTÅTT (Uttrykke seg) ☐
Uttrykker informasjonsinnhold - både verbalt og ikke-verbalt

0 **Alltid forstått** – Uttrykker idéer uten vanskeligheter
1 **Gjør seg vanligvis forstått** – Vanskeligheter med å finne ord eller fullføre tanker, MEN hvis vedkommende får tid på seg, trengs liten eller ingen hjelp
2 **Ofte** – Vanskelighter med å finne ord eller avslutte tanker OG trenger vanligvis hjelp.
3 **Av og til** – Begrenset evne til å uttrykke konkrete ønsker
4 **Sjelden eller aldri**

2. EVNE TIL Å FORSTÅ ANDRE (Forståelse) ☐
Forstår verbal informasjon (Evne uansett; med hørselshjelpemiddel som vanligvis brukes)

0 **Forstår** – Klar forståelse
1 **Forstår vanligvis** – Går glipp av visse deler/meningen av budskapet, MEN forstår det meste av samtalen
2 **Forstår ofte** – Går glipp av visse deler/meningen i meldingen, MEN forstår ofte samtalen ved gjentakelse eller forklaring
3 **Forstår av og til** – Reagerer bare på enkel, direkte kommunikasjon
4 **Forstår sjelden eller aldri**

3. HØRSEL
a. Evne til å høre (med hørselshjelpemiddel som vanligvis brukes) ☐

0 **Adekvat** – Ingen vanskeligheter med vanlig samtale, sosialt samkvem, høre på TV
1 **Minimale vanskeligheter** – Vanskeligheter i noen omgivelser (f.eks. en person som snakker lavt eller som er mer enn 2 meter unna)
2 **Moderate vanskeligheter** – Problemer med å føre normale samtaler, trenger stille omgivelser for å høre godt
3 **Alvorlige vanskeligheter** – Vanskeligheter i alle situasjoner (f.eks. den som snakker må snakke høyt eller svært langsomt, eller vedkommende sier at all tale er mumling)
4 **Ingen hørsel**

b. Bruker hørselshjelpemiddel ☐

0 Nei 1 Ja

4. SYN
a. Evne til å se i tilstrekkelige lysforhold (med briller eller med andre synshjelpemidler som vanligvis brukes) ☐

0 **Adekvat** – Ser små detaljer, inkludert vanlig trykk i aviser/bøker
1 **Minimale vanskeligheter** – Leser stor trykt tekst, men ikke vanlig trykt tekst i aviser/bøker
2 **Moderate vanskeligheter** – Begrenset syn, kan ikke lese avisoverskrifter, men kan gjenkjenne gjenstander
3 **Alvorlige vanskeligheter** – Identifisering av gjenstander er tvilsom, men det ser ut som om øynene følger gjenstander, ser bare lys, farger, former
4 **Ikke syn**

b. Bruker synshjelpemidler ☐

0 Nei 1 Ja

AVSNITT E. Sinnstilstand og atferd

1. TEGN PÅ MULIG DEPRESJON, ANGST ELLER NEDSTEMTHET
Kodes for tegn observert i løpet av de siste 3 dagene, uansett antatt årsak [Merk: Når det er mulig, spør vedkommende.]

0 Ikke tilstede
1 Tilstede, men ikke sett i løpet av de siste 3 dagene
2 Tilstede i 1–2 av de siste 3 dagene
3 Sett daglig i løpet av de siste 3 dagene

a. **Kom med negative uttalelser** – f.eks. *"Ingenting betyr noe", "Ville heller vært død", "Hva er vitsen", "Angrer på at jeg har levd så lenge", "La meg få dø".* ☐
b. **Konstant sint på seg selv eller andre** – blir f.eks. lett irritert, sint over mottatt hjelp ☐
c. **Utrykker, også ikke-verbalt, hva som ser ut som ubegrunnet frykt** – f.eks. frykt for å bli sviktet, overlatt til seg selv, være sammen med andre, intens frykt for spesielle ting eller situasjoner ☐
d. **Gjentatte klager over helsen** – søker f.eks. stadig legehjelp, stadig bekymring om kroppsfunksjoner ☐
e. **Gjentatte klager/bekymringer (ikke helserelaterte)** – søker f.eks. konstant oppmerksomhet/bekreftelse i forhold til avtaler, måltider, klesvask, klær, forhold ☐
f. **Trist, har det vondt, urolige ansiktsuttrykk** – f.eks. rynkede bryn, stadig rynket panne ☐
g. **Gråt, tar lett til tårer** ☐
h. **Tilbakevendende utsagn om at noe forferdelig kommer til å skje** – tror f.eks. at han eller hun kommer til å dø, få et hjerteinfarkt ☐
i. **Trekker seg fra aktiviteter av interesse** – f.eks. mangeårige aktiviteter, samvær med familie/venner ☐
j. **Redusert sosialt samvær** ☐
k. **Uttrykk, også ikke-verbalt, for mangel på livsglede (anhedoni)** – f.eks. *"Jeg har ikke glede av noe lenger"* ☐

2. SELVRAPPORTERT SINNSTILSTAND

0 Ikke i løpet av de siste 3 dagene
1 Ikke i løpet av de siste 3 dagene, men kjenner seg ofte slik
2 Sett i 1–2 av de siste 3 dagene
3 Daglig i løpet av de siste 3 dagene
8 Kunne ikke (ville ikke) svare

Spør: "I løpet av de siste 3 dagene, hvor ofte har du kjent . . "
a. *Liten interesse eller glede av ting du vanligvis gleder deg over?* ☐
b. *Engstelig, urolig eller usikker?* ☐
c. *Trist, deprimert eller håpløs?* ☐

ISBN: 978-1-622550-00-5

3. ATFERDSSYMPTOMER
Kodes for observerte tegn, uansett antatt grunn

0 Ikke tilstede
1 Tilstede, men ikke sett i løpet av de siste 3 dagene
2 Sett i 1–2 av de siste 3 dagene
3 Sett daglig i løpet av de siste 3 dagene

a. **Vandrende** – Går omkring uten mål og mening, tilsynelatende uten tanke på behov eller sikkerhet ☐
b. **Verbalt aggressiv** – andre blir f.eks. truet, skreket til, skjelt ut ☐
c. **Fysisk aggressiv** – andre ble f.eks. slått, dyttet, klort, seksuelt mishandlet ☐
d. **Sosialt upassende eller forstyrrende atferd** – laget f.eks. forstyrrende lyder eller støy, skrek, griset med eller kastet mat eller ekskrementer, hamstret, rotet i andres eiendeler ☐
e. **Seksuelt upassende atferd eller kler av seg offentlig** ☐
f. **Motsetter seg pleie** – motsetter seg f.eks å ta medisiner/injeksjoner, ADL-assistanse, spising ☐

AVSNITT F. Psykososialt velvære

1. SOSIALE RELASJONER
[Merk: Spør vedkommende, pleiepersonalet og familien, hvis tilgjengelig.]

0 Aldri
1 For mer enn 30 dager siden
2 8–30 dager siden
3 4–7 dager siden
4 I de siste 3 dagene
8 Kan ikke fastslå

a. Deltakelse i en sosial aktivitet vedkommende lenge hadde vært interessert i ☐
b. Besøk av en gammel venn eller familiemedlem ☐
c. Annen kontakt med en gammel venn eller familiemedlem – f.eks. telefon eller e-post ☐

2. FØLELSE AV ENGASJEMENT

0 Ikke tilstede
1 Tilstede, men ikke sett i løpet av de siste 3 dagene
2 Tilstede i 1–2 av de siste 3 dagene
3 Sett daglig i løpet av de siste 3 dagene

a. Fungerer bra sammen med andre ☐
b. Fungerer bra med planlagte eller strukturerte aktiviteter ☐
c. Aksepterer invitasjoner til de fleste gruppeaktiviteter ☐
d. Deltar i livet på institusjonen – f.eks. får eller beholder venner, er engasjert i gruppeaktiviteter, reagerer positivt på nye aktiviteter, assisterer ved gudstjenester/møter ☐
e. Tar initiativ til kontakt med andre ☐
f. Reagerer positivt på kontakt fra andre ☐
g. Tilpasser seg lett endringer i rutine ☐

3. RELASJONSPROBLEMER
0 Nei 1 Ja

a. Konflikt med eller gjentatt kritikk av andre pasienter/beboere ☐
b. Konflikt med eller gjentatt kritikk av personalet ☐
c. Personalet rapporterer vedvarende frustrasjon i forhold til vedkommende ☐
d. Familie eller nære venner rapporterer at de føler seg overveldet av vedkommendes sykdom ☐
e. Sier eller indikerer at han/hun føler seg ensom ☐

4. VIKTIGE LIVSBELASTNINGER I LØPET AV DE SISTE 90 DAGER – ☐
f.eks. periode med alvorlig, personlig sykdom, dødsfall eller alvorlig sykdom i nær familie/venn, tap av hjem, stort tap av inntekt/aktiva, utsatt for kriminalitet som for eksempel tyveri eller overfall, tap av kjørekort/bil

0 Nei 1 Ja

5. STERKE SIDER
0 Nei 1 Ja

a. Konsistent positivt syn på livet ☐
b. Finner mening i dagliglivet ☐
c. Sterkt og støttende forhold til familien ☐

AVSNITT G. Funksjonsstatus

1. EGEN ADL-UTFØRING
*Ta i betraktning **alle** episoder over en 3-dagers periode.*
Hvis alle episoder blir utført på det samme nivå, scores ADL på det nivået.
Hvis noen episoder er på nivå 6, og andre er mindre avhengige, scores ADL som en 5.
Fokuser ellers på de tre mest avhengige episodene [eller alle episoder hvis de ble utført færre enn 3 ganger]. Hvis den mest avhengige episoden er 1, scores ADL som 1. Hvis ikke, scores ADL som minst avhengig av disse episodene i området 2–5.

