

Development and Implementation of a Multilevel Intervention to Improve Pain Management in Swiss Nursing Homes

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List of abbreviations

BCW	Behavior Change Wheel
BPI	Brief Pain- Inventory
CFIR	Consolidated Framework of Implementation Research
CI	Confidence interval
COM-B	Capability Opportunity Motivation determine Behavior system
FTE	Full time equivalent
LPN	Licensed practical nurse
MDS	Minimum data set
NA	Nursing assistant
NH	Nursing home
ProQuaS	Identification and Development of Processes and interfaces to improve Quality of life in residents of Senevita
RAI	Resident assessment instrument
RN	Registered nurse
TDF	Theoretical Domains Framework

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Summary

Pain is a highly prevalent symptom in older people and particularly among nursing home residents. Under- or untreated pain can lead to severe physical and psychological consequences, such as impaired mobility, sleep disturbances and an increase of depressive symptoms. Despite the availability of evidence-based recommendations for the management of geriatric pain, pain management in nursing homes remains a persistent issue. Various barriers on the level of residents, care workers and the organizations have been reported to hinder adequate pain management. One critical aspect in this regard are common negative beliefs about pain and its management in older people, particularly in residents with cognitive impairment.

Previous studies to improve the adoption of evidence-based pain management in nursing homes showed mixed results. Yet, few studies have systematically investigated the factors contributing to the difficulties in implementation. Implementation science highlights the critical role of contextual factors in implementing new practices. Knowledge of the local hindering and facilitating factors towards the new practice, hence, is crucial to develop and select appropriate strategies to facilitate implementation and to help interpretation of varying implementation success.

The overall aim of this dissertation was to develop and implement a multilevel intervention to improve pain management in a group of Swiss nursing homes. Therefore, in the first phase, a comprehensive analysis of the implementation context, incorporating perspectives of care workers and residents was conducted. Based on these insights, in the second phase, a multilevel intervention and implementation strategies were developed and evaluated in a subsample of nursing homes.

This dissertation is embedded in the ProQuaS (Identification and development of interfaces and Processes to improve Quality of life of residents at Senevita) study, a three- years mixed-methods study focusing on potentially avoidable hospitalizations and pain management in nursing home residents. The ProQuaS project is conducted in the institutions of Senevita AG, a privately-owned nursing home group in Switzerland, with currently 26 institutions providing assisted-living and long-term care. This dissertation focuses on the pain management aspects of the overall project. Overall, this dissertation is structured in eight chapters. **Chapters 1 and 2** provide an overview of the topic and state the aims of this dissertation.

Chapter 1 provides a general introduction to the field of pain management in nursing homes, including an overview of the state of the science in pain management practice and interventions to improve pain management in NHs. Furthermore, a short introduction to principles of implementation science, the Swiss NH context in general and the ProQuaS project in specific, are provided. **Chapter 2** describes the aims of this dissertation.

The articles presented in **Chapters 3** and **4** constitute the findings of the contextual analysis, which has been conducted in the first phase of ProQuaS. **Chapter 3** reports a mixed-methods study, which integrated data of care worker surveys and focus group discussions to identify facilitating and hindering factors for pain management in nursing homes. The capability-opportunity-motivation determine behavior (COM-B) model was used to discuss implications for the selection and development of implementation strategies. Results from the questionnaire survey indicate, that lacking availability (60.9%) and application of non-pharmacological treatment (53.6%); reluctance of residents to report pain (51.1%) and lack of time for a comprehensive pain assessment (50.5%) are perceived to be the major barriers to pain management. Focus group discussions corroborated and extended the quantitative findings with facilitators, e.g., joint ward rounds with physicians, good knowledge of the resident, and further barriers, including high turnover and lacking established routines. The findings suggest that implementation strategies should aim at increasing pain management knowledge and foster motivational aspects to sustainable change in pain management practice, while at the same time factoring in contextual factors, such as high turnover.

Chapter 4 reports a qualitative study describing nursing home residents' perceptions of barriers and facilitators and their needs regarding pain management. We identified three central themes from the data: dealing with major life changes, managing pain, and using formal care. Overall, the interviews highlighted the multidimensionality of NH residents' pain experience and their corresponding needs. Participants perceived that care workers were not always able to respond adequately to these needs. Instead, participants indicated to have learned to cope with their pain using self-developed strategies and by directly consulting their physicians. These findings emphasize our findings of Chapter 3. Amongst others, strategies to improve pain management in nursing homes need to address prevailing attitudes and shortages in knowledge concerning pain

management in older people. Creating a common understanding of the biopsychosocial and spiritual dimensions of pain is crucial to enable the provision of person- centered pain management.

Chapter 5 comprises the study protocol of the second part of the ProQuaS study. It provides a detailed overview of the intervention and implementation strategies and the evaluation plan for the outlined hybrid II effectiveness- implementation study. Furthermore, the conceptual framework of ProQuaS is presented- highlighting potential associations between the intervention, implementation strategies, contextual/individual factors and outcomes. The conceptual model is based on the Consolidated Framework of Implementation Research (CFIR) and the Theoretical Domains Framework to provide a comprehensive understanding of facilitating and hindering factors. The intervention consists of a pain management guideline which has been derived from international recommendations to geriatric pain management and was adapted to the nursing homes' context in collaboration with a group of stakeholder from the participating nursing homes. The central implementation strategies are interactive training workshops for care workers of all levels and the training and introduction of pain champions on the participating wards. Additionally supporting strategies encompass preparatory and ongoing meetings with the nursing homes' leadership, adaptations of the residents' documentation software and the provision of cardboard pain assessment scales and printed copies of the pain management guidelines on the wards.

The articles presented in **Chapters 6** and **7** constitute the evaluation of the intervention and its implementation with regard to the residents and care workers. **Chapter 6** reports the effectiveness of the intervention on pain- related resident outcomes and the utility of implementation strategies with regard to the intervention's reach and acceptability. Using a quasi-experimental pre-post design with one pre- and two post- measures at three and six months after baseline, we could show that all pain-related resident outcomes improved over time. In a self-report subsample (n= 43), changes in intensity of average pain were significant at three months, and changes in intensity of worst pain were significant at three and six months. In addition, we looked at reach and acceptability of the intervention as perceived by care workers and found that about 76% of care workers were familiar with the guideline, 70.4% answered that the guideline is practical and correlates with their ideas of good pain assessment (75.9 %) and treatment (79.7 %). These findings

suggest, that our approach implementing a pain management guideline using interactive training workshops and introducing trained pain champions could partially improve residents' pain-related outcomes. However, a process evaluation will provide further insights into the underlying mechanisms and potential barriers of the implementation process.

Chapter 7 reports a quantitative process evaluation that explores the mechanisms of change related to our implementation strategies. Based on the conceptual framework of ProQuaS presented in **Chapter 5** we hypothesized that by conducting training workshops and introducing pain champions on the wards, we would increase care workers' self-efficacy in pain management. Furthermore, we hypothesized that self-efficacy in pain management is associated with adoption of the implemented pain management guideline. To test our hypotheses, we used data of the care worker questionnaire survey which was conducted at baseline, after three and six months. Our findings show that care workers' self-efficacy in pain management at three and six months was significantly higher compared to baseline. Self-reported adoption of the pain management guidelines was mixed, depending on the core component between 44% and 73%. We found significant associations between care workers' self-efficacy and adoption of two core components: 'conducting a comprehensive assessment' and 'use of PAINAD'. There were no significant associations with the components 'documentation' and 're-evaluation', though. These findings suggest that our strategies might have increased care workers' self-efficacy, however with regard to adoption, self-efficacy might not be the only contributing factor. Documentation and re-evaluation of residents' pain after (non-)pharmacological treatment might rather depend on memory processes. Our findings emphasize the importance of continuous commitment of internal facilitators, e.g., pain champions, to drive implementation efforts.

Chapter 8, ultimately synthesizes and discusses major findings of all studies in the context of the literature. Furthermore, strengths and weaknesses of the studies are discussed, and implications for future research and practice are presented. This dissertation contributes to the current literature in the field of pain management in nursing homes by using implementation science principles and behavioral theory to improve understanding of implementation challenges. Translation of this knowledge is facilitated by the detailed description of the local context, including determinants of change in pain management, on the one hand and the implementation strategies on the other hand.

Chapter 1

Introduction

1.1 Introduction

Pain is a distressing symptom which is highly prevalent among nursing home (NH) residents. Under- or untreated pain can result in a number of health consequences, such as impaired mobility and functioning, sleep disturbances, increased anxiety or depression (Scudds & Robertson, 2000; Smith et al., 2016). NH residents with cognitive impairments, such as dementia, are particularly at risk to suffer from under-recognized and –treated pain due to their inability of communicating pain (de Souto Barreto, Lapeyre-Mestre, Vellas, & Rolland, 2013). Over the last decades, several evidence-based guidelines for the management of pain in older people were developed (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2009; Fischer, 2014). However, a gap between these recommendations and NH practice is evident (Jablonski & Ersek, 2009; Lukas et al., 2013). Contextual factors in NHs, such as high turnover rates and low skill-grade mix of the care workers constitute general challenges to the implementation of guidelines and practice change. Shortfalls in care workers' pain management knowledge and negative beliefs towards pain in the elderly are some of the barriers known to hinder effective pain management in NHs (Kaasalainen et al., 2010). The overall aim of this thesis was to develop and test a contextually adapted implementation intervention to improve pain management in Swiss NHs.

1.2 Pain in older people

1.2.1 Prevalence and sources of pain in older people

Pain is a common symptom in older people, between 25 – 75% of older, community-dwelling people (>65 years) report pain (Patel, Guralnik, Dansie, & Turk, 2013; Thomas, Peat, Harris, Wilkie, & Croft, 2004). Prevalence of pain in NH residents tends to be higher since they are commonly a fragile subgroup of the general elderly population. Depending on the data source and assessment instrument, 40- 85% of NH residents report pain (Hunnicutt, Ulbricht, Tjia, & Lapane, 2017; Takai, Yamamoto-Mitani, Okamoto, Koyama, & Honda, 2010). Data on self-reported pain from Switzerland suggests that about 60% of NH residents have pain (Sommerhalder et al., 2015). Many studies indicate that the overall prevalence of chronic pain increases in populations with higher age (Helme & Gibson, 2001; Thomas et al., 2004). This can partly be explained by the higher prevalence of chronic conditions in this population group in general. Many age-related

health conditions, such as degenerative joint and spine diseases, but also neurological diagnoses can result in chronic manifestations of pain (Ferrell, Ferrell, & Osterweil, 1990; Thomas et al., 2004). A further highly prevalent condition in older people is cancer, here, the tumor itself or the cancer treatment can also lead to complex and chronic pain (Ferrell, Ferrell, & Rivera, 1995). Another reason of complex pain situations with high relevance in the older population, are end-of-life situations.

In general, pain can be categorized with regard to its source. On the one hand there is nociceptive pain, which “arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors” (International Association for the Study of Pain, 2017). On the other hand, neuropathic pain is “caused by a lesion or disease of the somatosensory nervous system” (International Association for the Study of Pain, 2017). Depending on the location of the lesion or disease it can be further specified into central and peripheral neuropathic pain. Figure 1 displays an overview of the common pain types and conditions in older people.

- Nociceptive – somatic: arthritis, gout, chronic low back pain, thermal (cold or heat) burns, pressure ulcers and wounds, skin rashes, fractures
- Nociceptive – visceral: pleurisy, diverticulitis, constipation, gastrointestinal ulcers
- Neuropathic – central: phantom limb pain, post-stroke pain syndrome
- Neuropathic – peripheral: diabetic neuropathy, shingles, post-herpetic neuralgia
- Mixed and undetermined: cancer, fibromyalgia, polymyalgia, rheumatic, headaches, mental health disorders (e.g., depression, posttraumatic stress disorder)

Figure 1: Common pain types and conditions in older adults based on Booker and Herr (2016)

1.2.2 Pain definitions, concepts and influencing factors

The International Association for the Study of Pain (IASP) defines pain as an “unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (International Association for the Study of Pain, 1979). With regard to its duration and underlying physiology, pain can be divided into acute or chronic. Acute pain is an indicator

of potential tissue damage, alerting the person to pay attention to the cause of pain and to protect the affected body part in order to prevent further damages (Lumley et al., 2011). Chronic or persistent pain on the other hand is defined as pain that “extends beyond the expected period of healing” (Turk & A., 2001). The alerting function is of less or no importance and the underlying physiology has completely changed due to structural changes in the brain.

The experience of pain is highly subjective and can be influenced by a broad range of factors beyond physical aspects. Previous research has established that psychological factors, the sociocultural background, attitudes, expectations and the individual meaning of pain can have an influence on the individual experience of pain (Turk & Okifuji, 2002). To embrace the subjectivity of pain experience in daily health care practice, McCaffery and Pasero (1999) proposed the following definition: “Pain is whatever the experiencing person says it is, existing whenever the experiencing person says it does”.

In this context, the concept of “total pain”, describes an individual experience stemming from the combination of emotional, psychosocial and spiritual elements which can manifest in physical pain (Mehta & Chan, 2008). This holistic concept was coined by Cicely Saunders in the context of end-of life care, but it can also be extended to the chronic pain experience of older people. The different domains of total pain have been emphasized in several qualitative studies capturing older persons’ experiences with chronic pain (Gran, Festvåg, & Landmark, 2010; Higgins, 2005; Vaismoradi, Skär, Söderberg, & Bondas, 2016). Acknowledging the concept “total pain” has important implications for pain management in older people. A comprehensive assessment of all dimensions of pain is key to successfully manage the individual pain situation. NH care workers need to be aware of the multidimensionality of pain and consider all relevant dimension in the residents’ care. An overview of the biopsychosocial dimensions related to pain is displayed in Figure 2.