0 **Uavhengig** – Ingen fysisk hjelp, oppsett eller tilsyn i noen episode
1 **Uavhengig, kun hjelp til tilrettelegging** – Hente ting eller utstyr eller sette det innen rekkevidde, ingen fysisk hjelp eller tilsyn i noen episode
2 **Tilsyn** – Tilsyn/instruksjon
3 **Begrenset hjelp** – Veiledet styring av armer/ben, fysisk veiledning uten vektbelastning
4 **Omfattende hjelp** – Vektbærende støtte (inkludert å løfte armer/ben) av 1 hjelper der vedkommende fremdeles utfører 50 % eller mer av oppgaver
5 **Maksimal grad av hjelp** – Vektbærende støtte (inkludert å løfte armer/ben) av 2+ hjelpere – ELLER – vektbærende støtte for mer enn 50 % av oppgavene
6 **Fullstendig avhengig** – Trenger all hjelp av andre i løpet av alle episoder
8 **Aktiviteten forekom ikke i løpet av hele perioden**

a. **Bading** – Hvordan beboeren bader/dusjer. Inkluderer flytting inn og ut av badekar eller dusj OG hvordan hver kroppsdel blir vasket: Armer, øverst og nederest på bena, brystet, magen, nedentil – BORTSETT FRA VASKING AV RYGG OG HÅR ☐
b. **Personlig hygiene** – Hvordan beboeren klarer sin personlige hygiene, inkludert å gre håret, pusse tenner, barbere seg, ta på seg makeup, vaske og tørke andikt og hender – BORTSETT FRA BAD OG DUSJ ☐
c. **Påkledning på overkroppen** – Hvordan vedkommende kler av/på seg, (yttertøy, undertøy) over midjen, inkludert proteser, ortodontiske festeanordninger, gensere, osv. ☐
d. **Påkledning på underkroppen** – Hvordan vedkommende kler av/på seg, (yttertøy, undertøy) fra midjen og ned, inkludert proteser, ortodontiske festeanordninger, belter, bukser, skjørt, sko, festeanordninger, osv. ☐
e. **Gåing** – Hvordan vedkommende går mellom steder i samme etasje innendørs ☐
f. **Bevegelse** – Hvordan vedkommende beveger seg mellom steder i samme etasje (går eller kjører rullestol). Hvis i rullestol, selvhjulpen i rullestolen ☐
g. **Forflytning til/fra toalett** – Hvordan vedkommende beveger seg av og på toalettet eller toalettstolen ☐
h. **Toalettbruk** – Hvordan pasienten bruker toalettet (eller toalettstol, bekken, urinal), tørker seg selv etter bruk av toalettet eller inkontinensepisode(r), skifter bind, håndterer stomi eller kateter retter på klærne – BORTSETT FRA FORFLYTNING TIL OG FRA TOALETTET ☐
i. **Mobilitet i seng** – Hvordan vedkommende beveger seg til og fra liggende stilling, flytter seg fra side til side og skifter kroppsstilling i sengen ☐
j. **Spising** – Hvordan vedkommende spiser og drikker (uavhengig av evne), Inkludert inntak av næring med andre midler (f.eks. sondemating, fullstendig parenteral ernæring) ☐

2. BEVEGELSE/GÅING

a. **Primær bevegelsesmåte** ☐
0 Gåing, ingen hjelpemidler
1 Gåing, bruker hjelpemidler – f.eks. stokk, rullator, krykke, manuell rullestol
2 Rullestol, motorisert rullestol
3 Sengeliggende

b. **4-meters gange på målt tid** ☐☐
*Legg ut en rett, uhindret bane. Få vedkommende til å stå stille med føttene like ved startlinjen. **Si deretter: "Når jeg ber deg om det, begynn å gå med normal fart (med stokk/rullator hvis det brukes). Dette er ikke en test om hvor fort du kan gå. Stopp når jeg ber deg om det. Er dette klart?"** Den som skal vurdere kan demonstrere testen. **Si deretter: "Begynn å gå nå."** Start stoppeklokken (eller tell sekunder) når den første foten kommer ned. Slutt telling når foten passerer 4-metersmerket. **Si deretter: "Du kan stoppe nå."***

Legg inn tid i sekunder, opptil 30 sekunder
30 30 eller flere sekunder til å gå 4 meter
77 Stoppet før testen var fullført
88 Nektet å utføre testen
99 Ikke testet – f.eks. går ikke av seg selv

ISBN: 978-1-622550-00-5

c. **Avstand gått** – Den lengste avstand vedkommende har gått på én gang uten å sette seg ned i løpet av de SISTE 3 DAGENE (med støtte etter behov)
- 0 Gikk ikke
- 1 Mindre enn 5 meter
- 2 5–49 meter
- 3 50–99 meter
- 4 100 meter eller mer
- 5 1 km eller mer

d. **Distanse vedkommende kjørte selv i rullestol** – Lengste distanse vedkommende kjørte selv i rullestol på én gang i løpet av de SISTE 3 DAGENE (inkludert uavhengig bruk av motorisert rullestol)
- 0 Kjørt i rullestol av andre
- 1 Brukte motorisert rullestol/scooter
- 2 Kjørte selv i rullestol mindre enn 5 meter
- 3 Kjørte selv i rullestol 5–49 meter
- 4 Kjørte selv i rullestol 50–99 meter
- 5 Kjørte selv i rullestol 100 meter eller mer
- 8 Brukte ikke rullestol

3. AKTIVITETSNIVÅ

a. **Totalt antall timer med trening eller fysisk aktivitet i løpet av de SISTE 3 DAGERNE** – f.eks. gåing
- 0 Ingen
- 1 Mindre enn 1 time
- 2 1–2 timer
- 3 3–4 timer
- 4 Mer enn 4 timer

b. **Antall dager i løpet av de SISTE 3 DAGENE da vedkommende gikk ut av huset eller bygningen hvor han/hun bor** (uansett hvor kort periode)
- 0 Ingen dager ute
- 1 Gikk ikke ut i løpet av de siste 3 dagene, men går vanligvis ut i løpet av en 3-dagers periode
- 2 1–2 dager
- 3 3 dager

4. FORBEDRINGSMULIGHET FOR FYSISK FUNKSJON
- 0 Nei
- 1 Ja

a. Vedkommende mener at han/hun er i stand til å forbedre ytelse mht. fysiske funksjoner

b. Pleiepersonalet mener at han/hun er i stand til å forbedre ytelse mht. fysiske funksjoner

5. ENDRING I ADL-STATUS SAMMENLIKNET MED FOR 90 DAGER SIDEN ELLER SIDEN SISTE VURDERING HVIS DET ER MINDRE ENN 90 DAGER SIDEN
- 0 Forbedret
- 1 Ingen endring
- 2 Avtatt
- 8 Usikkert

AVSNITT H. Kontinens

1. BLÆREKONTINENS
- 0 **Kontinent** – Full kontroll, BRUKER IKKE noen type kateter eller annet urinoppsamlingsutstyr
- 1 **Kontroll med kateter eller stomi i løpet av de** siste 3 dager
- 2 **Sjelden inkontinent** – Ikke inkontinent i løpet av de siste 3 dager, men har episoder med inkontinens
- 3 **Iblant inkontinent** – Sjeldnere enn daglig
- 4 **Ofte inkontinent** – Daglig, men har en viss kontroll
- 5 **Inkontinent** – Ingen kontroll
- 8 **Forekom ikke** – Ingen urinproduksjon fra blæren i løpet av de siste 3 dagene

2. HJELPEMIDLER TIL Å SAMLE URIN (bortsett fra bind/underbukser)
- 0 Ingen
- 1 Uridom
- 2 Innlagt kateter
- 3 Cystostomi, nefrostomi, ureterostomi
- 4 Bleier

3. TARMKONTINENS
- 0 **Kontinent** – Full kontroll, BRUKER IKKE noen type stomiutstyr
- 1 **Kontroll med stomi** – Kontroll med stomiutstyr de siste 3 dager
- 2 **Sjelden inkontinent** – Ikke inkontinent i løpet av de siste 3 dager, men har episoder med inkontinens
- 3 **Iblant inkontinent** – Sjeldnere enn daglig
- 4 **Ofte inkontinent** – Daglig, men har en viss kontroll
- 5 **Inkontinent** – Ingen kontroll
- 8 **Forekom ikke** – Ingen avføring i løpet av de siste 3 dagene

4. STOMI
- 0 Nei
- 1 Ja

AVSNITT I. Sykdomsdiagnoser

Sykdomskode
- 0 Ikke tilstede
- 1 Primærdiagnose/diagnose for nåværende opphold
- 2 Diagnose tilstede, får aktiv behandling
- 3 Diagnose tilstede, overvåket, men får ingen aktiv behandling

1. SYKDOMSDIAGNOSER

Muskel/skjelett
a. Lårhalsbrudd i løpet av de siste 30 dager (eller etter siste vurdering hvis under 30 dager)
b. Andre typer brudd i løpet av de siste 30 dager (eller etter siste vurdering hvis under 30 dager)

Nevrologisk
c. Alzheimers sykdom
d. Demens bortsett fra Altzheimers sykdom
e. Hemiplegi
f. Multippel sklerose
g. Lammelse
h. Parkinsons sykdom
i. Kvadriplegi
j. Slag/CVA

Hjerte eller lunge
k. Koronar hjertesykdom
l. Kronisk obstruktiv lungesykdom
m. Hjertesvikt

Psykiatrisk
n. Angst
o. Bipolar sykdom
p. Depresjon
q. Schizofreni

Infeksjoner
r. Lungebetennelse
s. Urinveisinfeksjon i løpet av de siste 30 dager

Andre
t. Kreft
u. Diabetes mellitus

2. ANDRE SYKDOMSDIAGNOSER

Diagnose	Sykdom Kode
a.	
b.	
c.	
d.	
e.	
f.	

[Merk: Tilføy flere linjer etter behov for andre sykdomsdiagnoser]

ISBN: 978-1-622550-00-5

AVSNITT J. Helsetilstand

1. FALL
- 0 Ingen fall i løpet av de siste 90 dager
- 1 Ingen fall i løpet av de siste 30 dager, men falt for 31–90 dager siden
- 2 Ett fall i løpet av de siste 30 dager
- 3 To eller flere fall i løpet av de siste 30 dager

2. NYLIGE FALL
[Hopp over hvis siste vurdert for mer enn 30 dager siden eller hvis dette er den første vurderingen]
- 0 Nei
- 1 Ja
- [tomt felt] Ikke aktuelt (første vurdering eller mer enn 30 dager siden siste vurdering)

3. HVOR OFTE FOREKOMMER PROBLEMET
Kodes for "tilstede" i løpet av de siste 3 dager
- 0 Ikke tilstede
- 1 Tilstede, men ikke sett i løpet av de siste 3 dagene
- 2 Tilstede i 1 av de siste 3 dagene
- 3 Tilstede i 2 av de siste 3 dagene
- 4 Sett daglig i løpet av de siste 3 dagene

Balanse
a. Vanskelig for eller ikke istand til å bevege seg til stående stilling uten hjelp
b. Vanskelig for eller ikke istand til å snu seg i motsatt retning når stående
c. Svimmelhet
d. Ustabil gange

Hjerte eller lunge
e. Brystsmerter
f. Problemer med å rense luftveier for slim

Psykiatrisk
g. Unormal tankeprosess – f.eks. mister tråden, blokkering, idéflukt, håndgipelighet, presisjon
h. Vrangforestillinger – Fikse idéer, uriktige oppfatninger, ikke samsvar med virkeligheten
i. Hallusinasjoner – Uriktige sensoriske oppfatninger

Nevrologisk
j. Afasi

Mave/tarm-status
k. Syrerefluks – Oppstøt av syre fra magen til halsen
l. Forstoppelse – Ingen avføring i 3 dager eller problemer med hard avføring
m. Diaré
n. Oppkast

Søvnproblemer
o. Problemer med å sovne eller å fortsette å sove, våkner for tidlig, rastløshet, ikke hvilesøvn
p. For mye søvn – Sover for mye som innvirker på vedkommendes normale funksjoner

Andre
q. Aspirasjon
r. Feber
s. Blødning fra mage/tarm eller underliv
t. Hygiene
u. Perifert ødem

4. DYSPNE (kortpustethet)
- 0 Ingen symptomer
- 1 Ses ikke under hvile, men tilstede når det utføres moderate aktiviteter
- 2 Ses ikke under hvile, men tilstede når det utføres normale, daglige aktiviteter
- 3 Tilstede ved hvile

5. FATIGUE (utmattelse)
Ute av stand til å fullføre vanlige, daglige aktiviteter – f.eks. ADL-er, IADL-er
- 0 **Ingen**
- 1 **Minimal** – Nedstatt energi, men fullfører vanlige, daglige aktiviteter
- 2 **Moderat** – På grunn av nedsatt energi, KAN IKKE FULLFØRE vanlige, daglige aktiviteter
- 3 **Alvorlig** – På grunn av nedsatt energi, KAN IKKE PÅBEGYNNE NOEN vanlige, daglige aktiviteter
- 4 **Ute av stand til å begynne på noen av de vanlige, daglige aktivitetene** – På grunn av nedsatt energi

6. SMERTESYMPTOMER
[Merk: Spør alltid vedkommende om smertehyppighet, intensitet og kontroll. Observer vedkommende og spør andre som er i kontakt med vedkommende.]

a. **Hvor ofte vedkommende klager eller viser tegn på smerte** (inkludert grimaser, skjære tenner, sukking, trekker seg tilbake ved berøring eller andre ikke-verbale tegn som tyder på smerte)
- 0 Ingen smerte
- 1 Tilstede, men ikke sett i løpet av de siste 3 dagene
- 2 Tilstede i 1–2 av de siste 3 dagene
- 3 Sett daglig i løpet av de siste 3 dagene

b. **Høyeste smertenivå tilstede**
- 0 Ingen smerte
- 1 Lett
- 2 Moderat
- 3 Alvorlig
- 4 Til tider er smertene forferdelige eller uutholdelige

c. **Smertens beskaffenhet**
- 0 Ingen smerte
- 1 En enkel episode i løpet av de siste 3 dager
- 2 Kommer og går
- 3 Konstant

d. **Gjennomtrengende smerte** – Vedkommende har opplevd plutselig, akutt oppblussing av smerte DE SISTE 3 DAGER
0 Nei 1 Ja

e. **Smertekontroll** – Nåværende behandlingsregime tilstrekkelig til å kontrollere smerte (etter vedkommendes mening)
- 0 Ingen problemer med smerte
- 1 Smertens intensitet akseptabel for vedkommende, ingen behandling eller endring i regime nødvendig
- 2 Tilstrekkelig kontrollert med behandlingsregime
- 3 Kontrollert når behandlingsregimet følges, men dette blir ikke alltid fulgt
- 4 Behandlingsregimet følges, men smertekontroll er ikke tilstrekkelig
- 5 Intet behandlingsregime følges, smerte ikke tilstrekkelig kontrollert

7. USTABILITET I TILSTANDEN
0 Nei 1 Ja

a. Tilstander/sykdommer som gjør kognitiv fungering, ADL, sinnsstemning – og atferd ustabile (fluktuerende, utrygge eller forverrende)
b. Opplever en akutt episode eller en oppblussing av et tilbakevendende eller kronisk problem
c. Sykdom i sluttfasen, forventet 6 eller færre måneder igjen å leve

8. SELVRAPPORTERT HELSE
Spør: "Generelt sett, hvordan vil du bedømme din egen helse?"
- 0 Utmerket
- 1 God
- 2 Mindre god
- 3 Dårlig
- 8 Kunne ikke (ville ikke) svare

9. TOBAKK OG ALKOHOL

a. Røyker tobakk daglig
- 0 Nei
- 1 Ikke i løpet av de siste 3 dagene, men røyker vanligvis daglig
- 2 Ja

b. Alkohol – Høyeste antall drinker ved "en enkel anledning" i løpet av DE SISTE 14 DAGENE
- 0 Ingen
- 1 1
- 2 2–4
- 3 5 eller flere

 ISBN: 978-1-622550-00-5

AVSNITT K. Munn- og ernæringsstatus

1. **HØYDE OG VEKT [CM OG KG – LANDSPESIFIKT]**
Registrer (a) høyde i cm og (b) vekt i kg. Baser vekt på den siste målingen i løpet av DE SISTE 30 DAGENE.

a. HØYDE (cm.) ☐☐☐ b. VEKT (kg.) ☐☐☐

2. **ERNÆRINGSSPØRSMÅL**
0 Nei 1 Ja

a. Vekttap på 5 % eller mer i løpet av SISTE 30 DAGER eller 10 % eller mer i løpet av DE SISTE 180 DAGENE ☐
b. Dehydrert ☐
c. Væskeinntak under 1000 ml per dag (færre enn sju –1,5 dl's glass/dag) ☐
d. Væskeproduksjon overstiger inntak ☐