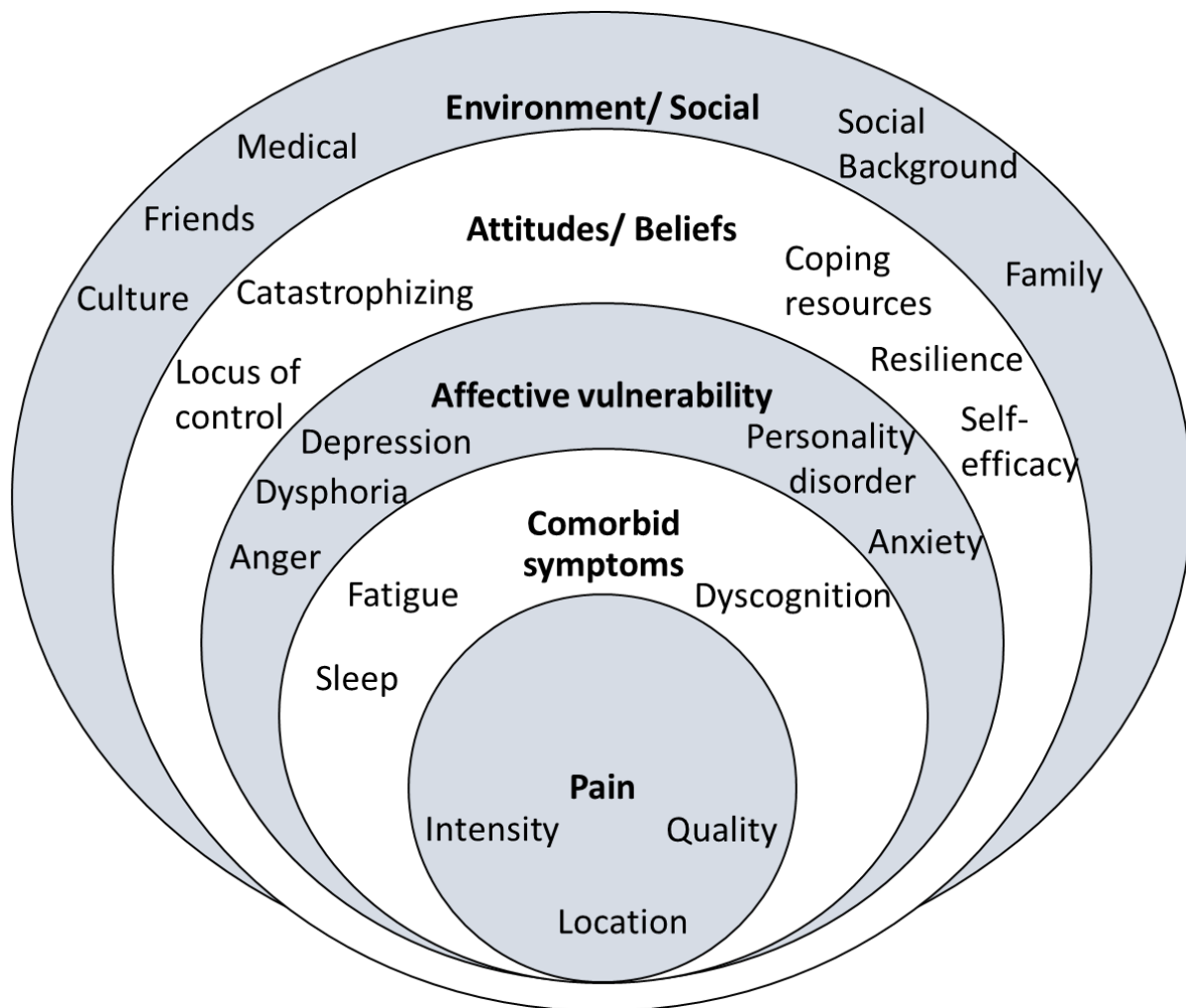


Figure 2: Overview of pain dimensions and influencing factors adapted based on Williams (2013)

1.3 Pain management in older people

Internationally, a range of guidelines for the management of pain in older adults have been developed (Abdulla et al., 2013; Fischer, 2014). Besides specific guidelines focusing on the pharmacological management of pain (American Geriatric Society Panel on Persistent Pain in Older Persons, 2009), interdisciplinary guidelines for pain management in nursing homes (Wulff et al., 2012) have been developed. In Switzerland, however no national guideline for the management of geriatric pain exists. The following two chapters give a broad overview of recommendations for pain assessment and treatment in NH residents.

1.3.1 Pain assessment

In general, the assessment of pain is a responsibility of all health care staff who are in contact with the resident. The consequent and timely reporting and documentation of pain- related outcomes provides basis for clinical decision-making and optimizing care for residents with pain (Hadjistavropoulos et al., 2007).

To gain an in-depth understanding of residents' individual pain situations, a comprehensive pain assessment should be conducted shortly after NH admission if pain is present, or later at the onset of new pain. The comprehensive assessment should comprise questions on general pain characteristics e.g., the duration, intensity, quality and location of the pain as well as precipitating and relieving factors (e.g., how efficient is the current treatment?). Further questions should assess how pain interferes with physical and psychosocial functioning. Additionally, attitudes and beliefs towards pain, former experiences with pain and its treatment as well as individual self-management strategies should be assessed (American Geriatric Society Panel on Persistent Pain in Older Persons, 2002).

In addition to a comprehensive assessment in residents with pain, it is essential that pain is reassessed on a regular base to monitor the pain situation and if necessary, adapt the treatment plan in a timely manner (Herr & Garand, 2001). Since pain is a highly subjective experience, the gold standard is to obtain the person's self-report of pain whenever possible (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2002).

With regard to measuring pain intensity in older adults with no to mild cognitive impairment, the use of the Verbal Descriptor Scale (a six-point scale providing verbal description of pain) or the Numeric Rating Scale (11-point scale, providing numbers from 1- 10 with two anchors: no pain/ worst pain) is recommended (Herr, Spratt, Mobily, & Richardson, 2004; Kang & Demiris, 2018). In older adults with mild cognitive impairment, the use of assessment instruments should be adapted by asking only about current pain instead of past values. Further, it might be necessary to explain the scale with easy language and give adequate time to answer (American Geriatric Society Panel on Persistent Pain in Older Persons, 2002).

To systematically assess pain behavior in cognitively impaired people, a range of behavioral observational assessment scales, such as the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) (Fuchs-Lacelle & Hadjistavropoulos, 2004) or the Pain

Assessment in Advanced Dementia (PAINAD) (Warden, Hurley, & Volicer, 2003) are recommended. These assessment tools provide a list of behavioral cues which are likely to indicate pain, e.g. concerning breathing, negative vocalization, facial expression or body language. Assessment of pain by observation should only be considered if lacking ability to communicate or impaired cognitive capacity restrain the person to self- report his/her pain.

1.3.2 Pain treatment

To increase quality of life for residents with chronic pain, comfort goals for the pain management should be established to enable and facilitate functioning and participation in daily activities (American Geriatric Society Panel on Persistent Pain in Older Persons, 2009). With regard to the complexity of chronic pain situation, a combined approach, incorporating pharmaceutical, psychological and non-pharmaceutical measures is most often recommended (Herman, Johnson, Ritchie, & Parmelee, 2009).

For the pharmaceutical treatment of chronic pain a stepwise approach is recommended. In this regard, the WHO ladder is a well- established treatment concept for malignant pain (World Health Organization, 1986). Depending on the underlying cause of pain, the WHO ladder can also be applied to the treatment of geriatric pain. However, special attention should be paid to the increased risk of side effects in the geriatric population due to changes in pharmacokinetics and pharmacodynamics (Kaye, Baluch, & Scott, 2010). In particular the use of opioids must be critically reviewed due to the high risk of adverse events. In an overview of Cochrane reviews that included 16 reviews of different opioid agents administered in chronic non-cancer pain, the authors found that the absolute event rate of experiencing any adverse event was 78 % compared to placebo treatment. The absolute event rate of experiencing any serious adverse event was 7.8% (Els et al., 2017). Because of its good safety profile, acetaminophen therefore is considered as the initial and ongoing medication of choice in the elderly population (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2009). In neuropathic pain the use of antidepressants has been recommended in a comprehensive systematic review and meta-analysis (Finnerup et al., 2015).

With regard to the non- pharmacological approaches, the American Geriatric Society recommends two categories of interventions: physical and psychological approaches (American Geriatric Society Panel on Persistent Pain in Older Persons, 2002). Physical interventions include the

application of cold or hot treatments, massage and positioning. Although the physical effects, such as improved blood circulation and alleviation of muscle tension are only temporary, physical interventions can also affect the psychosocial level by stimulating the senses and providing personal attention to the person (McFeeters, Pront, Cuthbertson, & King, 2016; Sansone & Schmitt, 2000). Besides passive strategies, active approaches such as participation in regular physical activity and physical therapy aimed at improving flexibility, strength, and endurance are known to reduce pain and enhance the functional capacity of older adults with chronic pain (Ettinger, Jr, Burns, Messier, & et al., 1997; Simmons, Ferrell, & Schnelle, 2002). Psychological approaches include two types of interventions: Provision of information about pain and pain management on the one hand and distraction from the pain on the other hand (Ferrell, Rhiner, & Ferrell, 1993; Moseley, 2004).

Beyond interventions on the individual level, close inter-professional collaboration between care workers, therapists and physicians is key for an effective pain management in NH residents (Wulff et al., 2012). Furthermore, the inclusion of pain- and other specialists should be discussed where appropriate (Wulff et al., 2012).

1.4 Challenges to pain management in nursing homes

Pain management in NHs involves a range of stakeholders, including residents, their families, care workers and physicians. Further it depends on system and organizational factors, including the availability of national pain management guidelines and staff characteristics of NHs. Challenges arise from high turnover rates of nursing staff resulting in fluctuating pain management knowledge and lack of stability in the care worker-resident relationship. On the other hand, a grade mix with generally high proportions of low qualified nursing assistants, who receive basic care training that does not cover pain management, can be an additional challenge for adequate assessment and treatment of NH residents' pain (Burla, Vilpert, & Widmer, 2014).

Beyond contextual factors on the system and organizational level, there are also barriers related to the different stakeholders involved in pain management. Beginning with the residents, attitudes towards pain and medication often impede an accurate pain assessment and adequate treatment (Rodriguez, 2001). A common believe among older people is that having pain is normal for older

adults, therefore they tend to underreport pain (Hadjistavropoulos et al., 2007). A further challenge for pain assessment and effective treatment is the prevalence of severe cognitive impairment in NH residents (Martin, Williams, Hadjistavropoulos, Hadjistavropoulos, & MacLean, 2005). Barriers on the health care staff level also include outdated attitudes towards pain, e.g., that people with dementia feel less pain, fear of residents' addiction to pain medication and lacking knowledge in the management of pain in older people (Jones, Fink, Pepper, et al., 2004; Jones, Fink, Vojir, et al., 2004; Tousignant-Laflamme et al., 2012). Further barriers can result from the interfaces between stakeholders (e.g. care workers and physicians). Interdisciplinary collaboration is an essential requirement for pain management, but also a source of difficulties due to communicational barriers on the other hand (Kaasalainen et al., 2010). For example, physicians are often located off-site the NHs, prolonging communication ways with the nursing staff and residents. In light of the wide range of barriers, a comprehensive approach involving the perspectives of all stakeholders is necessary to improve conditions for an effective pain management.

1.5 Interventions to improve pain management in NHs

The body of evidence regarding effective pain management interventions in nursing homes is limited in its quantity. Moreover, it substantially lacks high-quality studies. A recent systematic review identified 24 prospective, controlled studies on pain management (Knopp-Sihota, Patel, & Estabrooks, 2016). Studies included in the review comprise interventions focusing on non-/analgesic treatment or system modification and purely educational interventions. No clear evidence for specific interventions could be established, since interventions often comprised multiple strategies, making comparison more difficult. Similar results were reported in an earlier systematic review of prospective intervention studies and a literature synthesis about processes of pain care in NHs (Herman et al., 2009; Swafford, Miller, Tsai, Herr, & Ersek, 2009).

Overall, approaches to improve pain in NH residents can broadly be categorized into treatment approaches on the resident level and organizational approaches to improve NHs' pain management practice. Interventions focusing on treatment approaches look at different pharmacological and non-pharmacological approaches to alleviate pain in NH residents. Generally, these studies focus on testing efficacy of the treatment approaches. For example, one RCT showed a significant

reduction of pain and agitation in NH residents with moderate and severe dementia by an 8-week stepwise pharmacological treatment which was individually tailored based on a physical examination of the resident by a team of pain specialists (Husebo, Ballard, Fritze, Sandvik, & Aarsland, 2014).

Organizational approaches to improve pain management often involve a range of different strategies targeting one or several determinants of care workers' behavior, such as knowledge or memory. Several studies investigated the effect of educational training strategies on care workers' pain management knowledge (Drager et al., 2017; Gagnon, Hadjistavropoulos, & Williams, 2013; Jones, Fink, Pepper, et al., 2004). Not surprisingly, training strategies that use interactive approaches and extend over several sessions have been more effective in improving care workers' knowledge than solely lecturing.

Other studies investigated interventions to improve decision support in pain management, such as pain management algorithms or pain protocols (Ersek et al., 2016; Hadjistavropoulos et al., 2016; Kaasalainen et al., 2012). To facilitate the uptake of the respective tools, a range of strategies, such as printed educational material, reminder, training workshops and internal facilitators e.g., a pain team or champions have been used in the abovementioned studies. Due to the multitude of strategies used and limited comparable studies it remains unclear to which extent the interventions were effective and the strategies useful. With regard to pain-related resident outcomes, these studies did not show significant improvement. However, findings related to practice behavior e.g., use of standardized pain assessment tools, number of reported pain assessments, showed positive trends and partly significant improvements (Ersek et al., 2016; Hadjistavropoulos et al., 2016; Kaasalainen et al., 2012).

In comparison to that, one recent Canadian study tested the introduction of a nurse practitioner and a pain team in comparison with the introduction of a nurse practitioner on consultative base only. The authors could show significant improvements in pain-related resident outcomes and pain management practice behaviors in both groups compared to usual practice (Kaasalainen et al., 2016). This study was by far the most promising approach with regard to the improvement of outcomes, however introducing a nurse practitioner might not be a feasible strategy in every setting.

The body of literature further contains studies focusing on quality improvement approaches, such as audit and feedback based on pain-related quality indicators and PDCA- cycles (plan- do- check- act) aiming at pain management (Baier et al., 2004; Horner, Hanson, Wood, Silver, & Reynolds, 2005). Many studies using quality improvement approaches focus solely on the organizational level and base their evaluation on quality indicators. However, in these studies it remains unknown how and to which extent the approaches were implemented in the different NHs and which changes occurred on the care workers' level.

Overall, only few studies reported a theoretical base for its development of strategies, or reported contextual factors that would facilitate translation of the strategies to other settings, respectively. To conclude, there is only weak evidence in favor of specific strategies to improve pain management in NHs. To advance the field of pain management in NHs, it is necessary to gain an understanding of which and how contextual factors influence the success of implementation. Therefore more rigorous approaches building on a strong theoretical base are needed.

1.6 Implementation science

Implementation research can be defined as “the scientific inquiry into questions concerning implementation - the act of carrying an intervention into effect, which in health research can be policies, programs, or individual practices (collectively called interventions).” (Peters, Adam, Alonge, Agyepong, & Tran, 2013). In contrast to clinical studies, which strive to maximize internal validity, implementation research works with and in “real world” conditions. The overall objective of implementation science hence, is to bridge the gap between research evidence and everyday practice. To facilitate this process, this discipline is characterized by involvement of all relevant stakeholders and contextual adaptations of existing interventions. Implementation science uses a broad range of research designs to explore what kind of interventions work where and why (Bauer, Damschroder, Hagedorn, Smith, & Kilbourne, 2015).

1.6.1 Key elements of implementation research

The implementation context plays a central role with regard to the effectiveness of an intervention in the real world. Knowledge about the local barriers and facilitators is key to inform the selection, development, tailoring and adaption of appropriate implementation strategies. A comprehensive

contextual analysis in the planning phase can provide important insights into the implementation context. Furthermore, knowledge about contextual factors is essential to interpret finding from the implementation and to inform scale up in other settings (Grimshaw, Eccles, Lavis, Hill, & Squires, 2012).

Implementation strategies are “methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice” (Proctor, Powell, & McMillen, 2013, p. 2). They comprise the active ingredients of the implementation process and therefore should be tailored to the needs of a specific context (Powell et al., 2017). Overall, there is a wide range of discrete implementation strategies, such as provision of educational material or audit and feedback (Powell et al., 2015). According to the intervention and the specific context, several discrete strategies can be combined into an overall implementation strategy.

Since the success of implementation is central with regard to the effectiveness of an intervention, evaluation approaches should expand beyond measuring service and patient outcomes and include so called implementation outcomes. They serve as indicators of the success of the implementation efforts. Frequently measured outcomes are, e.g., acceptability (stakeholders’ shared approval of the intervention), feasibility (stakeholders appraisal of intervention’s practicability) and fidelity (degree to which an intervention was implemented as intended) of an intervention (Proctor et al., 2011). Study designs that combine the evaluation of an intervention’s effectiveness and the utility of implementation strategies are called hybrid effectiveness- implementation designs. Depending on the evidence base of the tested intervention, there are three types of hybrid designs with different foci of evaluation: in a hybrid type I design, interventions’ effectiveness is primarily tested and few implementation outcomes are assessed; a hybrid type II design concurrently assesses the effectiveness of the intervention and utility of implementation strategy, in hybrid type III designs on the other hand, effectiveness of the intervention is a prerequisite and therefore the main focus lies in testing and comparing the utility of different implementation strategies (Curran, Bauer, Mittman, Pyne, & Stetler, 2012).

1.6.2 Implementation frameworks

To inform and guide the different phases of implementation research, i.e., planning, designing, implementation and evaluation, a multitude of implementation frameworks have been developed and published over the last decade. In 2012, a systematic review has identified about 61 different

frameworks and models for implementation and dissemination (Tabak, Khoong, Chambers, & Brownson, 2012). These can broadly be categorized into (a) process frameworks for describing and guiding the processes of implementation; (b) determinant frameworks, which are supposed to increase the understanding of influences on implementation and (c) evaluation frameworks, that guide the evaluation of the implementation processes (Nilsen, 2015).

This thesis will focus on three frameworks/models in particular: The Consolidated Framework of Implementation Research (CFIR) (Damschroder et al., 2009), the Theoretical Domains Framework (TDF), both determinant frameworks and the Capability, Opportunity and Motivation determine Behavior system (COM-B), a behavioral model (Michie et al., 2011).

The CFIR is a “meta- theoretical” framework that synthesizes several theories from the field of implementation, dissemination and organizational change into a list of 39 constructs. The constructs that potentially influence implementation, can be grouped into five domains: inner setting, outer setting, characteristics of individuals, the intervention and the process by which implementation is accomplished (Damschroder et al., 2009). An overview of the domains and constructs of CFIR is displayed in Figure 3 (below). With regard to its comprehensiveness, the CFIR provided overall guidance to the conceptualization and development of the different phases of implementation in ProQuaS. Furthermore, the domains ‘inner setting’, ‘outer setting’ and ‘characteristics of individuals’ provided the basis for the collection of contextual data in both parts. The TDF originates from a synthesis of 33 theories of behavior change and consists of 14 domains. They depict potential influences on changing behavior and comprise the following theoretical concepts: Knowledge, Skills, Memory, Attention and Decision Processes, Behavioral Regulation, Social Influences, Environmental Context and Resources, Social/ Professional Role & Identity, Beliefs about Capabilities, Optimism, Beliefs about Consequences, Intentions, Goals, Reinforcement and Emotion (Cane, O’Connor, & Michie, 2012). The TDF has been used in several studies to analyze determinants of behavior change in health care professionals (Huijg et al., 2014; Squires et al., 2019). Furthermore, a range of studies reported a combined use of CFIR and TDF in implementation studies (Birken et al., 2017). In the context of ProQuaS, we used the TDF to complement the CFIR with constructs on the individual level to enable a comprehensive overview of influencing factors in the second part.

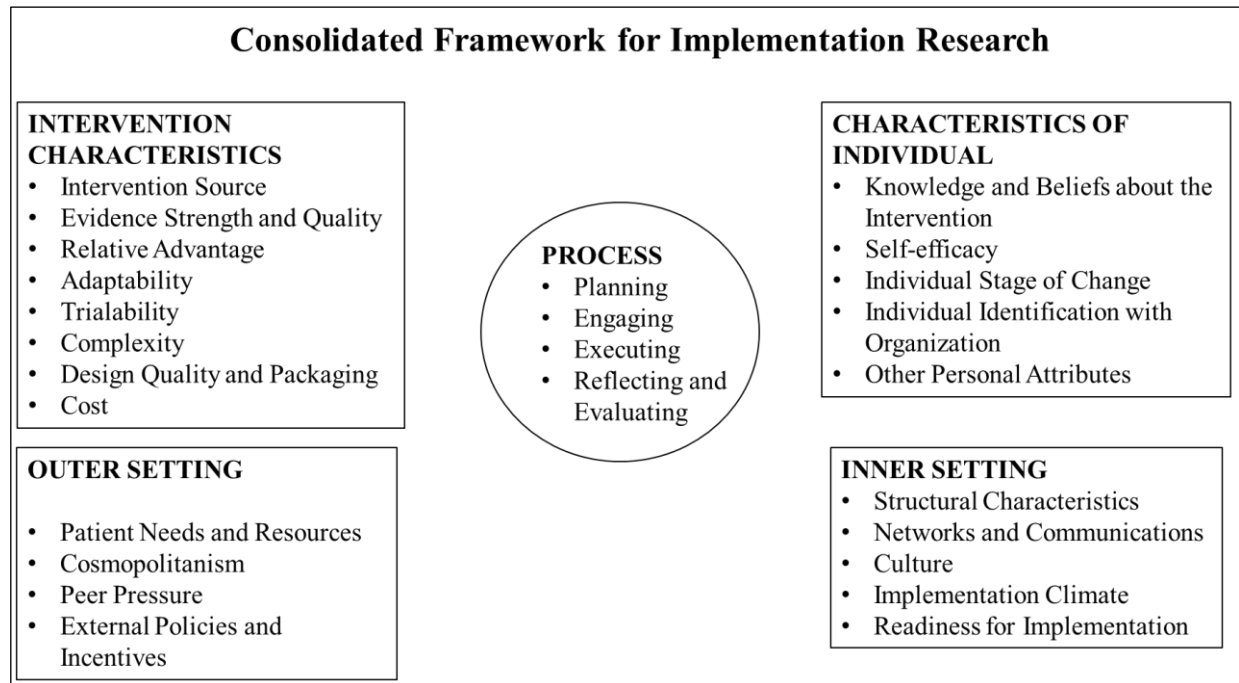


Figure 3: Consolidated Framework for Implementation Research adapted based on Damschroder et al. (2011)

The COM-B model is a model of behavior which has been derived from previous behavior change models and depicts the interactions between its three components (capability, opportunity and motivation) and their mutual influence on the performance of a behavior (Michie et al., 2011). The basic idea behind the model is that to change a specific behavior, at least one of the model's components needs to change (Michie, Atkins, & West, 2014). The COM-B model is linked to the behavior change wheel, a broader classification system for the development of behavior change interventions (see Figure 4 below). The behavior change wheel itself consists of a layer of nine broad intervention functions (e.g., persuasion, education) that are likely to promote change, as well as seven policy categories (e.g., regulation, service provision) linkable to the COM-B model (Michie et al., 2014). The behavior change wheel and COM-B model have been applied successfully in a multitude of settings and on multiple levels, e.g., individual, organizational and system levels (Ayakaka et al., 2017; Steinmo et al., 2016). The COM-B model and behavior change wheel were primarily used in the first part of ProQuaS to inform the development of our implementation strategies. First, we used the COM-B model to identify determinants for behavior

change in pain management. In a next step, we used this information to select appropriate intervention functions from the behavior change wheel.

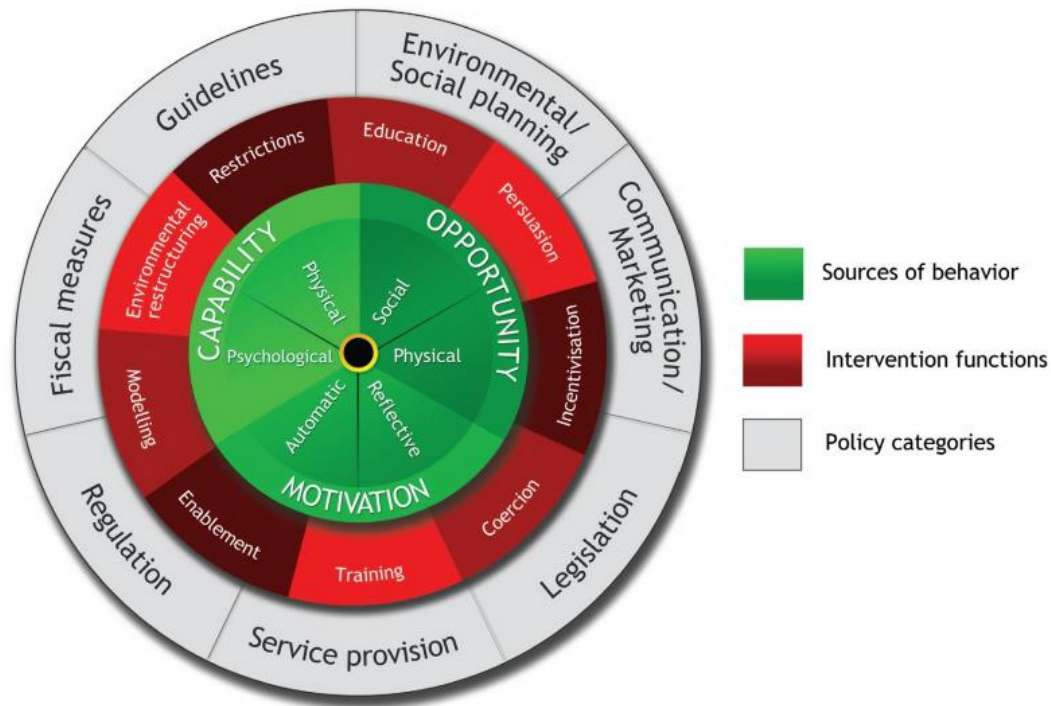


Figure 4: Overview of the Behavior Change Wheel and COM-B model (inner wheel) (Michie, van Stralen, & West, 2011)

1.7 The Swiss context and the ProQuaS study

As highlighted in the previous chapter, knowledge of the local contextual factors is central for successful implementation. The following two sub-chapters describe the general Swiss NH setting and details about the backdrop of this dissertation, the ProQuaS (Identification and development of interfaces and Processes to improve Quality of life of residents at Senevita) study.

1.7.1 Swiss nursing home context

Overall, in the 26 cantons of Switzerland there are about 1560 NHs with an average capacity of 62 beds. Less than half, 707 NHs, are privately-owned, some of which are organized in larger groups associated with a private institution (Swiss Federal Office of Statistics, 2017). The workforce in Swiss NHs constitutes about 30% registered nurses, 40% licensed practical nurses and 30%

unqualified health care workers, i.e. nursing aides (Merçay, Burla, & Widmer, 2016). The number of nurse practitioners in Switzerland is generally small and currently no nurse practitioner is employed in a NH (Maier & Busse, 2017). The scarcity of highly qualified nursing staff in the NH sector highlights the need for new and alternative approaches to facilitate the implementation of new practices e.g., guidelines.

Due to the federal organization of the health sector in Switzerland, there is no standardized system for collaborations between NHs and physicians. In most cantons NH residents have the right to choose a responsible physician at their admission to a NH and many keep their family physicians. Therefore, it is common in many Swiss NHs to collaborate with several physicians, which often leads to challenges in care worker – physician communication, since not all physicians are visiting on a regular base. However, other NHs have an institutional physician who is responsible for most or all residents, depending on the canton and NH policy. Institutional physicians can have regular ward rounds, which is a major facilitator for communication processes and inter-professional collaboration.

1.7.2 ProQuaS study and Senevita AG

This dissertation is embedded in the ProQuaS study (Identification and development of interfaces and Processes to improve Quality of life of residents at Senevita). The ProQuaS study is conducted within the Senevita AG, a privately-owned group of 26 NHs in the German-speaking part of Switzerland (as at 12/2018). The associated NHs are located in eight different cantons and have an average capacity of 43 beds (ranging from 11-116 beds). Further, the Senevita AG is part of the Orpea group, a large European operator with long-term facilities in eight European countries.

In 2015, the former CEO of Senevita AG contacted the Institute of Nursing Science, University of Basel concerning a project to improve pain management in their associated NHs. On basis of a proposal outlining the ProQuaS study, Senevita AG agreed that all associated NHs would participate in the data collection of the first phase and a subsample would engage in the implementation of the ProQuaS intervention. In addition, Senevita AG agreed to establish a ProQuaS sounding board that would meet on a regular base, i.e., quarterly. Members of the sounding board were all employed by Senevita AG and hold a position in different NHs: two nursing assistants, one registered nurse, one director of nursing, one NH administrator, and one regional manager.

The sounding board meetings were moderated by members of the ProQuaS research group and project-related topics were discussed, such as general processes and structures of NHs related to pain management, comprehensibility of questionnaire items and first results. After termination of the first phase, the composition of the sounding board changed and included the local responsible persons of the four participating NHs, mostly directors of nursing and one NH administrator, and one to two persons from Senevita AG management.

The ProQuaS study comprised two parts which are described below, an overview of the study is displayed in Figure 5.

Part 1: Contextual analysis: multi- center, cross sectional study in all 20 NHs belonging to the Senevita group at that time:

- Quantitative data collection (June- August 2016): Questionnaire survey of care workers, ward managers and NH administrators focusing on the topics pain management, potentially avoidable hospitalizations, work environment, structures and processes of wards and NHs.
- Qualitative data collection (October- December 2016): semi-structured individual interviews with residents, focus group interviews with care workers and semi- structured telephone interviews with physicians collaborating with participating NHs. Focus of the interviews were the perception of barriers and facilitators of pain management.
- Theoretical basis for the data collection was the CFIR to gain a comprehensive understanding of the contextual factors with regard to pain management.

Part 2: Development and implementation of a pain management intervention: multi-center implementation- effectiveness study (hybrid 2) in 4 NHs of Senevita AG

- Contextual adaption of international pain management guidelines for the development of a facility guideline;
- Development and tailoring of implementation strategies based on the findings of Part 1 using the COM-B model and the behavior change wheel: interactive training workshops for care workers and introduction and training of pain champions in the NHs;
- Quantitative data collections pre- implementation, after three and six months (November 2017- November 2018): pain- related resident outcomes, process and implementation outcomes at the care worker level;

- Qualitative data collections after three and six months (March 2018- November 2018): Focus group interviews with care workers and semi- structured interviews with pain champions focusing on implementation outcomes, barriers and facilitators of implementation.