3. **HVORDAN MATEN BLIR GITT**
0 **Normalt** – Svelger alle typer mat
1 **Modifisert uavhengig** – f.eks. tar små slurker av væske, inntar begrenset mengde fast føde, behov for tilpassing kan være ukjent
2 **Krever tilpasset diet for å svelge fast føde** – f.eks. mekanisk diet (puré, opphakket, osv.) eller er bare istand til å innta spesiell mat
3 **Krever tilretteleggelse for å svelge væsker** – f.eks. tyktflytende væske
4 **Kan bare svelge puré av fast føde OG tyktflytende væske**
5 **Kombinert oral og parenteral eller sondemating**
6 **Bare nesesonde for mating**
7 **Ernæringssonde i magen** – f.eks. PEG-sonde
8 **Bare parenteral mating** – inkluderer alle typer parenterale matinger, slik som total parenteral ernæring (TPN)
9 **Aktiviteten forekom ikke** – i løpet av hele perioden

4. **PARENTERALT ELLER ENTERALT INNTAK** ☐
Andel av SAMLET ANTALL KALORIER mottatt gjennom parenteral ernæring eller sondemating i løpet av DE SISTE 3 DAGENE
0 **Ingen parenteral/enteral sonde**
1 **Parenteral/enteral sonde, men ikke kaloriinntak**
2 **1–25 % av samlet antall kalorier gjennom hjelpemidler**
3 **26 % eller mer av samlet antall kalorier gjennom hjelpemidler**

5. **TANN ELLER MUNN**
0 Nei 1 Ja

a. Har tannprotese (fjernbar bro) ☐
b. Har brukne, skadede, løse eller naturlige tenner som på annen måte ikke er intakte ☐
c. Rapporterer smerte/ubehag i munn eller ansikt ☐
d. Rapporterer tørr munn ☐
e. Rapporterer problemer med å tygge ☐
f. Betent eller blødende tannkjøtt ved siden av naturlige tenner eller tannrester ☐

AVSNITT L. Hudens tilstand

1. **MEST ALVORLIG TRYKKSÅR** ☐
0 Ingen trykksår
1 Hudområde med vedvarende rødhet
2 Delvis tap av hudlag
3 Dype krater i huden
4 Brudd i huden som eksponerer muskel eller ben
5 Ikke kodbart, f.eks. nekrotisk vev dominerer

2. **TIDLIGERE TRYKKSÅR** ☐
0 Nei 1 Ja

3. **SYNLIGE SÅR I HUDEN – IKKE TRYKKSÅR** – *f.eks. venøst sår, arteriesår, blandet venøst - arterielt sår, diabetisk fotsår* ☐
0 Nei 1 Ja

4. **ALVORLIGE HUDPOBLEMER** – *f.eks. lesjoner, 2. og 3. grads forbrenning, helende operasjonssår* ☐
0 Nei 1 Ja

5. **HUDFLENGER ELLER KUTT** – *Ikke operasjonssår* ☐
0 Nei 1 Ja

6. **ANDRE HUDPROBLEMER ELLER ENDRINGER I HUDENS TILSTAND** – *blåmerker, utslett, kløe, marmorering, herpes zoster, intertrigo, eksem* ☐
0 Nei 1 Ja

7. **FOTPROBLEMER** – *f.eks hallux valgus, hammertær, overliggende tær, strukturelle problemer, infeksjoner, sår* ☐
0 Ingen fotproblemet
1 Fotproblemer, ingen begrensning mht. gange
2 Fotproblemet begrenser gåing
3 Fotproblemet hindrer gåing
4 Fotproblemer, går ikke av andre grunner

AVSNITT M. Interesser for aktiviteter

1. **GJENNOMSNITTLIG TID ENGASJERT I AKTIVITETER** – f.eks. alene, i en sosial gruppe ☐
[Merk: Når vedkommende er våken og ikke mottar behandling eller ADL-pleie]
0 Ingen
1 Lite – mindre enn 1/3 av tiden
2 Noe – fra 1/3 – 2/3 av tiden
3 Mye – mer enn 2/3 av tiden

2. **AKTIVITETSPREFERANSER OG ENGASJEMENT** (tilpasset til nåværende evner)
0 Ingen preferanser, har ikke deltatt i løpet av de siste 3 dager
1 Ingen preferanser, deltok i løpet av de siste 3 dager
2 Foretrakk ikke å delta
3 Foretrakk vanligvis å delta, men ikke i løpet av de siste 3 dager
4 Foretrakk å delta i løpet av de siste 3 dager

a. Kort, leker eller puslespill ☐
b. Aktiviteter på datamaskin ☐
c. Samtale eller snakke på telefonen ☐
d. Håndarbeid eller kunst ☐
e. Dans ☐
f. Diskutere/mimre om livet ☐
g. Trening eller sport ☐
h. Hagearbeid eller planter ☐
i. Hjelpe andre ☐
j. Musikk eller sang ☐
k. Kjæledyr ☐
l. Lese, skrive eller løse kryssord ☐
m. Åndelige eller religiøse aktiviteter ☐
n. Gå på tur eller handle ☐
o. Spasere eller kjøre rullestol utendørs ☐
p. Se på TV eller høre på radio ☐

3. **TID MED SØVN I LØPET AV DAGEN** ☐
0 Våken hele eller det meste av dagen (ikke mer enn en liten blund om morgenen eller ettermiddagen)
1 Hadde flere små blunder
2 Sover det meste av tiden, men er våken og klar i visse perioder (f.eks. under måltider)
3 Sover stort sett eller reagerer ikke

ISBN: 978-1-622550-00-5

AVSNITT N. Medisinering

1. LISTE OVER ALLE LEGEMIDLER

Oppfør alle aktive resepter og alle reseptfrie legemidler tatt i DE SISTE 3 DAGENE

[Merk: Bruk dataregistreringer hvis det er mulig, legg bare inn for hånd dersom det er absolutt nødvendig.]

For hvert legemiddel registrer:

a. **Navn**

b. **Dose** – Et positivt tall som for eksempel 0,5, 5, 150, 300.
[Merk: Skriv aldri bare 0 etter et desimaltegn (X mg). Bruk alltid en null før et desimaltegn (0,X mg).]

c. **Enhet** – Kodes ved å bruke følgende liste:

dr	(dråper)	**mekv**	(milliekvivalent)	**Støt**	(eks.nesespray)
g	(gram)	**mg**	(milligram)	**%**	(prosent)
l	(liter)	**ml**	(milliliter)	**u**	(unit/enheter)
mcg	(mikrogram)	**an**	(andre)		

d. **Administrasjonsvei** – Kodes ved å bruke følgende liste:

po	(gjennom munnen/peroralt)	**rek**	(rektalt)	**et**	(enteralt/gjennom sonde)
sl	(sublingualt/under tunga)	**top**	(lokalt)	**td**	(gjennom huden)
im	(intramuskulært)	**ih**	(inhalasjon)	**ø**	(øye)
iv	(intravenøst)	**nas**	(nasalt)	**an**	(andre)
sc	(subkutant)				

e. **Hyppighet** – Kod antall ganger per dag, uke eller måned medikamentet blir administrert ved å bruke følgende liste:

1T	(hver time)	D	(daglig)
2T	(hver 2. time)	**K**	(ved sengetid)
3T	(hver 3. time)	**2D**	(2 ganger daglig;
4T	(hver 4. time)		inkluderer hver 12 timer)
6T	(hver 6. time)	**3D**	(3 ganger daglig)
8T	(hver 8. time)	**4D**	(4 ganger daglig)
5D	(5 ganger daglig)	**4U**	(4 ganger i uken 4/7)
Q2D	(annenhver dag)	**5U**	(5 ganger i uken 5/7)
Q3D	(hver 3. dag)	**6U**	(6 ganger i uken 6/7)
U (ukentlig)		**1M**	(1 gang i måneden)
2U	(2 ganger i uken 2/7)	**2M**	(to ganger hver måned)
3U	(3 ganger i uken 3/7)	**OTH**	(annet)

f. **Etter behov**
0 Nei **1** Ja

g. **Legemiddelkode lagt inn med datamaskin**

	a. Navn	b. Dose	c. Enhet	d. Måte	e. Hyppighet	f. Etter behov	g. ATC-kode
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							

Merk: Legg til flere linjer etter behov for eventuelle andre legemidler som brukes
[Forkortelser er landspesifikke for enhet, administrasjonsvei, hyppighet]

2. ALLERGIER MOT LEGEMIDLER
0 Ingen kjente allergier mot legemidler **1** Ja ☐

AVSNITT O. Behandling og undersøkelser/prosedyrer

1. FOREBYGGENDE
0 Nei **1** Ja

a. Blodtrykk målt i løper av DET SISTE ÅRET	☐
b. Kolonoskopi i løpet av DE SISTE 5 ÅRENE	☐
c. Tannundersøkelse i løpet av DET SISTE ÅRET	☐
d. Øyeundersøkelse i løpet av DET SISTE ÅRET	☐
e. Hørselsundersøkelse i løpet av DE SISTE 2 ÅRENE	☐
f. Influensa-vaksine i løpet av DET SISTE ÅRET	☐
g. Mammogram eller brystundersøkelse i løpet av DE SISTE 2 ÅRENE (for kvinner)	☐
h. Pneumoni-vaksine i løpet av DE SISTE 5 ÅR eller etter 65 års alder	☐