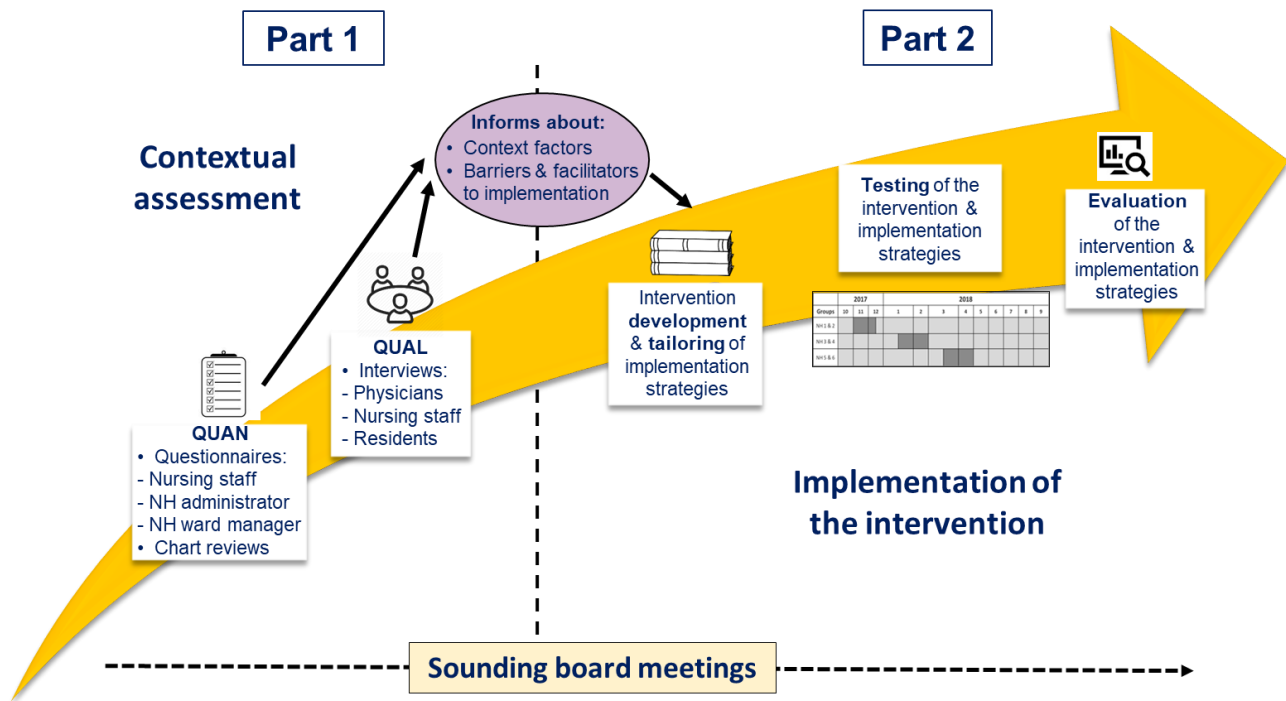


Figure 5: Overview of the ProQuaS study

1.8 Research gap and rationale for this dissertation

Pain management in nursing homes is a complex undertaking regarding the high prevalence of persistent pain and severe cognitive impairment in NH residents. Despite the availability of international guidelines for the management of geriatric pain, adoption into NH practice remains insufficient. In consideration of the high numbers of NH residents reporting pain and the negative consequences of under- or untreated pain, it is crucial to improve pain management practice in NHs.

As shown above, the body of literature dealing with pain management interventions in older people is limited in its quantity and quality. A range of approaches were tested in different settings using more and less rigorous designs. Lacking clarity in the description and evaluation makes it difficult to directly compare effectiveness and utility of implementation approaches. Overall, only few studies could show clear improvements in pain-related resident outcomes. The most promising approach builds on the use of nurse practitioner as champions to facilitate change in pain management. However with regard to the Swiss NH setting, nurse practitioner are not available, therefore innovative approaches accounting for this shortage are needed. Furthermore, to advance the field of pain management in NHs it is crucial to increase our understanding of which strategies work how and why with regard to improving pain management, calling for comprehensive evaluation approaches.

Implementation science highlights the importance of considering the implementation context with regard to the intended practice change. A preparatory contextual analysis therefore is pivotal to gain an understanding of barriers and facilitators of the target practice. This knowledge provides a basis for development and selection of appropriate interventions and implementation strategies. Since a sustainable improvement in pain management practice requires a change in the care workers' behavior, models and theories of behavior change can provide useful guidance.

To our knowledge, no study has investigated pain management in NHs from a behavioral perspective involving principles of implementation science. This dissertation will contribute to the understanding of barriers and facilitators of pain management from the perspective of care workers and residents with pain. Further, it will extend the knowledge base for effective implementation strategies in Swiss NHs. Given the extensive description of contextual factors, findings of this dissertation can also be applied to comparable NHs internationally.

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Chapter 2

Study aims

This dissertation includes the following aims:

- (I) To generate a comprehensive understanding of barriers and facilitators of pain management in nursing homes from the perspectives of care workers (**Chapter 3**)
- (II) To explore nursing home residents' perceptions of barriers, facilitators and needs with regard to pain management (**Chapter 4**)
- (III) To present a protocol for evaluating an implementation- effectiveness study to improve pain management in nursing homes by addressing behavior change of the care workers (**Chapter 5**)
- (IV) To evaluate the effectiveness and implementation of a pain management guideline in nursing homes using training workshops for care workers and training and introduction of pain champions. (**Chapter 6**)
- (V) To explore the underlying mechanisms and processes of the implementation strategies (training workshops for care workers and training and introduction of pain champions), using behavioral theory (**Chapter 7**)

Chapter 3

A Contextual Analysis to Explore Barriers and Facilitators of Pain Management in Swiss Nursing Homes

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3.1 Abstract

Purpose: As part of a contextual analysis, this study aimed to generate a comprehensive understanding of barriers and facilitators to pain management in nursing homes to identify potential leverage points for future implementation studies.

Design: An explanatory sequential mixed-methods study embedded in a cross-sectional study in 20 Swiss nursing homes (data collection: July- December 2016)

Methods: Quantitative data were collected via care worker questionnaire surveys comprising 20 items assessing perceptions of barriers to pain management. Descriptive statistics were computed. In the subsequent qualitative strand we conducted four focus group discussions with care workers (registered nurses, licensed practical nurses and nursing aides) using a knowledge-mapping approach. Findings of both strands were merged and mapped onto domains of the COM-B system, a model for behavior, to identify determinants for behavior change.

Findings: Data from 343 completed care worker surveys (response rate 67.3%) and four focus groups with care workers were analyzed. Items rated most problematic were: Lacking availability (60.9%) and application of non-pharmacological treatment (53.6%); reluctance of residents to report pain (51.1%) and lack of time for a comprehensive pain assessment (50.5%). Focus groups partly corroborated quantitative findings and complemented them with facilitators, such as close collaboration with physicians and further barriers, e.g. organizational factors, such as high turnover and a lack of established routines in pain management.

Conclusions: Our approach using a behavioral model highlighted a need for implementation strategies that improve pain management knowledge and focus on motivational aspects to establish new routines and habits related to pain management among care workers.

Clinical Relevance: Our findings suggest that future approaches to improve pain management in nursing homes should go beyond provision of education and training. To establish new practices or adapt existing ones, a more complex approach e.g., introduction of external or internal facilitators, is necessary to influence motivation and ultimately change behavior.

Keywords: COM-B, Mixed-methods, Nursing home, Pain management

3.2 Background

The prevalence of untreated and undertreated pain in nursing home (NH) residents is high: 40–85% of residents report pain (Takai, Yamamoto-Mitani, Okamoto, Koyama, & Honda, 2010). Poorly treated pain impacts quality of life, increases depressive symptoms and limits functional capabilities, leading to higher care demands (Smith et al., 2016). In recent decades, international expert panels have developed evidence-based guidelines for pain management in older people (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2009). However, passive dissemination of guidelines alone does not result in practice changes of pain management (Grimshaw, Eccles, Lavis, Hill, & Squires, 2012). To overcome the gap between recommended and actual practice, a comprehensive approach, using implementation strategies that target behavior change of health professionals, is recommended (Powell et al., 2017).

Previous studies have identified a range of barriers to pain management: At the organizational level, a lack of pain management policies and high proportions of unqualified care workers can impede effective pain management (Kaasalainen et al., 2010). Further, negatively biased attitudes or misconceptions about pain and pain management in older people among care workers and residents are known factors to hinder appropriate pain management (Kaasalainen et al., 2010; Veal et al., 2018).

Despite high relevance of adequate pain management for residents' quality of life, related research suffers from a general paucity of rigorous and effective intervention studies. Current literature reviews criticize the lacking theoretical underpinning of interventions and insufficient rigor of evaluations (Herman, Johnson, Ritchie, & Parmelee, 2009; Knopp-Sihota, Patel, & Estabrooks, 2016). One approach for overcoming these gaps, is the use of behavioral theory in the development of strategies to identify factors hindering and facilitating pain management in the specific context (Michie, Johnston, Francis, Hardeman, & Eccles, 2008).

This study is embedded in the ProQuaS project, a mixed-method project aiming to develop and test an implementation intervention to improve pain management in Swiss nursing homes. As part of a preparatory contextual analysis, this study is guided by the COM-B model, the Capability, Opportunity and Motivation determine Behavior system (Michie, van Stralen, & West, 2011). The COM-B model has been derived from existing behavior change models by a team of behavioral researchers (Michie et al., 2011). It represents the idea that changing a specific behavior requires

changing at least one of the models components: capability, opportunity and motivation with regard to the specific behavior or competing and supporting behaviors (Michie, Atkins, & West, 2014). In this context, capability is understood as the psychological and physical capacity of an individual to perform a specific behavior or activity; Opportunity comprises social and physical factors which hinder, enable or elicit the specific behavior externally. Motivation on the other hand, incorporates automatic processes, involving emotions and impulses and reflective processes, such as making plans and evaluations (Michie et al., 2011, p.4).

The overall aim of this study is to inform the development and selection of contextually adapted implementation strategies in the context of the larger ProQuaS study, to ultimately improve pain management in nursing homes. This study has three specific aims: (1) to assess care workers' perceptions regarding specific barriers to pain management; (2) to explore barriers and facilitators of pain management in depth by focus groups with care workers; and (3) to map the merged results of the quantitative and qualitative strand onto components of the COM- B model and to discuss implications for potential strategies.

3.3 Methods

This study encompasses an explanatory sequential mixed- methods design (quan → QUAL) using a cross-sectional care workers' survey in 20 Swiss NHs, followed by focus group discussions with care workers (Creswell & Plano Clark, 2018). Ethical approval for this study has been obtained from the responsible ethics committee (EKNZ 2016-00621).

Quantitative Strand

Sampling and data collection. This study is embedded in a convenience sample of 20 NHs belonging to Senevita AG, a privately-owned NH group, at the time of the survey. The questionnaire survey was conducted in July and August 2016. Eligible respondents included care workers from all educational backgrounds (registered nurses (RNs), licensed practical nurses (LPNs) and nursing aides (NAs)) who worked in direct resident care, had been employed for at least one month and were sufficiently fluent of German to understand the survey questions. Questionnaires were distributed by local coordinators (e.g., director of nursing); participation was voluntary and anonymous. To ensure confidentiality, a pre-stamped envelope was provided with

each questionnaire. Informed consent was implied by returning the questionnaire. In addition, to provide organizational information about each NH, NH administrators filled out a facility questionnaire.

Variables and measurement. To assess care workers' perceptions of barriers towards pain management, we adapted a list of items used in a previous study (Jones et al., 2004). The items were adapted to the Swiss-German context via a forward-backward translation process and cross-cultural adjustments in accordance with accepted scientific guidelines (Maneesriwongul & Dixon, 2004). Based on a literature review, we then added 11 items about non-pharmacological treatment, reactions to residents' pain, physician availability and inter-professional communication. Content validity of the adapted version's final 20 single items was rated good to excellent by seven geriatric experts (I-CVI: 0.93). Items were rated on a 4-point Likert-type scale ranging from "no problem" to "major problem." For the analysis we calculated the proportion of "moderate problem" and "major problem" responses in relation to the other answer options. These barrier items were optional for NAs; therefore, few NAs have been included in the related analysis. In additional items, we assessed sociodemographic factors including age, sex, years of work experience, educational background and working percentages.

In the facility questionnaire, NH administrators were asked to provide information on organizational factors (e.g. number of beds, staffing). Further, three self-developed items assessed readiness for implementation and availability of resources regarding a pain management project, e.g., "How do you rate the readiness and capacity of your NH to participate in a project about pain management concerning staff resources". Items were rated on a 5-point Likert-type scale ranging from "not good at all" to "very good".

Data analysis. Descriptive statistics were computed, including means, medians, distributions and confidence intervals. All analyses were carried out using R statistical computing software (R Development Core Team, 2018).

Qualitative Strand

Focus group interviews. For the care worker focus groups, a purposeful sample of three NHs was assembled based on their high ratings of the three items assessing readiness for implementation pertaining to the facility questionnaire. Since these NHs were potential

intervention sites for the second phase of the overall project, the barriers and facilitators their staff noted were of specific interest regarding this (intervention development) phase.

The local study coordinators recruited a convenience sample of care workers, applying the same inclusion criteria as for the quantitative strand. A written study information package was provided; participants signed a consent form prior to their interviews. The interview guide was based on the results of this study's quantitative strand.

Each of these interviews began with an open discussion about general difficulties and facilitating factors in pain management; then, participants were probed about the items rated most problematic on the barriers scale. Discussion was moderated by the first author; a facilitator (research assistant) added emerging aspects to a mind map following the approach described by Burgess-Allen and Owen-Smith (2010). Following the discussion on each topic, these aspects were summarized by the moderator and feedback requested from the participants. Discussions were recorded with a digital audio recorder. After data collection was complete, all groups' mind maps were integrated into a meta-map. For this step, aspects of each group's map were summarized and refined according to the content analysis approach described by Mayring (2010). To describe themes, meaningful quotations from the recorded discussions were selected and transcribed verbatim.

Integration

Integration of data occurred in two stages. First, based on analyses of the facility questionnaire items, NHs were sampled for the focus groups. Additionally, development of the focus group interview guide was informed by results of the care worker questionnaire. Secondly, following individual analyses, results of the quantitative and qualitative strands were integrated into a joint display. Findings were organized by their underlying themes, with quantitative and qualitative results displayed side by side to facilitate interpretation (Curry & Nunez-Smith, 2015). In a final step, to identify behavioral determinants regarding the development of future interventions, integrated findings were mapped onto components of the COM-B model.

3.4 Results

Results of the quantitative strand

The overall sample of the quantitative strand comprised 343 care workers (response rate 67.3 %) and 20 NH administrators. Sample characteristics of NHs and respondents are listed in Table 1. Overall, 192 care workers responded to the barrier items (RNs: 32.6%, LPNs: 45.1%, NAs: 22.3%). The following items were considered most challenging (moderate/major problem) regarding ward-level pain management: low availability (60.9%, CI: 52.6- 68.7) and application of non-pharmacological treatment options (53.6%, CI: 47.3- 63.6); residents' reluctance to report pain (51.1%, CI: 43.4- 59.8); lack of time for comprehensive pain assessments (50.5%, CI: 44.1- 60.4). Further results are displayed in Table 2 (below).

Nursing home characteristics (n=20)	Mean (SD)	N (%)
Number of beds: Long term care	46.3 (35)	
Time since opening (years)	10.5 (9.5)	
Readiness and capacity (scale 1-5):		
- staffing resources	2.8 (0.89)	
- time resources	2.6 (0.79)	
- perceived willingness of the care workers	3.6 (0.88)	
Care worker characteristics (n= 343)		
Age (years)	38.6 (13.6)	
Gender (female)		296 (89.2)
Registered nurses		61 (18.2)
Licensed practical nurses		94 (28.1)
Nursing aides		180 (53.7)
Years of work experience in nursing care	11.4 (11.1)	

Table 1: Characteristics of participating nursing homes and respondent

Barrier items	RN LPNs		& Nursing assistants		All *	
	N	%	N	%	N	%
Lacking availability of non-pharmacological treatment	141	63.1	36	50.0	184	60.9
Lacking application of non-pharmacological treatment	140	56.4	36	47.2	183	53.6
Reluctance of residents to report pain	141	51.1	35	45.7	184	51.1
Inadequate time to assess pain comprehensively	141	50.4	36	52.8	184	50.5
Insecurity of care workers regarding pain assessment in residents with communication difficulties	142	43.7	37	48.6	187	48.3
Inadequate availability of physicians	138	38.4	35	51.4	180	41.1
Inadequate flow of information among the care workers	141	34.0	34	44.1	182	36.4
Resident reluctance to take pain medication	139	32.4	35	51.4	182	37.4
Inadequate care worker knowledge	142	28.2	35	37.1	179	31.1
Inadequate flow of information between care workers and therapists	140	25.0	33	45.5	179	29.1
Inadequate communication between care workers and physicians	142	26.8	34	41.2	182	29.1
Resident fear of side effects	141	25.5	34	29.4	183	28.5
Family concerns about side effects (n=185)	141	28.4	36	27.8	185	28.5
Physician reluctance to prescribe	140	29.3	33	27.3	178	28.5
Residents' pain is not taken seriously	143	19.6	38	34.2	189	25.2
Availability of drugs	142	21.8	35	34.3	188	23.8
Slow (non-timely) reaction to residents' pain reports	142	19.7	38	31.6	188	22.5
Lacking PRN prescription for pain medication	141	19.1	36	27.8	185	21.2
Lacking qualification of care workers to administer pain medication (e.g., at night or on weekends)	143	16.1	35	37.1	186	17.9
Nurses' concern about side effects	140	12.9	36	5.6	184	11.4

Table 2: Results of the barrier items: proportions of answers indicating moderate or major problem by educational background (*eight missing observations for the level of educational background)

Results of the qualitative strand

Focus groups. In total four focus groups, each including three to five participants (RNs and LPNs, or only NAs) were conducted. Overall, 17 care workers (13 female; mean age 37.6 years (SD= 11); median professional experience 6 years (range: 1–32)) participated. The findings were structured according to the overarching themes of pain assessment and pain management.

Pain assessment.

Attitudes towards pain. Assumptions and preconceptions regarding pain were seen as major barriers to its assessment. In the discussions, participants differentiated between residents' attitudes toward their own pain and those of care workers. Reports indicated that many residents tended either not to report their pain at all, or to delay reporting it until timely intervention (which would prevent high pain levels) was impossible. However, some care team members' attitudes were also considered hindrances to appropriate pain management. Participants mentioned situations where colleagues dismissed residents' reports of pain as simple attention-seeking behavior.

Well, there are differences, some [nurses] say we [always] have to take the residents' pain [complaints] seriously. But it can also happen that someone says that it is nothing, the resident only wants attention, and he actually has no pain. It is very individual how pain is perceived among the nursing staff. (LPN)

Individuals' life experiences or pain histories were discussed in the groups as potential influences on these attitudes.

Conducting an adequate pain assessment. A common difficulty perceived by the participants was the assessment of pain in residents with communication deficiencies. Particularly in residents with dementia, interpreting behavioral cues and distinguishing them from challenging behavior requires both experience and knowledge of the resident.

Some residents cannot express themselves. Of course we can recognize the pain in their faces but where or how intense the pain is or what kind of pain, they can't tell us. This is also difficult for us. (NA)

Registered nurses also discussed their experiences regarding nursing aides' routine pain assessment. Participants reported often only receiving information on the presence of pain, but no further details on its location or intensity. Reassessment of the resident by a registered nurse was perceived as very time consuming. In addition, participants from various NHs mentioned that their

care documentation software contains a form to comprehensively assess and document pain situations. Although the software's format is considered practical and easy to understand, the assessment forms are not used in daily practice. Participants assumed that this behavior does not result from time issues, but from their care teams' turnover and lack of routine.

Pain management.

Non-pharmacological treatment. Non-pharmacological treatment was seen as one of the care workers' central functions. Care workers of all levels were aware of their options, e.g., distraction with conversations, television or music, application of hot or cold pads, aromatic care or other strategies for resident activation. Nevertheless, time pressure and limited availability of such options were reported as barriers to their application. Although non-pharmacological options were perceived as valuable regarding residents' pain management, participants agreed that they were insufficiently applied in daily practice.

We use...[non-pharmacological treatment] too little. We have not internalized it yet.

We all have ideas or thoughts about it, but the application is not there yet. (RN)

Some participants attributed this paucity to frequent changes in the care teams and lack of stable routines and standards in the NHs.

Collaboration with physicians. Many decisions regarding pain management require interprofessional collaboration. Participants reported that direct communication with a physician is often hindered by lacking availability of the responsible physicians. In particular, general practitioners assigned to small numbers of residents in an NH are difficult to reach, as they rarely participate in regular ward rounds. Participants agreed that assigning one physician to all residents of each NH would facilitate communication processes in pain management and in general.

Results of the integrated data

Barriers that have been frequently reported in the quantitative part were corroborated and amended by the qualitative findings. Furthermore, in the focus group discussions, care workers addressed facilitators of pain management, such as joint ward rounds with physicians and good knowledge of the residents. The identified pain management barriers and facilitators cover all domains of the COM-B model except 'physical capability' (Table 3 below). Many of the barriers relate to the 'physical opportunity' and 'psychological capability' domain and concern several

members of the inter-disciplinary team, e.g. physicians and nursing assistants, as well as organizational factors, such as high turnover. Not all findings could directly be linked with the COM-B model, e.g. reluctance of residents to report pain- these findings will be addressed in the discussion section.

COM-B domains		Barriers & facilitators
Capability	Psychological	<ul style="list-style-type: none"> - Attitudes towards pain in older people - Difficulties to interpret behavior in residents with dementia - Need for training of nursing assistants in pain assessment
	Physical	
Opportunity	Social	<ul style="list-style-type: none"> - Joint ward rounds of physicians and nurses ↑
	Physical	<ul style="list-style-type: none"> - Time constraints for the application of non-pharmacological treatment - High turnover - Limited availability of non-pharmacological options - Inadequate availability of physicians - Single physician who is responsible for all residents↑
Motivation	Reflective	<ul style="list-style-type: none"> - Perceived lack of time for pain assessment - Little intentions to assess pain comprehensively on a regular base
	Automatic	<ul style="list-style-type: none"> - No established routines regarding (a) pain assessment and (b) application of non- pharmacological treatment

Table 3: Summary of barriers and facilitators assigned to COM-B domains

3.5 Discussion

This study aimed to develop a comprehensive understanding of pain management barriers and facilitators in Swiss nursing homes by integrating findings of a care worker survey and focus groups discussions and mapping them onto the COM-B model. Results of the survey suggest barriers mainly at the resident (i.e., reluctance to report pain) and organizational level (e.g., scarcity of resources, particularly non-pharmacological treatment options or time for pain assessments).

There are some differences between the NAs' and RNs/LPNs' perception of barriers. In general, nursing assistants are more critical of aspects which are related to the direct care of residents and the communication thereof (e.g. residents' reluctance to take pain medication, non-timely reaction to residents' pain reports, inadequate communication among care workers). We suppose that these findings reflect the NAs' close involvement in the residents' daily care and perceptions of their limited range of influence for the residents' pain management.

Findings of the qualitative strand partly corroborated these results and provided additional comprehensive insights into perceived barriers and facilitators of pain management. However, some qualitative findings diverged from the quantitative part and will be discussed in the following. Based on the COM-B model we now discuss which factors could be targeted to effect behavior change in pain management, and how these considerations can translate into potential implementation strategies.

Capability

Much current literature on pain management in NHs emphasizes the central role care workers' knowledge and attitudes towards pain play in effective pain management (Kaasalainen et al., 2010; Tarzian & Hoffmann, 2005). Yet, our quantitative data indicate that only about 30% of care workers perceived "care workers' lack of knowledge in pain management" as being problematic. Focus groups' participants on the other hand, emphasized that NAs lack training in pain assessment skills. These findings may support the hypothesis that care workers, particularly RNs and LPNs tend to overestimate their own capabilities and instead focus on the shortcomings of nursing assistants. A lacking understanding of one's own limitations might pose an additional barrier for improving pain management which needs to be considered in the development of implementation strategies. In Switzerland, most NAs receive only a short training on basic care competencies not covering clinical knowledge and skills. However, in Swiss NHs of all care workers, NAs spend by far the most time providing direct care to residents; therefore, they should be closely involved in pain assessment (Liu, 2014). A future NA training curriculum should comprise modules on pain assessment in older people with and without cognitive impairment. To overcome attitudinal barriers, this training should offer a bio-psychosocial perspective on pain (Hadjistavropoulos et al., 2011; Swafford et al., 2014). However, training will only be successful if, rather than simply delegating improvement to NAs, registered and licensed practical nurses

commit both to supporting their assessment and reporting skills, and to actively listening and responding to their concerns.

Echoing observations of previous studies, roughly half of the surveyed care workers perceived the “reluctance of residents to report pain” as a major barrier to pain management (Jones et al., 2006; Martin, Williams, Hadjistavropoulos, Hadjistavropoulos, & MacLean, 2005). However, whether this perceived reticence can be attributed solely to the residents is open to discussion. I.e., shortfalls in care workers’ communication skills and attitudes might also influence residents’ readiness to discuss their pain. The focus group participants also agreed that a trustful relationship facilitates residents’ willingness to open up. The importance of genuine interest in the resident’s situation and appreciative communication has previously been described in interview studies with NH residents (Gran, Festvåg, & Landmark, 2010; Gudmannsdottir & Halldorsdottir, 2009). Implementation strategies aiming to improve knowledge and attitudes to pain management might therefore be beneficial to increase care workers’ understanding and awareness towards residents in pain. The enhanced understanding can influence the care workers’ beliefs about consequences of their actions which in turn reinforces changes of their pain management practice (Ajzen, 1991).

Opportunity

Findings concerning the physical component of the opportunity domain emphasize organizational factors’ influence on daily practice. Care workers stressed the impact of high turnover rates and low staffing resources on quality of care, as they hinder development of a trusting, communicative care worker-resident relationship. Further, a perceived scarcity of time leads to regular implicit rationing, especially in relation to psycho-social, emotional or educational resident needs (Jones, Hamilton, & Murry, 2015). Accordingly, pain management – particularly the application of non-pharmacological interventions and comprehensive pain assessments –is at high risk of being affected by implicit rationing. There is a paucity of evidence that any currently available intervention strategies effectively prevent implicit rationing; however, the authors of the above-mentioned review recommend that nursing curricula should include implicit rationing in the context of clinical decision making (Jones et al., 2015).

Regarding the social component of the opportunity domain, our findings highlight the importance of close interprofessional collaboration in pain management. Joint physician/care worker ward rounds have been perceived as a major facilitator to approach residents’ pain

situations. Joint visits to residents enable a shared view of the pain situation, thereby promoting interprofessional communication and decision making. The advantages of physicians' nursing home visits have been previously described (Fleischmann et al., 2016).

Our findings related to the opportunity domain highlight important implications regarding the development of implementation strategies. Firstly, strategies have to take account of high turnover of care workers, leading to fluctuating pain management knowledge. Secondly, to facilitate the adoption of new pain management practices, close collaboration with responsible physicians should be considered to ensure their buy-in and support to improve uptake.

Motivation

More than half of the participating care workers perceived that “inadequate time to assess pain comprehensively” hinders optimal pain management on their wards. Worse yet, focus group participants reported that, largely due to the constant influx of new care workers, many of their wards had not yet established routines concerning pain assessment. The absence of organizational pain management guidelines and routine procedures has serious implications regarding the reflective and automatic motivation of care workers to carry out pain assessments. To motivate the care workers to change, it is essential that they perceive regular pain assessment not only as a core component of their professional role, but an essential step in ensuring each resident's well-being. A similar rationale has been discussed regarding the application of non-pharmacological pain treatments. With regard to the development of implementation strategies, one approach to motivating care workers to adopt new routines could be modelling. Previous studies have shown that enlisting opinion leaders or champions to act as role models, i.e., exemplifying daily evidence-based pain management practice, can effectively encourage care workers to emulate target behaviors (Flodgren et al., 2011).

Strengths and limitations

A key strength of the present study was the rich data derived from survey questionnaires, and focus group discussions. The explanatory sequential design facilitated discussion of findings from different perspectives thereby providing depth to our understanding. The application of the COM-B model helped to structure barriers and facilitators in a constructive way, highlighting the most promising approaches to develop strategies to facilitate change in pain management.

Nonetheless, this study was also subject to several limitations. First, its scope was limited in terms of sampling, as only NHs associated with one Swiss NH group were included. Furthermore, we included NHs that indicated high readiness for implementation, discussions with care workers from less implementation-ready NHs might have yielded different insights. However, the exemplary approach of identifying leverage points for behavior change in pain management can easily be translated to other NHs. Furthermore, qualitative findings regarding care workers might be limited by the tendency to perceive fewer barriers/ facilitators in relation to matters of less personal interest, leading to non-exhaustive reporting.

3.6 Conclusions and implications

The aim of this study was to generate a comprehensive understanding of barriers and facilitators of pain management in nursing homes with regard to developing implementation strategies. The findings of this study emphasize two central implications: First, strengthening pain management knowledge and communication skills is key to enabling practice change. A particular focus should be training for nursing assistants, enabling them to get actively involved in pain assessment and management. In view of the high turnover in NHs, a sustainable educational structure, providing continuous training opportunities for new staff needs to be established.

Secondly, to achieve sustainable behavior change, motivational aspects need to be considered, too. It is crucial that NHs establish pain management policies based on current pain management guidelines within their organization to provide a basis for care workers to develop pain management routines in their team. Furthermore, to support the adoption and maintenance of new routines, external or internal facilitators, e.g., champions, opinion leaders should be identified and trained.

3.7 References

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Chapter 4

Who to talk to about my pain? A Brief Qualitative Study on Perception of Pain and its Management in Swiss Nursing Home Residents

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4.1 Abstract

Purpose

The prevalence of pain in nursing home (NH) residents is high. Insufficiently treated pain reduces quality of life and often leads to negative health consequences. Pain experience in older people can be influenced by physical, psycho-social, emotional and spiritual factors. Therefore, to inform development of NH pain management interventions, we studied residents' pain related perceptions and needs.