2. BEHANDLINGER OG PROGRAMMER SOM ER SATT IGANG ELLER PLANLAGT I LØPET AV DE SISTE 3 DAGENE (ELLER SIDEN SISTE VURDERING DERSOM DET ER MINDRE ENN 3 DAGER SIDEN)
0 Ikke forskrevet OG ikke gjennomført
1 Forskrevet, ikke satt i gang
2 1–2 av de siste 3 dagene
3 Daglig i løpet av de siste 3 dagene

Behandlinger

a. Kjemoterapi	☐
b. Dialyse	☐
c. Infeksjonskontroll – f.eks. isolasjon, karantene	☐
d. IV-medisinering	☐
e. Oksygenbehandling	☐
f. Strålebehandling	☐
g. Suging	☐
h. Trakeotomi-pleie	☐
i. Transfusjon	☐
j. Ventilator eller respirator	☐
k. Sårpleie	☐

Programmer

l. Planlagt toalettreningsprogram	☐
m. Program for palliativ pleie (terminalregime)	☐
n. Snuregime/ legges i riktig posisjon	☐

3. BEHANDLING/PLEIETJENESTER I LØPET AV DE SISTE 7 DAGENE – *f.eks. terapeut eller terapiassistent under veiledning av en terapeut*
[Merk: Tell bare behandlinger etter innleggelse]

A. **Antall dager** behandling er planlagt i løpet av DE SISTE 7 DAGENE
B. **Antall dager** behandling ble gitt i **15 minutter eller lenger**
C. **Samlet antall minutter** gitt i løpet av DE SISTE 7 DAGENE
(eller *forskrevet* dersom antall dager gitt = 0 og dager planlagt > 0)

	Antall dager planlagt A	Antall dager gitt B	Samlet antall minutter i siste uke C
a. Fysioterapi			
b. Ergoterapi			
c. Hjelp av logoped eller audiopedagog / audiograf			
d. Respiratorisk behandling			
e. Funksjonsrehabilitering eller gåtrening med offentlig godkjent pleier			
f. Psykoterapi (med offentlig godkjent personell for mental helse)			

4. BRUK AV SYKEHUS OG AKUTTAVDELING
Kodes for antall ganger i løpet av DE SISTE 90 DAGER (eller siden siste vurdering dersom det er MINDRE ENN 90 DAGER SIDEN)

a. Innlagt på akuttavdeling med overnatting	☐☐
b. Øyeblikkelig hjelp (ikke medregnet overnatting)	☐☐

5. LEGEBESØK ☐☐
Antall dager i løpet av DE SISTE 14 DAGER legen har undersøkt vedkommende (eller siden innleggelse hvis mindre enn 14 dager i institusjonen).

Legg inn 0 hvis ingen.

6. LEGENS FORSKRIVNINGER ☐☐
Antall dager i løpet av DE SISTE 14 DAGER legen har endret vedkommendes forskrivning (eller siden innleggelse hvis mindre enn 14 dager i institusjonen).

Ikke inkluder forskrivninger fornyet uten endringer.

Legg inn 0 hvis ingen.

7. BEVEGELSESHINDRENDE
0 Ikke brukt
1 Brukt sjeldnere enn daglig
2 Brukt daglig – bare om natten
3 Brukt daglig – bare om dagen
4 Brukt natt og dag, men ikke konstant
5 Konstant bruk i 24 timer (kan omfatte perioder uten bruk)

a. Sengehest helt opp på alle åpne sider av sengen	☐
b. Fastspenning av kroppen	☐
c. Fiksering av beboer i stol med sele eller belte	☐

ISBN: 978-1-622550-00-5

St. Mark`s inkontinensskår

	Aldri	Sjelden	Av og til	Ukentlig	Daglig
• Lekkasje av fast avføring	☐0	☐1	☐2	☐3	☐4
• Lekkasje av flytende avføring	☐0	☐1	☐2	☐3	☐4
• Lekkasje av luft	☐0	☐1	☐2	☐3	☐4
• Endring av livsstil*	☐0	☐1	☐2	☐3	☐4

*Hvor ofte har lekkasjeplagene begrenset aktiviteter i hverdagslivet

	Nei	Ja
• Behov for å bruke bleie/bind eller propp pga lekkasje av avføring	☐0	☐2
• Bruk av forstoppende medikamenter (Antidiarémidler f eks Imodium)	☐0	☐2
• Manglende evne til å utsette avføring i 15 minutter	☐0	☐4

Aldri: ingen tilfeller de siste fire ukene
Sjelden: 1 tilfelle de siste fire ukene
Av og til: >(mer enn)1 tilfelle de siste fire ukene, men <(mindre enn) 1 tilfelle i uka
Ukentlig: 1 eller flere tilfeller i uka, men < (mindre enn)1 tilfelle per dag
Daglig: 1 eller flere tilfeller per dag

Legg sammen resultat fra hver rad: minimumssum = 0 = perfekt kontinens,
maksimumssum = 24 = helt inkontinent

Sum ☐☐

Spørsmål om hjelpemidler og tiltak

1. Inkontinens

Hjelpemidler/tiltak ved eventuell urin- og/eller avføringsinkontinens
(Flere kryss mulig)

☐ Ikke aktuelt
☐ Bleier
Hvis pasienten bruker bleier: Sett kryss ved ca antall bleier per døgn:
☐ 1 – 2 ☐ 3 – 4 ☐ 5 – 6 ☐ 7 eller flere

Hvis pasienten bruker bleier: Type/størrelse:

	Dag	Natt
Lett absorbsjonsevne	☐	☐
Middels absorbsjonsevne	☐	☐
Stor absorbsjonsevne	☐	☐

☐ Analpropp
☐ Faste toalettider
(tilrettelegging for å gå på toalettet til faste tidspunkter eller faste intervaller)
☐ Tarmskylling
☐ Trening av bekkenbunnsmuskulatur
☐ Biofeedback
☐ Elektrostimulering
☐ Andre tiltak.....
☐ Ingen tiltak

2. Obstipasjon

Hjelpemidler/tiltak som har blitt iverksatt for å tømme tarmen
(flere kryss er mulig)

- ☐ Ikke aktuelt
- ☐ Oljeklyster
- ☐ Saltvannsklyster
- ☐ Klyx
- ☐ Microklyster (Microlax/toilax klyster)
- ☐ Manuell fjerning ("plukking")
- ☐ Medikamenter (tabletter/dråper/stikkpiller/mixtur)
- ☐ Faste toalettider
  (tilrettelegging for å gå på toalettet til faste tidspunkter eller faste intervaller)
- ☐ Fysisk aktivitet
- ☐ Kostholdstiltak
- ☐ Andre tiltak.....
- ☐ Ingen tiltak

3. Diaré/løs avføring

Hjelpemidler/tiltak som har blitt iverksatt for å gjøre avføringen fastere
(flere kryss er mulig)

- ☐ Ikke aktuelt
- ☐ Antidiarémidler (f. eks Imodium)
- ☐ Kostholdstiltak
- ☐ Andre tiltak.....
- ☐ Ingen tiltak

Intervjuguide fokusgruppeintervju

Deltakere: fagledere fra XX og XX, endringsagent, to sykepleiere fra hvert sykehjem.

Introduksjon (7 minutter)

Et overordnet spørsmål i dette prosjektet er: hvordan er det fornuftig å gå fram hvis man skal innføre noe nytt/en ny måte å gjøre ting på i sykehjem.

Dere har vært med i et prosjekt hvor vi sammen har prøvd ut to forskjellige undervisningsopplegg. Hensikten med undervisningen var å lære mer om mage-tarmproblematikk blant sykehjemspasienter, samt å lære å bruke et instrument for kartlegging og tiltak.

Dere kommer fra to forskjellige sykehjem – XX og XX. Dere har vært deltakere i to forskjellige undervisnings-/opplæringsprogram. Grunnen til dette er at vi ønsker å sammenligne erfaringer fra to forskjellige opplegg.

- Begge sykehjemmene har fått en dag med workshop med mer eller mindre likt innhold. Det ene sykehjemmet fikk så oppfølgende veiledning av Lene i en periode på ca 3 mnd. I tillegg ble det rekruttert en «endringsagent (samarbeidspartner)». Dette var en av sykepleierne som deltok på workshoppen.

Hensikten med intervjuet er å få vite noe om hvordan dere opplevde undervisningsoppleggene og på hvilken måte dere greide å bruke det dere lærte i hverdagen etterpå.