Design

A qualitative descriptive sub-study (embedded in ProQuaS), a larger pain project)

Methods

A purposeful sample of eight NH residents with severe pain and no severe cognitive impairment based on information from the Minimum Data Set, participated in semi-structured interviews between October and December 2016. The audio-recorded interviews were transcribed verbatim and analyzed inductively using thematic analysis.

Results

Three central themes were identified from the interview data: dealing with major life changes, managing pain, and using formal care. The interviews highlighted the multidimensionality of pain experience in NH residents. In complex pain situations, participants perceived that care workers did not respond adequately to their needs. They had learned to cope with their pain using self-developed strategies and direct consultations with their physicians.

Conclusions

The perceived lack of responsiveness may prompt NH residents to bypass care workers with their pain management concerns. This study's findings will inform the development of an educational intervention for NH care workers.

Clinical Implications

To respond adequately to NH residents' needs, care workers at all levels need to understand the multidimensionality of individual pain experience.

Key Practice Points:

- Pain experience in nursing home residents reflects biopsychosocial and spiritual dimensions of their life.
- Maintaining and fostering resident's resources and self-management strategies to deal with their pain should be a central concern of care workers
- Responsiveness to residents' needs and a person-centered approach to pain management are essential to handle pain situations.
- Addressing care workers' ability to understand the various dimensions of pain situations is a crucial aspect of interventions to improve pain management practice in nursing homes.

Keywords

Pain experience, Nursing home, Pain management, Supportive care needs

4.2 Introduction

Nursing home (NH) residents' high prevalence of multimorbidity and generally declined health status increases their risk of experiencing pain. Between 40% and 85% of NH residents report pain, in comparison to 20% – 50% of similarly-aged persons in the general population (Soldato et al., 2007; Takai, Yamamoto-Mitani, Okamoto, Koyama, & Honda, 2010). In Switzerland, about 60% of NH residents report pain (Sommerhalder et al., 2015).

It is well established that under- or untreated pain leads to impairment of mobility and other functions, sleep disturbances, anxiety, depression and overall decreased quality of life (Smith et al., 2016). As functional decline leads to increased care dependency, adequate pain management is particularly important in this vulnerable population.

Background

Today, our understanding of chronic pain embraces a holistic perspective allowing us to look beyond the biomedical paradigm, which limits pain to its physical component. Cicely Saunders' concept of "total pain", which incorporates physical, psychosocial, emotional and spiritual components in end-of-life care, can be extended to chronic pain situations among NH residents (Mehta & Chan, 2008).

Various studies have investigated the subjective experience of pain in NH residents, each stressing pain's multi-dimensional nature (Gran, Festvåg, & Landmark, 2010; Higgins, 2005; Vaismoradi, Skär, Söderberg, & Bondas, 2016). Its social and emotional aspects' importance to the NH resident-specific pain experience was illustrated in a phenomenological study by Gudmannsdottir and Halldorsdottir (2009). That study described how, for NH residents, emotionally momentous events such as moving away from home or losing a spouse or close friend translated into pain and physical suffering.

In addition to NH residents' experience of pain, other studies have focused on their use of pain-related coping and self-management strategies (Crowe, Gillon, Jordan, & McCall, 2017; Lansbury, 2000; Tse, Pun, & Benzie, 2005). After highlighting the importance of residents' chronic pain self-management strategies, these studies call on involved nurses to provide appropriate support.

Previous studies have shown that pain management in NHs often faces barriers arrayed across several levels. As in other countries, the majority of direct care in NHs in Switzerland is provided by non-qualified staff such as nursing aides, whose training does not include the complexity of assessing and treating chronic pain in older adults. In addition, a general low skill grade mix in the care workers' workforce, which is composed of 30% registered nurses, 40% licensed practical nurses and 30 % nursing aides contributes to the organizational challenges to pain management in Swiss NHs and internationally (Merçay, Burla, & Widmer, 2016).

Furthermore, deficits in specific pain management knowledge and skills in care workers impede adequate assessment and treatment of pain in NH residents (Zwakhalen, Hamers, Peijnenburg, & Berger, 2007). On the resident level, negative beliefs and misconceptions about pain frequently result in a reluctance to report pain (Kaasalainen et al., 2010; Martin, Williams, Hadjistavropoulos, Hadjistavropoulos, & MacLean, 2005). Moreover, the presence of severe cognitive impairment in NH residents can be a major challenge for pain assessment and effective treatment (Martin et al., 2005).

A recent meta-synthesis on pain and pain management in NHs identified “normalizing suffering” as the central metaphor (Vaismoradi et al., 2016). The authors note how care workers, residents and family caregivers often see pain and suffering as a normal part of ageing. This common belief leads to limited pain reports of residents on the one hand and to pain situations that go unrecognized by care workers on the other hand. To improve pain management in NHs, it is crucial to explore and understand all stakeholders' beliefs regarding pain and its management.

This study is part of a larger project, ProQuaS (Identification and development of interfaces and processes to improve quality of life of residents at Senevita), which was conceived to develop and test an implementation intervention to improve pain management in NHs (Brunkert, Ruppen, Simon, & Zúñiga, 2018). The overall project is guided by the consolidated framework of implementation research (CFIR) (Damschroder et al., 2009). As a “meta-theoretical” framework, the CFIR provides a list of 39 underlying constructs and sub-constructs that influence implementation. One of these, “Patient needs & resources”, stresses the importance of exploring the residents' needs in connection with the intervention to be implemented. Accordingly, this sub-study aims to explore residents' perceptions and needs regarding pain management. Based on its

findings, content will be developed for an educational training module for care workers within the overall project.

4.3 Methods

Design

A qualitative descriptive study using thematic analysis (Braun & Clarke, 2006).

Sample/Participants

The overall project is based in a sample of 20 privately owned NHs in the German-speaking part of Switzerland. For this qualitative sub-study, a purposeful sample of eight residents with severe pain was included. Participants were pre-screened via the Resident Assessment Instrument Minimum Data Set (RAI-MDS). Data of the RAI-MDS is obtained with a standardized tool at semiannual resident assessments. Inclusion criteria included presence of at least moderate daily pain or severe non-daily pain, and no to mild cognitive impairment, with a cut-off of <4 on the cognitive performance scale (ranging from 0= intact to 6= very severe cognitive impairment), available from the RAI-MDS (Morris et al., 1994). Based on these inclusion criteria, we contacted NHs with three or more eligible residents. Next the respective nursing director assessed further inclusion criteria: non-critical current health status, sufficient command of German and at least one month of residence in the NH. Eligible residents were then approached by the nursing director, who provided oral and written information about the study in a face-to-face conversation. Due to logistical and time constraints, sample size was limited to 8 residents.

Data collection

Interview guides. Semi-structured interview guides were developed in an interdisciplinary group (consisting of two registered nurses with experience in long-term care [FZ], one physician and one physical therapist [TB]). Following this group's recommendations, each interview begins with a comprehensive assessment of the current pain situation informed by recent pain management guidelines (American Geriatric Society Panel on Persistent Pain in Older Persons, 2002; Fischer, 2014). It then deals with the resident's perception of pain management and potential needs for improvement. A summary of the interview guide is provided in Table 1.

	Extract of interview questions
Introduction	<ul style="list-style-type: none">• How are you today?• How are you doing in this NH?
Comprehensive pain assessment	<ul style="list-style-type: none">• Where do you have pain?• What do you think are the reasons for the pain?• How does the pain impact your daily living/mood?
Pain management	<ul style="list-style-type: none">• What do you do when you have pain?• Who do you turn to, when you are in pain?• What kind of treatment do you receive for your pain?
Experience of pain management	<ul style="list-style-type: none">• How do you perceive the care workers/physician with regard to pain management?• How do you experience collaboration between care workers and physicians?
Satisfaction with pain management	<ul style="list-style-type: none">• How satisfied are you with the pain management?• What could be improved?

Table 1: Summary of the interview guide

Interviews. Semi-structured face-to face interviews were conducted by the first author and a research assistant (clinical nurse specialist in long-term care) in participating residents' NH rooms. Data were collected between October and December 2016. There was no contact between interviewers and participants prior to the study. Interviews lasted between 20 and 45 minutes and were audio-recorded with a digital device. Interview data were transcribed verbatim with F4/5 software by two research assistants and checked for accuracy after completion by the first author. Both interviewers kept field notes of observations made during the interviews.

Descriptive data concerning the prescription of pain medication was retrieved from the resident documentation directly after conducting the interviews.

Ethical considerations

Approval for this study was obtained from the responsible ethics committee (EKNZ 2016-00621) within the scope of the ProQuaS project. Informed written consent was obtained from all

participants and, as appropriate, their legal representatives prior to the interviews. With regard to the inclusion criteria we only recruited residents who were able to provide informed consent, i.e. a value less than 4 (moderate or less cognitive impairment) on the cognitive performance scale (Morris et al., 1994).

Data analysis

After familiarization with the data via repeated readings of the transcripts, interview data were coded using thematic analysis described by Braun and Clarke (2006). Analysis was inductive; codes were generated and refined iteratively by the first author. The codes were then organized into potential themes and sub-themes according to their thematic coherence. To increase reliability and trustworthiness as well as to verify the results, preliminary findings were repeatedly discussed with a group of experienced qualitative researchers to refine the thematic structure and to reflect upon their interpretation. Data organization and analyses were facilitated with using Atlas.ti 7. For publication purposes, all quotes have been translated from Swiss-German to English by the first author.

4.4 Findings

The eight study participants lived in three NHs and had an average age of 82 years. Details of the participants' characteristics, physical pain situations and the pharmacological pain management are provided in Table 2. Overall, the participants' diagnoses depict very common pain situations in NHs with non-malignant chronic pain resulting from e.g. osteoarthritis or diabetic neuropathy. We identified three central themes from the interview data: dealing with major life changes, managing pain, and using formal care. An overview of the identified themes and corresponding sub-themes can be found in Table 3 (below).

Participant	Age	Sex	NH	Physical sources of pain	Pain medication	P.R.N. medication
Res1	93	F	A	Knee osteoarthritis	Paracetamol 1500mg, Diclofenac gel	Tramadol 150mg, Metamizol 3000mg
Res2	70	M	B	Diabetic neuropathy, amputation of toes	Paracetamol 1500mg, Metamizol 4000mg, Oxycodone 120mg	Oxynorm 100mg
Res3	65	M	B	Complex chronic neurological conditions (polio, cerebral palsy)	Metamizol 2000mg, Fentanyl patch 50 µg/h	
Res4	78	F	B	Knee osteoarthritis, diverse physical conditions	Lornoxicam 12mg, Chondroitin Sulfate Sodium 800mg, Paracetamol 2000mg, Diclofenac patch 10mg	Metamizol 3000mg
Res5	92	F	A	Chronic shoulder pain	Resident insists on no medication	Paracetamol 500mg
Res6	92	M	A	Osteoarthritis in several joints	Diclofenac gel, Paracetamol 500mg	Metamizol 500mg
Res7	92	F	C	Chronic back and hip pain	Fentanyl patch 75 µg/h	Paracetamol 500mg, Morphine 30mg
Res8	73	F	C	Post-polio-syndrome (progressive impairment of several body structures)	Currently no medication	Paracetamol 500mg

Table 2: Characteristics of participants

Themes	Sub-themes
Dealing with major life changes	Contemplating losses and impairments
	Being confined in a pleasant place
Managing pain one's own way	Self-managing pain
	Using physical pain treatment
Using formal care	Reticence towards care workers
	Consulting physicians as a last resort

Table 3: Overview of themes and sub-themes

Dealing with major life changes

Contemplating losses and impairments. In recent years, most participants had experienced personal losses such as the deaths of spouses, close friends or family members. Transition to a NH was yet another major and comparatively recent life change: Although all had been living in NHs for more than a year, they thought often about their pre-admission lives. Leaving their own homes and giving up their former lives was also perceived as a kind of loss. *“It wasn’t easy for me as I had to give up my apartment; also my daughter has died, that was very, very painful” (Res1).*

Another aspect participants repeatedly brought up was the increasing number of diseases and symptoms they had been experiencing in recent years. They reported feeling distressed by the magnitude of impairment to their body structures and their own general vulnerability. One resident felt overwhelmed by the accumulation of issues affecting her: *“You know, I have so many other... [health problems]. Sometimes I can’t even say [how many]. I think I’m perhaps schizophrenic with all these issues” (Res4).* In some participants the multitude and severity of health-related changes, combined with an increasing loss of independence in activities of daily living resulted in feelings of incapacitation. Encapsulating these increasing impairments’ corrosive effect on one’s sense of self, one resident commented, *“I can’t see anymore, can’t read, can’t write, [I feel like] half a person” (Res6).*

Being confined in a pleasant place. In their (relatively) new NH living environment, the majority of participants perceived that they were in good hands, or had “*a new family*” (Res1). In contrast, some reported having few meaningful contacts. Despite being surrounded by other residents, some actively isolated themselves, as they had found no adequate conversational counterparts in the new environment. “*I do have contacts at lunch and dinner.... But besides that, I’ve secluded myself. Because it’s difficult for me to find someone to discuss things*” (Res3).

With regard to their admission to the NH, participants emphasized their perceived loss of independence. The realization that the NH would probably be their last stop in life was distressing, leading to the conflicting feeling of imprisonment, albeit in an overall nice place:

Resident: And now I feel like I’m in jail. Wonderful, in this regard, there is nothing to complain about the living situation. It is rather for me, I have a hard time. I’ve never thought that my end of life would be like this. That’s like a jail, an incredible, wonderful jail” (Res2).

Managing pain one’s own way

The majority of participants had been suffering from pain for many years. As summarized in Table 2, their pain situations resulted from various physical conditions (e.g., osteoarthritis, diabetes) affecting various body parts. Most of the participants received pain medication (WHO I-III), two participants received no medication at the time of data collection.

Self-managing pain. Most participants reported having undergone extensive diagnostic and treatment procedures seeking pain relief. However, with regard to their chronic conditions, complete cures were unfeasible or unavailable, resulting in ongoing pain: „*I’ve already been everywhere – in the hospitals you know – and there’s nothing they can do for me anymore. This is, eh, this is how it is*” (Res3). Consequently, participants indicated little hope for improvement. Experience had taught them that “*it doesn’t get better: You learn to live with it and deal with it*” (Res8). However, participants also reported that, over time, growing accustomed to constant pain led to an altered perception of it, making it more bearable: “*I got so used to the pain, I don’t think of it as pain, but something unpleasant*” (Res8).

Long experience had made the residents experts regarding their own pain. On the one hand they reported personal strategies to cope with chronic pain, e.g., “*I try to be positive about the*

pain. You know, there was always coming something new. And in the past I've managed it, like if a family gets a new child, and my family is now a bunch of pain-children" (Res4). On the other hand, participants' strategies to alleviate their pain ranged from physical measures, e.g. daily exercises, to distraction and relaxation, e.g. listening to music, to spiritual measures such as prayers: *"I do lots of breathing exercises, it relaxes the body. Because if you're in pain, you get tensed automatically. And if you're doing breathing exercises you can relax better"* (Res8).