I og med at dere har vært med i en pilotstudie er deres erfaringer viktige med tanke på videreutvikling av undervisningsoppleggene. Vi ønsker en samtale knyttet til deres erfaringer og bruke disse i arbeidet med videreutvikling.

Vi kommer også til å stille noen spørsmål relatert til datasamlingen.

XX leder diskusjonen. XX noterer hovedessenser underveis og kan i tillegg stille utdypende spørsmål hvis hun ser behov for det.

Vi ønsker en diskusjon som får fram både aspekter (mapping) og dybde (mining).

Det er viktig å understreke at:

- Informasjon som kommer fram innen gruppen holdes innenfor gruppen.
- Det er ingen rette eller gale svar
- Det er OK å være uenige
- Det er viktig å respektere hverandres synspunkter
- Det er viktig med en diskusjon hvor alle er med
- Det ikke er lov å avbryte eller ha sidediskusjoner underveis

Samtalen blir tatt opp på lydbånd, som står midt på bordet.

Åpningsspørsmål (ca 5 min)

- Vi starter med en presentasjonsrunde: Fortell navnet, hvor dere jobber, roller, og hva dere syns er mest inspirerende med å jobbe med pasientgruppen på sykehjem.

Introduksjonsspørsmål (ca 5 min)

- Tenk tilbake på første gang dere fikk informasjon om prosjektet. Hva var førsteinntrykket?

Overgangsspørsmål (ca 5 min)

- Hvilke tanker/erfaringer har dere når det gjelder framgangsmåter knyttet til det å skulle innføre/implementere nye prosedyrer/rutiner ved sykehjemmet?

Nøkkelspørsmål 1(ca 8 min)

- Fortell om erfaringer fra workshoppen?
  - Faglig innhold?
  - Arbeidsmåte?
  - Hva kunne dere tenkt dere annerledes?

Nøkkelspørsmål 2 (ca 8 min)

- Tenk tilbake på første gang dere leste gjennom retningslinjene for kartlegging av pasientenes tarmfunksjon. Hva var førsteinntrykket? (ta med og vise fram)

- Fortell om erfaringene med å jobbe med retningslinjene på workshoppen?

- Fortell om erfaringene med å kartlegge pasientene ved hjelp av retningslinjene etter workshoppen?

Hvis ikke dekkende besvart: spør om plusser og minuser knyttet til erfaringer med retningslinjene
Hvis ikke dekkende besvart: spør om plusser og minuser med det å bruke retningslinjene og det å få dokumentert resultatet av kartleggingen, sykepleiediagnosene og tiltakene i Gerica?

Her går vi over til å snakke om erfaringer fra XX og XX hver for seg (spørsmål 3 og 4)

Nøkkelspørsmål 3 (ca 8 min)

- Fortell om erfaringen med rollen som endringsagent?
  - Hva tenker dere andre ved XX om XX rolle?
- Fortell om erfaringene med møtene/veiledningen med Lene i tiden etter workshoppen?
  - XX, XX, XX; hva mener dere?

Nøkkelspørsmål 4 (ca 8 min)

- Hva tenker dere fra XX når dere hører på erfaringene med det utvidede tilbudet til XX?

Nøkkelspørsmål 5 (ca 8 min)

- Hvilke faktorer bidro til at dere fikk brukt det dere lærte under workshoppen og retningslinjene i pleien?
- Hvilke faktorer bidro til at dere ikke fikk brukt det dere lærte under workshoppen og retningslinjene i pleien?

Nøkkelspørsmål 6 (ca 8 min)
Fortell om følelser dere har hatt under arbeidet med dette prosjektet?

Avslutningsspørsmål (ca 7 min)
Hvis dere skulle gitt noen råd til en som leder arbeidet med å planlegge og innføre(implementere) en ny rutine/retningslinjer vet ditt sykehjem, hva ville rådene vært?

Er det noe som ikke er berørt som dere synes er viktig å løfte fram?

Datasamling (ca 7 min)
Fortell om erfaringen med å ha deltatt i arbeidet med datasamling til prosjektet?

Totalt 84 min

Intervjuguide for individuelle intervju

Gerica og sykepleiedokumentasjon som samhandlingsredskap

1. Under gruppeintervjuet ble det nevnt at mange føler seg utrygge på data. Kan du fortelle litt mer om det (er det noe som er uttalt, på hvilken måte er dette er tema)?
2. Hvordan opplever du dine kollegers trygghet på å skulle formulere seg skriftlig i Gerica?
3. Hvilke tanker har du om egen trygghet rundt hva og hvordan du skal dokumentere i Gerica?
4. Under gruppeintervjuet ble det nevnt at sykepleieplaner ble satt inn i permer. Kan du si litt om bakgrunnen for den praksisen? (i stedet for å bruke Gerica?)
5. For sykehjem A: både under prosjektperioden og i intervjuet snakket dere om at det var vanskelig å få «alle» til å dokumentere og evaluere tiltakene. Kan du fortelle litt mer om det?

Hverdagen på sykehjemmet

6. Kan du fortelle litt om rollen som primærkontakt? (Kan en sykepleier være primærkontakt)?
7. Hva er det som styrer en vanlig arbeidsdag (fortell litt om arbeidslistene)?
8. Hvordan er samarbeidet/rollefordelingen mellom sykepleiere, hjelpepleiere og assistenter?
9. Under intervjuet nevnes det å kartlegge pasientene ved hjelp av retningslinjene og utarbeide sykepleieplaner som en administrativ oppgave. Hva tenker du når jeg løfter det fram nå?
    - (Opplever du at denne type oppgaver er ansett som viktig?)
    - (Er dette en oppgave som vil stå på en arbeidsliste?)

Prosjektgjennomføring og endringsprosesser

10. Kan du si noe om hvilke faktorer ved sykehjemmet som du tror bidro positivt til at dere fikk gjennomført prosjektet?
11. Kan du si noe om hvilke faktorer ved sykehjemmet som du tror kan ha virket negativt inn på gjennomføringen?
12. Under gruppeintervjuet ble det nevnt at det å forstå målsetningen med et prosjekt og informasjon til alle er viktig for å få folk inkludert i gjennomføringen. Det å invitere flere til «workshoppen» ble nevnt som et tiltak for dette prosjektet. Kan du se andre måter å gå fram på? (Hvordan kunne vi ha jobbet annerledes for å få inkludert flere?)
13. Tror du det ville vært en god ide med en endringsagent fra hver avdeling? Hvordan tror du det ville vært fornuftig å få organisert dette?

14. Når det skal gjennomføres endringer, hva mener du er viktige lederoppgaver/lederansvar?
    - (Fagleder/Enhetsleder)

Retningslinje for sykepleiefaglig vurdering og håndtering av avføringsinkontinens

Definisjon fekalinkontinens (FI): «Fekalinkontinens er ufrivillig lekkasje av fast eller flytende avføring som oppleves som et sosialt eller hygienisk problem»

Vurderingen tar utgangspunkt i en *generell vurdering av mage-/tarmfunksjon.* Deretter vurderes *mulige årsaker (etiologi)* og hva som *kjennetegner* avføringsinkontinensen til aktuell pasient. Resultatet av vurderingen skal lede fram til en *sykepleiediagnose*. Sykepleiediagnosen blir bestemmende for valg av *sykepleietiltak.* Når det gjelder gamle handler det ofte om sammensatte årsaker og problemstillinger.

Generell vurdering av mage-/tarmfunksjon relatert til inkontinens:
Vurderingen baseres på spørsmål til/observasjon av pasient

Har pasienten hatt ufrivillig lekkasje av fast eller løs avføring de siste 8 ukene:

☐ Nei →dokumenter pasienten som kontinent for avføring

☐ Ja → fullfør vurderingen

Avføringshyppighet/avføringsmønster før flytting til sykehjem:

☐ Flere ganger om dagen

☐ Hver dag

☐ Mellom 3 til 6 ganger i uka

☐ Mindre enn 3 ganger i uka

☐ Vet ikke

Avføringshyppighet/avføringsmønster de siste syv dagene:

☐ Flere ganger om dagen

☐ Hver dag

☐ Mellom 3 til 6 ganger i uka

☐ Mindre enn 3 ganger i uka

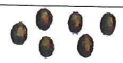
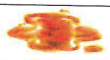
Farge på avføring (vanligvis):

☐ Brunsvart

☐ Brun

☐ Lys gul/grå

Konsistens på avføring (vanligvis):

1		Adskilte, harde klumper som nøtter (vanskelig å få ut)	
2		Pølseformet, men med klumper	
3		Pølseformet, men med sprekker på overflaten.	
4		Pølse-/slangeformet; smidig og myk.	
5		Myke klumper med skarpe kanter (enkle å få ut).	
6		Bløte deler med ujevne kanter, en grøtaktig avføring.	
7		Vandig, ingen faste deler	

Bristolskala for avføring: Dr Heaton (Skotnes et al 2008)

Smerter/ubehag før, under eller etter avføring:

☐ Ja

☐ Nei

Blod i avføring:

☐ Ja

☐ Nei

Endringer i avføringsmønster de siste fire ukene:

☐ Ja

☐ Nei

Unormalt stor anstrengelse ved avføring:

☐ Ja

☐ Nei

Hvor ofte har pasienten ufrivillig lekkasje av avføring:

☐ Mindre enn en gang i måneden

☐ Noen ganger i måneden

☐ Noen ganger i uka

☐ Hver dag og/eller natt

Avføringsbehov eller avføringsinkontinens om natten:

☐ Ja

☐ Nei

Har pasienten ufrivillig lekkasje av urin:

☐ Ja

☐ Nei

☐ Pasienten har blærekateter

Inspiser/eksplorer anus og rektum. Har pasienten:

☐ Sår/sprekkdannelser rundt anus

☐ Hemoroider

☐ Slapp indre/ytre lukkemuskel

☐ Rektumobstipasjon

☐ Rektal prolaps

☐ Ingen av alternativene over

☐ Annet.....

Sykepleiediagnose - Avføringsinkontinens

Relatert til (r.t): Mulig årsaker til pasientens avføringsinkontinens:

☐ Obstipasjon

☐ Rektumobstipasjon

☐ Kronisk diaré/løs avføring

☐ Akutt diaré

☐ Ufullstendig tømming av tarm

☐ Tap av kontroll over lukkemuskel

☐ Skade/abnormalitet i lukkemuskel

☐ Manglende evne til å utsette avføringsavgang

☐ Manglende evne til å kjenne avføringstrang

☐ Plutselig avføringstrang (urge)

☐ Selvrapportering av manglende evne til å føle rektal oppfylling

☐ Føler rektal oppfylling, men rapporterer manglende evne til å få ut fast avføring

☐ Uoppmerksom på avføringstrang

☐ Redusert kognitiv funksjon/demens, men med kortikal kontroll over defekasjonsprosess (f eks husker ikke hvor wc er)

☐ Demens med manglende kortikal kontroll over defekasjonsprosess

☐ Stress

☐ Generelt nedsatt muskeltonus

☐ Immobilitet (feks forflytning seng-stol, avhengig av rullator, sengeliggende)

☐ Nevrologiske skader/sykdommer (ryggmargsskade, MS, Parkinson, hjerneslag)

☐ Apati/synes ikke å bry seg (evt depresjon)

☐ Svikt i evne til egenomsorg relatert til wc besøk

☐ Utilfredsstillende toalettforhold (skjerming, i rett tid, sittestilling)

☐ Bivirkninger fra medikamenter

☐ Feilbruk/misbruk av avføringsmidler

☐ Faktorer i omgivelsene (for eksempel utilgjengelig toalett, manglede hjelpemidler)

☐ Kostvaner

Fører til (f.t): Hva kjennetegner pasientens avføringsinkontinens:

☐ Konstant siv av bløt avføring

☐ Ufrivillig lekkasje av fast avføring

☐ Ufrivillig lekkasje av løs avføring

☐ Avføringslukt

☐ Rød/sår hud i perineum

☐ Avføringsflekker på klær/sengeklær

Aktuell sykepleiediagnose:

.....

.....

.....

.....

.....

Sykepleietiltak:

☐ Forklar etiologien til problemet og gi begrunnelse for tiltak for pasient/pårørende

☐ Bestem målet for avføringsprogrammet sammen med pasient/pårørende

☐ Diskuter prosedyrer og forventede resultater med pasient/pårørende

☐ Undervis pasient om kosthold og mosjon som fremmer generell tarmfunksjon

☐ Tilby ernæring som fremmer generell tarmfunksjon

☐ Unngå ernæring som kan forårsake diare

☐ Iverksett tilpasset toalett-treningsprogram

☐ Iverksett tilpasset aktivitetsprogram

☐ Legg forholdene til rette for personlige ritualer

☐ Sørg for riktig sittestilling på WC

☐ Sikre privatliv under toalettbesøk

☐ Tilby tilpasset assistanse ved toalettbesøk

☐ Manuell fjerning av avføringsknoller fra rektum

☐ Eksplorer rektum

☐ Administrer laxativer som foreskrevet

☐ Rengjør perineum og området rundt etter hver avføring

☐ Bruk spesialhudkremer i perinealområdet

☐ Hold sengetøy og klær rene

☐ Administrer bleier ved behov

☐ Administrer analpropp etter behov

☐ Overvåk for tilstrekkelig tarmtømming

☐ Overvåk tarmfunksjon (frekvens, konsistens, farge, mengde)

☐ Overvåk diett og væskebehov

☐ Overvåk for bivirkninger ved administrering av legemidler

☐ Overvåk tarmlyder

☐ Overvåk for tegn på diare, obstipasjon og rektumobstipasjon

Individualisering og konkretisering av sykepleietiltak:

.....

.....

.....

.....

.....

.....

.....

.....

.....

Behov for henvisning til:

☐ Sykehjemslege

☐ Fysioterapeut

☐ Ergoterapeut

Begrunnelse for henvisning:

.....

Retningslinjene er utarbeidet etter:

Bulechek GM (Ed) (2013). Nursing interventions classification (NIC). St. Louis: Mosby Elsevier.

Bulechek GM (Ed) (2006). Klassifikasjon av sykepleieintervensjoner (NIC). Oslo: Akribe.

Herdman T (2012). Nursing Diagnoses. Definitions and Classification (2012 – 2014). North America Nursing Diagnosis Association (NANDA). Chichester: Wiley-Blackwell/NANDA International

Herdman T (2012). Omvårdnadsdiagnoser: definitioner og klassifikation 2012 – 2014. Lund: Studentlitteratur

Norton C et al (2009). Conservative and Pharmacological Management of Faecal Incontinence in Adults. In: Abrams P et al. Incontinence 4th Edition 2009.

Fonda D et al (2005). Incontinence in the frail elderly. In: Abrams P et al. Incontinence 3th Edition

NICE (National Institute for Health and Clinical Excellence)(2007). Faecal incontinence: the management of faecal incontinence in adults. NICE clinical guideline 49.

Skotnes LH, Omli R, Einarsen EK, Dahlhaug L (2008). Eliminasjonsproblemer. I: Kirkevold et al (Ed.). Geriatrisk sykepleie. Oslo: Gyldendal Akademiske.

Kunnskapsundersøkelse

1. Hva heter første del av colon etter overgang fra tynntarm?

☐ Colon transversum

☐ Colon descendens

☐ Colon ascendens

☐ Colon sigmoideum

2. Hvor er pylorus plassert?

☐ I overgangen mellom magesekken og tynntarmen

☐ I overgangen mellom spiserøret og magesekken

☐ I overgangen mellom tynntarmen og tykktarmen

3. Enkelte mage-/tarmsykdommer kan føre til redusert oppsuging av jern. Hvor i fordøyelsessystemet skjer absorbsjon av jern?

☐ Magesekken

☐ Tynntarmen

☐ Tykktarmen

4. Kronisk betennelse i magesekkens slimhinner kan skade cellene slik at danningen av Intrinsisk Faktor reduseres. Hva er konsekvensene?

☐Melkesukkeret laktose vil ikke bli nedbrutt som normalt i tarmen og pasientene kan få diareplager og magesmerter.

☐Vitamin D_3 vil ikke bli absorbert fra tarmen som normalt, noe som vil påvirke kalsiumomsetningen i benvevet som igjen kan føre til osteoporose.

☐Vitamin B_{12} vil ikke bli absorbert som normal. Dette påvirker nydanningen av røde blodceller og pasientene får symptomer på anemi.

5. Hva kjennetegner de essensielle aminosyrene?

☐ De dannes av spesielle celler i tarmveggen og bidrar til nedbrytning av nukleinsyrer

☐ De produseres i pankreas og utskilles i tynntarmen og bidrar i omsettingen av glukose.

☐ De må tilføres gjennom kosten og er nødvendig for kroppens nydanning av proteiner

6. I hvilken del av mage-/tarmsystemet får tarminnholdet tilsatt bukspytt og galle?

☐ I tykktarm

☐ I magesekk

☐ I tynntarm

7. Karbohydrater dominerer et normalt kosthold.
Karbohydratet cellulose blir ikke fordøyd, men bidrar til:

☐ Mer effektiv absorpsjon av enkle næringsstoffer og dermed mindre voluminøs avføring.

☐ Økt nedbryting av proteiner som bidrar til redusert væskeinnhold i avføringen.

☐ Økt peristaltikk og økt væskeinnhold i avføringen som bidrar og mykere avføring.

8. Hvilket av næringsstoffene brytes ned av enzymet pepsin?

☐ Proteiner

☐ Fett

☐ Karbohydrater

9. Hvilken betydning har tynntarmens segmenteringsbevegelser?

☐ Bevegelsene bremser hastigheten på tarminnholdet hvis det er gitt signaler om at innholdet har for lav ph til å gå over til tykktarmen.

☐Bevegelsene trer i kraft i forbindelse med virusinfeksjoner i tarmen og bidrar til rask gjennomstrømming av tarminnhold gjennom hele tynntarmen.