Using physical pain treatment. To alleviate their pain, most participants took medication regularly. However, regarding the effectiveness of their pharmaceutical treatments, their perceptions varied. Some, who were unsure as to what kind of analgesic medication they were taking, questioned the benefit of taking medication at all:

Interviewer: And do you feel the painkillers help you with your pain?

Resident: Maybe, some for sure. But I can't judge exactly because I take the pills without knowing them" (Res6).

In contrast, other participants with long histories of medication intake knew exactly which medications they were taking and which they needed if their pain increased.

In addition to pharmacological approaches, participants received a range of non-pharmacological treatment options to deal with their physical pain. Some used aids such as walking frames or joint braces to enable them to move around with less pain and thus support their daily activities. *"I get up, [it's] very difficult, then I take my friend, this cane, then I get to my walking frame and then it's ok"* (Res1). Some also received regular physical therapy and walking training.

Using formal care

Reticence towards care workers. In general, participants reported feeling well taken care of and having a good relationship with their care team. However, regarding their pain situations, their overall impression was somewhat different. For various reasons, participants did not always speak freely about their pain with their care workers. Partly, they were hesitant either to burden the care workers or to be considered complainers: *„Well, I tell them, they don't know what pain I*

have. I'm not saying anything. I can't tell [them]. I'm no complainer, I don't want to burden other people with it as well" (Res1). However, participants also reported a sense that the care workers did not always take them seriously. In this context, a couple of participants complained about the lack of life experience of some care workers, not all of them *"are mature enough for the job they are doing"* (Res3). The participants assumed that this lack of experience might lead to a limited capability of being responsive to their emotional needs: *"I can bear lots of pain.... [But] I have the feeling... [the care workers] don't respond to my pain. They quickly bolt the door. Maybe they don't want to burden themselves"* (Res2). Another aspect of this apparent lack of engagement is the perception that care workers have a very limited capacity to help with complex pain situations:

Interviewer: In case you're experiencing pain, do you talk to the nurses about it?

Resident: With the nurses, what should they do with me? They just come along to help me with my stockings and ask me how I am. They can't do anything"
(Res4).

Based on experiences such as this, residents have little incentive to talk to care workers about their pain.

Consulting physicians as a last resort. While the majority of participants reported keeping their family physicians when moving to their NH, Others had to change to their homes' institutional physicians. Participants appreciated that, due to their long relationship, their family physicians would have a good knowledge of their health trajectories and preferences regarding treatment: *"She knows me, knows my sensitivity and she gives me medication that I can tolerate"* (Res1). Although the participants reported to have few regular appointments, they were glad to be able to reach their physicians when changes in their pain situation occur: *"I have my medication and if the situation comes again, then I go to my doctor and tell him what it's like and then we have to start again"* (Res2). A familiar person to turn to when necessary was perceived as a valuable resource. However, some participants saw consulting their physicians as a last resort when self- management strategies had failed.

4.5 Discussion

This study explored the perspectives of NH residents regarding their pain experience and perceptions concerning pain management. To our knowledge this is the first qualitative study to explore the needs of NH residents concerning pain management in Switzerland. Much of the published literature covers North America (Martin et al., 2005), Australia (Higgins, 2005; Yates, Dewar, & Fentiman, 1995) and North European countries, i.e., Scandinavia (Gudmannsdottir & Halldorsdottir, 2009). However, from an implementation science perspective, developing an understanding of the local context concerning stakeholders' needs and resources is key for successful implementation (Damschroder et al., 2009; Rycroft-Malone, 2004).

Asked about their current pain situation, participants spontaneously reported a range of experiences and incidents beyond their physical conditions that caused them painful feelings. The experience of existential losses was central in this regard. By highlighting the multidimensionality of pain experience in NH residents, this study's findings emphasize the need for a comprehensive assessment considering all dimensions related to *total pain* (Mehta & Chan, 2008). Only based on a comprehensive understanding of a resident's needs and goals can the care team develop and apply an individual treatment plan.

Regarding pain treatment, the participants agreed that their experience had taught them to deal with pain via diverse self-management strategies. These findings are comparable to those of a recent meta-synthesis of 17 studies describing coping strategies of people aged over 65 years (Crowe et al., 2017). Here, the authors identified the following meta-themes central to coping strategies: 'adjusting to the inevitable'; 'doing it my way without medication'; and 'the importance of support in managing the struggle'. These findings emphasize the importance of considering the residents' own resources to deal with pain. From a health care provider's perspective, satisfactory pain management requires acknowledgement of the resident's experience with pain and a willingness to learn from him/her. Therefore, a comprehensive pain assessment should include the resident's personal self-management strategies to provide support where necessary.

Building upon the topics noted above, one of this study's most startling findings involves the residents' perceptions of care workers' functions regarding their pain management. Our data suggest that participants perceived that care workers played only a marginal role in managing their

pain; therefore, few participants sought their help when in pain. In contrast, a physician was perceived as a helpful resource in situations where residents could not deal with their pain via self-directed strategies. These findings corroborate those of a phenomenological study with NH residents in Iceland (Gudmannsdottir & Halldorsdottir, 2009). One of that study's themes, "distant nurses" expressed how residents associated the nurse with daily medication but not with pain management. Rather, physicians were perceived to be responsible for pain management decisions. The perception of an unbalance in the distribution of responsibilities and competences between care workers and physicians might constitute an intangible barrier for residents, making it a potential key issue in NH pain management.

As noted, this study's findings are limited to residents with no to mild cognitive impairment. While the general population of NH residents certainly includes persons with severe cognitive impairment, concerning our intention to develop an intervention in a group of Swiss NHs, the included sample represents the majority of the participating NHs' residents. Further limitations of this sub-study's findings might arise from the rather small sample of NH residents included. In the overall research project, in addition to the residents, we surveyed all care workers employed by the 20 participating NHs. To gain a comprehensive understanding of barriers and facilitators to pain management we also interviewed a sample comprised of both care workers and physicians.

Implications for nursing education, practice and research

With regard to efforts to improve pain management in NHs, this study's findings have several important implications. One is that participants' common perception of care workers' unresponsiveness discourages the participants from discussing their pain with them. To set the stage for effective pain management, it is crucial that care workers are both compassionate and open to residents' needs.

This reflects a key tenet of person-centered care: Caring relationships with residents and mutual respect allow health care workers to support residents' overall well-being (McGilton et al., 2012). Unfortunately, our participants' perception of limited professional competence among their care workers indicate a barrier to such relationships. As a matter of course, non-qualified nursing aides – who deliver the bulk of direct care of residents – do, in fact, have limited professional knowledge. However, they play a central role in recognizing pain during their care routines and

reporting it to the nurses in charge. Therefore, to enhance their value, non-professional care workers should receive on-the-job training, including case studies to enhance their overall understanding of residents' situations. As with all other care workers, nursing aides need to understand the multidimensionality of pain in order to recognize each resident's situation as a whole. This knowledge will enable them to be more responsive to residents needs, particularly regarding the non-physical dimensions of total pain.

Within the context of the ongoing discussion of professionalism in nursing, our findings highlight the need to investigate understanding of care workers' professional roles regarding pain management. Untrained personnel constitute the largest part of Swiss and international NHs; however, registered nurses supervise their care and manage complex resident situations personally. Therefore, as part of their professional roles, RNs in NHs need to be more proactive concerning residents' pain management. By assuming an active role, registered and licensed practical nurses should support residents according to their cognitive abilities. This might range from supporting cognitively intact residents in their pain self-management to monitoring and advocating for residents unable to express their needs. However, by focusing on RNs' and licensed practice nurses' professional roles in NHs, future studies will be able to advance our understanding of barriers to and facilitators of pain management.

4.6 Conclusions

The immediate purpose of this sub-study was to explore NH residents' needs and perceptions regarding pain management. Its longer-term goal is to inform the ProQuaS project's development of an intervention to improve pain management in Swiss NHs. Our central finding was the tendency among NH residents to bypass care workers with their pain management concerns due to their shared perception that those workers lacked the experience and/or competence to engage professionally with such problems. This highlights the need for a shift towards a more patient-centered culture in NHs. Besides the provision of the necessary education and training to all staff with resident contact, approaches such as role-modeling might help to change pain management practice of care workers. A clear understanding of and awareness to all stakeholders' beliefs is crucial to prevent residents' pain disappearing from view.

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Chapter 5

A theory-based hybrid II implementation intervention to improve pain management in Swiss nursing homes: A mixed- methods study protocol

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5.1 ABSTRACT

Aim

To present a protocol for evaluating an implementation intervention to improve pain management in nursing homes by addressing behavior change of the care workers.

Background

Pain management in nursing homes often is inadequate despite the availability of evidence-based pain management guidelines. Barriers to pain management in nursing homes occur on several levels including lack of knowledge and negative beliefs towards pain of care workers. A comprehensive approach incorporating contextual and behavioral factors is needed to sustainably improve pain management practice.

Design

A hybrid type II effectiveness-implementation design comprising an incomplete non-randomized stepped-wedge design and concurrent focus groups is proposed.

Methods

A convenience sample of six nursing homes will be included. Implementation of a facility pain management policy will be facilitated by introduction of a facility pain champion and training of all care workers in pain assessment and management. Quantitative outcomes assessed at baseline, after three and six months include self-efficacy in pain management and attitudes to pain of care workers as well as functional interference from pain and pain intensity in residents. Feasibility and acceptability of the intervention and implementation strategies as well as potential barriers to implementation will be explored in focus groups and interviews. (Protocol approved in October 2017).

Conclusion

The proposed intervention implementation has been developed in a participatory approach involving relevant stakeholders. To further improve contextual fit, development of implementation strategies was guided by the consolidated framework of implementation research. Findings of this research are expected to inform adaptations to the implementation of the intervention.

Keywords

Consolidated Framework for Implementation Research, hybrid effectiveness- implementation design, mixed-methods, nursing home, pain management, Theoretical Domains Framework

Trial registration

ClinicalTrials.gov (NCT03471390)

Why is this study needed?

- Unrecognized or untreated pain has an impact on quality of life and increases risk of negative health consequences for nursing home residents
- Adherence of care workers to pain management guidelines in Swiss nursing homes is low
- To facilitate the uptake of a facility pain management policy in the participating NHs, the proposed study builds on a comprehensive contextual analysis and uses tailored implementation strategies

5.2 Introduction

Pain management is of critical concern in nursing home residents, since under- or untreated pain can have a severely impact on quality of life. Previous studies have found, that between 40- 85 % of NH residents experience pain (Boerlage, van Dijk, Stronks, de Wit, & van der Rijt, 2008; Ferrell, Ferrell, & Rivera, 1995; Takai, Yamamoto-Mitani, Okamoto, Koyama, & Honda, 2010). Despite the availability of evidence- based guidelines for geriatric pain management (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2009; Fischer, 2014), clinical practice and studies show that care workers do not or only partly adhere to them (Jablonski & Ersek, 2009).

Background

With the increasing age and high prevalence of multimorbidity in NH residents, pain management in NHs becomes more complex and therefore calls for an increased awareness. Unrecognized or undertreated pain can impair mobility and lead to increased dependency in activities of daily living (ADL), sleep disturbances and increased symptoms of anxiety and depression (Ferrell, 2004; Scudds & Robertson, 2000). Effective pain management in NH residents is challenged by the high prevalence of cognitive impairment, which can impede the ability to communicate pain. Studies have shown that residents with severe cognitive impairments are at high risk for unrecognized pain and, additionally, to receive less analgesic medication compared with residents with mild or no cognitive impairment (Balfour & Rourke, 2003; Reynolds, Hanson, DeVellis, Henderson, & Steinhauer, 2008). In persons unable to self- report pain, the use of an observational scale for pain assessment, such as the Pain Assessment in Advanced Dementia Scale (PAINAD) or the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) is recommended by several guidelines (Abdulla et al., 2013; Fuchs-Lacelle & Hadjistavropoulos, 2004; Warden, Hurley, & Volicer, 2003). In Switzerland, 40% of the residents in NHs have a diagnosis of dementia and about 59% have at least one diagnosis related to cognitive impairment (Kaesler, Storni, & Santos-Eggimann, 2012). However, the standardized use of observational scales has not yet been widely established in Swiss NHs.

Despite the high complexity of residents, care workers in NHs often lack specific knowledge in geriatric pain management (Zwakhalen, Hamers, Peijnenburg, & Berger, 2007). Further barriers

that have been described to hinder an effective pain management are negative beliefs of residents and care workers towards pain in older people, limited inter-professional collaboration and insufficient communication between nurses and physicians (Jones et al., 2004; Kaasalainen et al., 2010). The body of evidence regarding effective pain management interventions in NHs is generally limited with a substantial lack of high-quality studies. In a recent systematic review and meta-analysis of pain management interventions only 24 prospective controlled trials could be identified (Knopp-Sihota, Patel, & Estabrooks, 2016). Due to the high variability between intervention strategies and outcome measures no clear evidence in favor of specific interventions could be determined. Similar conclusions were made in an earlier review of prospective intervention studies; here, the authors further criticized lacking scientific rigor in a majority of studies (Herman, Johnson, Ritchie, & Parmelee, 2009). Likewise, in their review about processes of pain care in NHs, Swafford, Miller, Tsai, Herr, and Ersek (2009) could not identify clear evidence in favor of specific implementation strategies due to inadequate study designs and high design variability.

One recent study by Kaasalainen et al. (2016) showed beneficial effects for pain-related resident outcomes and practice behavior of NH care workers by implementing a nurse practitioner-led pain team. The inter-professional pain team met monthly or every other month. Further, the nurse-practitioner (NP) conducted educational workshops and other quality improvement initiatives at the facilities. A second arm of this study comprised the implementation of NPs on an advisory basis, which led to similar positive results. These findings are encouraging and show that improvement of pain management in NHs is possible. However, regarding the Swiss context, the implementation of NPs to improve pain management seems not feasible. To date the number of NPs in Switzerland is small, with to our knowledge currently no NP being employed in a NH (Maier & Busse, 2017). On the other hand, about 30% of care workers in Swiss NHs are registered nurses (Merçay, Burla, & Widmer, 2016). In consideration of these facts, we propose to investigate the implementation of facility pain champions, licensed or registered nurses with extensive training in pain management in combination with comprehensive training of all care workers.

This proposed study constitutes the second phase of a larger research project, ProQuaS (Identification and Development of Interfaces and Processes to improve Quality of Life of Residents at Senevita). The first phase of ProQuaS comprised a comprehensive analysis of

contextual factors, barriers and facilitators to pain management in a privately- owned group of NHs in Switzerland (**Chapter 3-4**). Results of this first phase contributed widely to the understanding of local needs regarding pain management and hence, have provided a basis for the tailoring of the implementation strategies. Overall objective of this proposed study, hence, is to evaluate the implementation intervention regarding its effectiveness on resident and care workers' outcomes and explore the impact of implementation.