☐Bevegelsene flytter tarminnholdet fram og tilbake for på den måten å bidra til god kontakt med tarmveggen og sikre effektiv blanding av tarminnholdet og fordøyelsesvæskene

10. Gastrokolisk refleks er en autonom refleks i de indre organer. Hva bidrar den til?

☐ Den virker stimulerende og kan føre til avføringstrang.

☐ Den virker dempende og bidrar til å hindre ufrivillig avgang av avføring.

☐ Den bidrar til å sikre tilstrekkelig absorbsjon av væske fra fordøyelseskanalen.

11. Vanlige aldersforandringer i mage-/tarmkanalen er blant annet lavere peristaltisk aktivitet og at tykktarmen produserer mindre mukus. Hva kan det føre til?

☐ Det suges opp mer væske i tykktarmen og tarmen smøres dårligere noe som øker risikoen for obstipasjon.

☐ Tarmen greier i mindre grad å nyttiggjøre seg effekten av fiber og bakteriefloraen kan bli endret noe som øker risikoen for obstipasjon og luftplager.

☐ Absorbsjon av næringsstoffer i tynntarmen endres og tarminnholdet får lavere ph-verdi noe som øker risikoen for obstipasjon og magesmerter.

12. Du ønsker å undersøke om en pasient kan ha en rektumobstipasjon. Hvordan kan du mest presist undersøke dette?

☐ Du foretar en utvendig palpasjon av magen for å undersøke om colon ascendens virker unormalt oppfylt.

☐ Du foretar en rektal eksplorasjon og undersøker med en finger om det er avføring/avføringsknoller i endetarmen.

☐ Du observerer pasienten på toalettet i forbindelse med avføring for å undersøke om hun presser unormalt mye.

13. I hvilken form absorberes proteiner fra tarmen?

☐ Som triglyserider

☐ Som aminosyrer

☐ Som monosakkarider

14. Hva er melena?

☐ Sort, grøtet avføring med råtten lukt. Ofte forårsaket av blødning i magesekk eller tolvfingertarm.

☐ Sort avføring med normal konsistens og råtten lukt. Ofte forårsaket av for høyt inntak av jerntabletter, eller enkelte grønnsaker som for eksempel rødbeter.

☐ Brun, grøtet avføring med større eller mindre spor av friskt blod. Ofte forårsaket av blødning i tykktarm eller endetarm.

15. Du observerer avføringen til en pasient og ser at den er forholdsvis løs, grålig og glinsende. Hva kan det være et tegn på?

☐ Svikt i levercellenes galleproduksjon som fører til ufullstendig spalting og absorbsjon av proteiner fra fordøyelseskanalen.

☐ Svikt i enzymproduksjonen i pankreas som fører til ufullstendig spalting og absorbsjon av fettstoffer fra fordøyelseskanalen.

☐ Svikt i ventrikkelens utskillelse av lipase som fører til ufullstendig spalting og absorbsjon av fettstoffer fra fordøyelseskanalen.

16. Hvilken påstand er riktig:

☐ Endetarmen er ca 15 cm lang og fungerer normalt som lagringsplass for avføring mellom tarmtømming.

☐ Endetarmen er ca 20 cm lang og ender opp i rektumampullen. Rektumampullen fungerer som lagringsplass for avføring mellom tarmtømming.

☐ Endetarmen er ca 10 cm lang og skal normalt være noenlunde tom mellom tarmtømmingene.

17. Studier viser at forekomst (prevalens) av avføringsinkontinens blant pasienter på sykehjem er:

☐Mellom 7-15%

☐Mellom 20 – 35%

☐Mellom 40 – 60%

18. Hvilke legemidler er mest vanlige med tanke på at de fører med seg bivirkninger som øker risiko for obstipasjon?

☐ Kodein og andre opioidanalgetika, verapamil, enkelte legemidler med antikolinerge effekter (f.eks. mange psykofarmaka).

☐ Ikke-steroide antiinflammatoriske midler (NSAID), enkelte antihypertensiva og enkelte kvalmestillende medikamenter.

☐ Enkelte legemidler mot migrene, mange antibakterielle legemidler (f.eks antibiotika), og legemidler mot MS (multippel sklerose).

19. Hvilke to påstander er riktige:

☐ Indre lukkemuskel (m. sphincter ani internus) består av glatt muskulatur og er viljestyrt. Når avføringstrang kommer, kan vi styre denne muskelen til enten å slippe avføringen ut eller presse den tilbake til tarmen. Tegn på slapp ytre lukkemuskel er at du fører en finger inn i anus og ber pasienten «knipe og trekke opp», uten at du i særlig grad kan kjenne at muskelen trekker seg sammen rundt fingeren.

☐ Indre lukkemuskel (m. sphincter ani internus) består av glatt muskulatur og er ikke viljestyrt. Når tykktarmbevegelser presser avføring inn i endetarmen, stimuleres trykkfølsomme sanseceller noe som automatisk vil åpne lukkemuskelen. Hvis du fører en finger inn i anus, trekker den ut og ser at åpningen «gaper», kan det bety unormalt slapp indre lukkemuskel.

☐ Ytre lukkemuskel (m. sphincter ani externus) består av tverrstripete muskulatur og er viljestyrt. Når avføringstrang kommer, kan vi styre denne muskelen til enten å slippe avføringen ut eller presse den tilbake til tarmen. Tegn på slapp ytre lukkemuskel er at du fører en finger inn i anus og ber pasienten «knipe og trekke opp», uten at du i særlig grad kan kjenne at muskelen trekker seg sammen rundt fingeren.

☐ Ytre lukkemuskel (m. sphincter ani externus) består av tverrstripete muskulatur og er ikke viljestyrt. Når tykktarmbevegelser presser avføring inn i endetarmen, stimuleres trykkfølsomme sanseceller noe som automatisk vil åpne lukkemuskelen. Hvis du fører en finger inn i anus, trekker den ut og ser at åpningen «gaper», kan det bety unormalt slapp/skadet ytre lukkemuskel.

20. Når ventrikkelen (magesekken) er tom er den et hulrom som hos de fleste personer rommer mellom:

☐ 100 - 300 ml

☐ 50 – 150 ml

☐ 250 - 500 ml

21. Hva antas å være de <u>største</u> risikofaktorene for avføringsinkontinens blant pasienter på sykehjem?

☐ Forløsningsskader etter fødsler, overvekt, obstipasjon

☐ Kjønn (kvinner), ryggmargsskader, skader etter kreftbehandling

☐ Diare, redusert mobilitet, demens

22. Hvilke matvarer har en naturlig lakserende effekt?

☐Linser, nøtter, epler

☐Fiken, lakris og melasse

☐Yoghurt, blåbær og ingefær

23. Når du skal gjennomføre en eksplorasjon ved å føre en finger inn i pasientens endetarm, hvordan bør pasienten ligge under undersøkelsen?

☐På venstre side med lett bøyde knær og hofter

☐På høyre side med lett bøyde knær og hofter

☐På ryggen med bøyde knær og hofter

24. Du har sammen med pasienten kommet fram til at dere skal øke fiberinnholdet i kosten som tiltak mot obstipasjon. For god og trygg effekt må du i tillegg iverksette tiltak som sikrer:

☐At pasienten samtidig får økt mengde proteiner i kosten slik at tarminnholdet blir voluminøst og slik sikrer optimal effekt av økt fiberinnhold.

☐At pasienten samtidig får tilstrekkelig med væske slik at tarmen greier å nyttiggjøre seg effekten av økt fiberinnhold

☐At pasienten samtidig får økt mengde lettfordøyelige karbohydrater i kosten slik at tarmen greier å nyttiggjøre seg effekten av økt fiberinnhold.

25. Du skal administrere et avføringsmiddel som suppositorium (stikkpille). Hva kjennetegner korrekt administrasjon?

☐ Pasienten legger seg i venstre sideleie med lett bøyde knær mot brystet. Stikkpillen føres med en finger inn i anus og plasseres 3-4 cm inn i analkanalen. Ved avføring i analkanalen bør stikkpillen plasseres midt i avføringsmassen for best effekt.

☐ Pasienten ligger i høyre sideleie med lett bøyde knær mot brystet. Stikkpillen føres med en finger inn i anus og plasseres 5-7 cm inn i endetarmen. Ved avføring i endetarmen bør stikkpillen plasseres mest mulig midt i avføringsmassen for best effekt.

☐ Pasienten ligger i venstre sideleie med lett bøyde knær mot brystet. Stikkpillen føres med en finger inn i anus og plasseres 5-7 cm inn i endetarmen. Ved avføring i endetarmen bør stikkpillen plasseres inn mot tarmveggen for best effekt.

26. Under forutsetning om et vanlig kosthold vil mesteparten av avføringen bestå av:

☐ Ufordøyde matrester

☐ Avstøtte epitelceller og tykktarmsbakterier

☐ Defekte røde og hvite blodlegemer, samt avfallsprodukter fra proteinsyntesen.