Conceptual framework

Changing practice in NHs and other healthcare organizations is a complex undertaking due to potentially influencing factors on multiple levels (Ersek & Jablonski, 2014). It is crucial to change behavior of care workers besides processes on the organizational level, to sustainably implement new pain management practices. The conceptual framework for this research builds on the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF) (Cane, O'Connor, & Michie, 2012; Damschroder et al., 2009). An illustration of the conceptual framework for this study is shown in Figure 1.

The CFIR, is a “meta-theoretical” framework providing a list of concepts which are supposed to influence implementation. The 39 concepts have been derived from a synthesis of existing theories from the field of implementation, dissemination and organizational change and can be assigned to five domains: inner setting, outer setting, characteristics of individuals, the intervention and the process by which implementation is accomplished (Damschroder et al., 2009). In this research, the CFIR is considered to inform the overarching implementation processes. In the first phase of this research project a comprehensive analysis of the context in the participating NHs was conducted. Here, CFIR provided a systematic overview of potentially influencing factors for implementation. Building on these insights we selected potential covariates mainly from the domains “inner setting” and “characteristics of individuals” to account for their influence on the implementation from an organizational perspective.

To gain a more in-depth understanding of the individual determinants of change we further consider the TDF for our research. The TDF consists of 14 domains depicting potential influences on changing behavior. The domains comprise the following theoretical concepts: Knowledge, Skills, Memory, Attention and Decision Processes, Behavioral Regulation, Skills, Social

Influences, Environmental Context and Resources, Social/Professional Role & Identity, Beliefs about Capabilities, Optimism, Beliefs about Consequences, Intentions, Goals, Social/Professional Role & Identity, Optimism, Reinforcement and Emotion and can be further subdivided into 84 constructs (Cane et al., 2012). In this research we will refer to domains of the TDF to explore potential barriers to individual behavior change from the care workers' perspective using investigator- developed questionnaire items and focus groups.

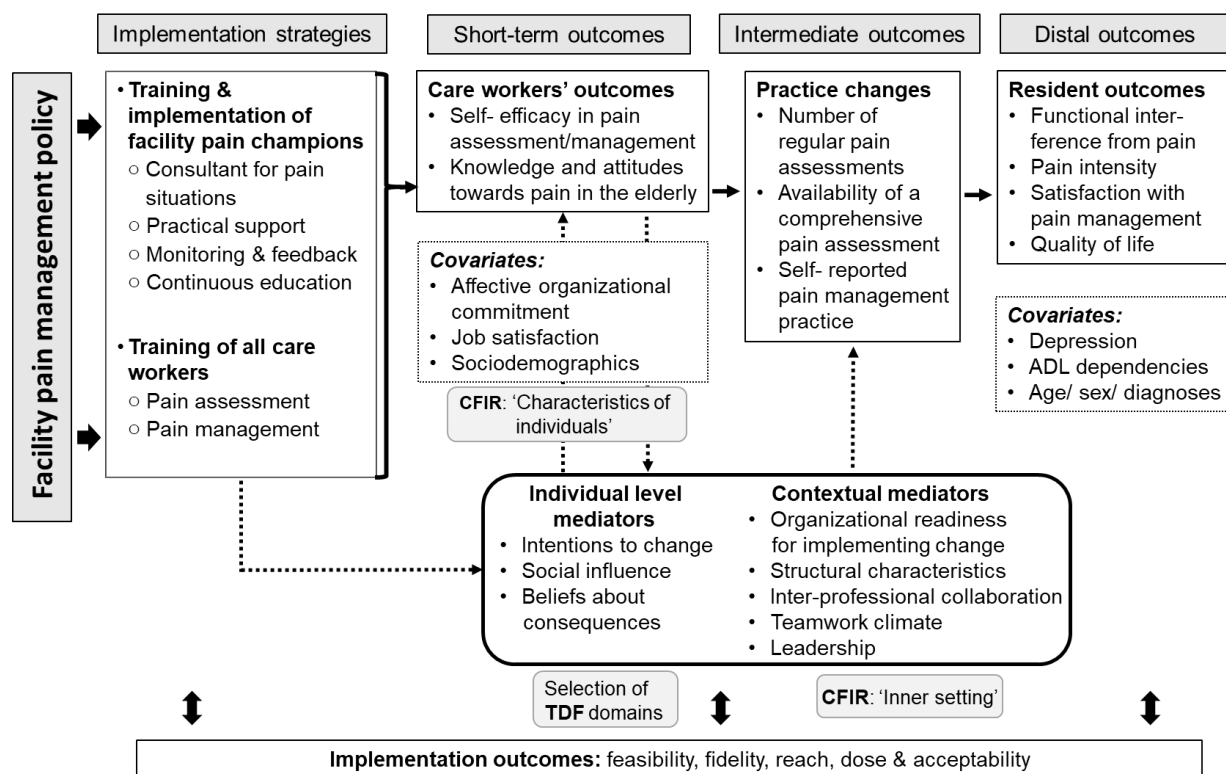


Figure 1: Conceptual framework

5.3 THE STUDY

Aims

This protocol outlines a study testing an implementation intervention to improve pain management in nursing homes by addressing behavior change of the care workers.

Objectives of the proposed study:

- (Ia) To assess the effectiveness of the intervention on care workers' outcomes and pain management practice
- (Ib) To explore the effectiveness of the intervention on resident outcomes
- (II) To explore acceptability, feasibility and utility of the implementation strategies and to identify potential barriers and facilitators to implementation from the perspective of the care workers and pain champions
- (III) To develop an understanding of how contextual and individual behavioral factors influence the uptake of the intervention by integrating findings of the quantitative and qualitative part

Design/ Methodology

Study design

The proposed study is a hybrid type II effectiveness- implementation design which uses a mixed-methods concurrent embedded design to evaluate effectiveness and of implementation at the same time (Curran, Bauer, Mittman, Pyne, & Stetler, 2012; Curry & Nunez- Smith, 2015). The quantitative part encompasses a non- randomized incomplete stepped- wedge design with one before and two after measurements of resident and care workers' outcomes (Hemming, Lilford, & Girling, 2015). The embedded qualitative part comprises focus groups and individual interviews to explore implementation outcomes and potential barriers and facilitators to implementation. The trial is registered on ClinicalTrials.gov (NCT03471390).

Study sample and recruitment

In the 26 cantons of Switzerland there are about 1560 NHs with an average capacity of 62 beds. Less than half (707 NHs) are privately-owned (Swiss Federal Office of Statistics, 2017). The overall study is embedded in a group of 25 privately-owned NHs in the German-speaking part of Switzerland. The associated NHs are located in eight different cantons and have an average capacity of 43 beds (ranging from 11-116 beds). For logistical and financial reasons, the proposed study is limited to a convenience sample of six NHs from the associated group.

Inclusion/ Exclusion criteria

All 25 associated NHs will be invited to participate and included based on their agreement to the study contract. In case more than six NHs are interested to participate we will choose NHs based on the number of beds with regard to the sample size. For the care workers' questionnaire survey and focus groups, all registered nurses, licensed practical nurses/certified caregivers, nursing assistants, nurse aides and other care workers older than 16 years, working in direct resident care in a participating NH for at least one month will be included, as well as students, apprentices and interns who are employed at least six months in total. Care workers with a temporary employment for less than six months and those not able to speak and understand German are excluded. For the data collection at the resident level, all residents living in a participating NH, who are older than 64 years and provide written informed consent to participate signed by the resident or in case of severe cognitive impairment by his/her legally acceptable representative will be included. Whereas residents with a critical current health status or terminal life situation with a known life expectancy less than three months as well as short term residents with an anticipated length of stay of less than six months will be excluded.

Intervention

In Switzerland to date no national guideline or national experts' recommendations for pain management in older people is available. From the contextual analysis in the first part of this research project we know that in the participating NH group no facility pain management policies are in place, either. For this study we developed an evidence- based facility pain management policy based on current recommendations of different international expert panels (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2009; Fischer, 2014; Wulff et al., 2012). To adapt the policy to the Swiss and local context of the participating NH group we invited one external pharmacist, one physician and 25 nursing directors associated with the NH group and all assigned pain champions to give feedback to the policy. Adaptions have been made based on consensus between first and last author. The final policy includes the following core elements: (1) conduct of a comprehensive pain assessment on admission of new residents with pain or residents with new or deteriorating pain situations; (2) use of PAINAD (Warden et al., 2003) for the observational assessment of pain in residents with severe cognitive impairment; (3) re-evaluation of pain intensity/pain presence after pharmacological or non-pharmacological interventions; (4) regular documentation of pain assessment results (before/ after intervention).

Besides the core elements, the policy comprises recommendations concerning the application of pharmaceutical and non- pharmaceutical approaches in pain management according to the above-mentioned guidelines.

Implementation strategies

The proposed implementation strategies aim to improve pain management by targeting behavior change amongst care workers using facility pain champions and training of all care workers. Implementation strategies have been developed using a participatory approach involving relevant stakeholders from all levels of the NH group in regular sounding board meetings. Further we incorporated results of the first part of the overall research project (**Chapter 3-4**). An overview of the implementation strategies and the corresponding behavior change techniques can be found in Table 1.

Pain champions will be recruited from the local staff of the participating NHs. With regard to scarce staffing resources available, we specified only minimal requirements for the recruitment: (a) preferably a registered nurse (RN) otherwise a licensed practical nurse (LPN); (b) several years of professional experience in a nursing home; (c) interest in pain management and (d) time for the training. We recommend recruiting approximately one pain champion per 30 residents in the NH. In October 2017 the future champions receive a 5-day training (eight hours) provided by educational staff of a vocational training institute for nursing. Curriculum for the champions has been developed by the educational staff in close collaboration with the researchers. For the content of the curriculum we considered the geriatric pain competences proposed by the work of Swafford et al. (2014) and recent recommendations to pain management of older people (American Geriatric Society Panel on Persistent Pain in Older Persons, 2002, 2009; Wulff et al., 2012). Besides contents related to pain management topics, about one third of the curriculum comprises interactive classes on coaching, pedagogy and communication. Training will be conducted by Master's level nurses with expertise in pain management, long term care, coaching and pedagogy. Over the course of the intervention four 3-hour refresher meetings, led by the first and last author will take place to recap contents of the training, to discuss experiences and enable professional exchange between champions of different NHs.

Implementation strategies	Behavior Change Techniques
(1) Pain champion:	
- Consultant for complex pain situations	- Social support (practical)
- Practical support for pain assessment and management decisions	- Social support (practical) - Instructions on how to perform the behavior - Demonstration of the behavior - Behavioral practice/ rehearsal
- Monitoring and feedback based on review of nursing documentations & observations	- Review behavior goals - Review outcome goals - Discrepancy between current behavior and goal - Feedback on behavior
- Continuous education with short courses and introduction of new employees	- Information about health consequences - Instructions on how to perform the behavior - Verbal persuasion about capability
(2) Training of all care workers:	
- Instructions on pain assessment and management	- Information about health consequences - Instructions on how to perform the behavior - Verbal persuasion about capability

Table 1: Implementation strategies and associated behavior change techniques to change care workers' behavior (Michie et al., 2013)

Training of the care workers comprises two sessions of two hours of instructions on pain assessment and pain management each in the NHs. Training sessions were developed based on the new pain management policies and further comprise interactive discussions of exemplary resident situations. Training is provided according to the educational background separating RNs and LPNs from nursing assistants (NA). Correspondingly, training contents for the NAs have been simplified and adapted to their professional role. Three trainers (RNs with expertise in long term care) will deliver the training sessions face to face in the different groups. The date of the first training represents the official start of the intervention in the NHs.

Tailoring of the implementation strategies is planned with regard to activities of the pain champions. In consideration of potentially different educational backgrounds and positions in the organizations, pain champions might have varying capabilities and opportunities regarding their

role implementation. Taking this into account we decided to define only minimal instructions concerning their tasks. The champions were asked to give at least three short courses related to pain management in six months, review the nursing documentation of all residents every three months and take over at least one baseline training session for the NAs.

Study procedures

Randomization and blinding

Due to the high logistical efforts for the NHs to prepare all study procedures and the small number of cluster units, we decided against randomization of starting points of the intervention. Participating NHs may choose their starting group with regard to competing demands of concurrent projects. Because of the participatory nature of the intervention neither blinding of NH care workers, nor blinding of the outcome assessors at the resident level is possible due to the repeated data collection procedure.

Data collection

Data collection will start in November 2017 in the first group of NHs and is planned to be completed in October 2018. Mixed-methods data collection comprises: (A) care worker questionnaire surveys; (B) structured interviews with residents or responsible nurse, respectively and (C) chart reviews of nursing documentation all at baseline (T0), after three (T1) and six months (T2); (D) focus group discussions with care workers (T1, T2); (E) interviews with pain champions (T2) and (F) pain champions' questionnaire surveys (monthly); A detailed overview of the data collection procedures is shown in Figure 2.

Groups	2017			2018									
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct
NH 1 & 2	A B C			F	A B C D F	F	F	A B C D E F					
NH 3 & 4				A B C			F	A B C D F	F	F	A B C D E F		
NH 5 & 6						A B C				F	A B C D F	F	A B C D E F

= control phase
 = training delivery phase
 = intervention phase

Figure 2: Overview of study procedures (A: care workers' questionnaires; B: residents' assessment; C: chart reviews; D: focus groups with care workers; E: interviews with pain champions; F: pain champions' questionnaire)

Variables and Measurement

Care workers' questionnaire survey

Data from the care workers will be obtained with questionnaire surveys at T0, T1 and T2. The questionnaires comprise different instruments and investigator- developed items relating to the conceptual framework of the project (Figure 1). Also, we will collect data on age, sex, type of profession, percentage of employment, usual working shift, institutional and professional experience. An overview of the constructs measured in the questionnaires can be found in Table 2. All instruments which have not been available in German were translated through a forward-backward translation procedure and cross-cultural adaptation in accordance with scientific guidelines (Maneesriwongul & Dixon, 2004).

Type	Constructs	Instruments
Outcome	Care workers` self- efficacy in pain management	Investigator- developed items based on Bandura (2006) and Chiang, Chen, and Huang (2006)
	Knowledge and attitudes to pain	Pain in Older Adults Knowledge Survey (Fetherstonhaugh, Lewis, McAuliffe, & Bauer, 2016)
Covariate	Teamwork climate	Safety Attitudes Questionnaire (Sexton et al., 2006)
	Inter- professional collaboration	Safety Attitudes Questionnaire (Sexton et al. 2006)
	Affective organizational commitment	Commitment Organisation, Beruf und Beschäftigungsform (Felfe, Six, Schmook, & Knorz, 2014)
	Job satisfaction	Investigator- developed items
	Satisfaction with pain management	Investigator- developed items
Mediator	Organizational readiness for change	Organizational readiness for implementing change (Shea, Jacobs, Esserman, Bruce, & Weiner, 2014)
	Barriers to change behavior based on TDF	Investigator- developed items (Cane et al., 2012)

Table 2: Overview of constructs measured in the care workers' questionnaire

Resident interview and minimum data set

Data of the residents will be retrieved from two different sources: the Minimum Data Set (MDS) of the Resident Assessment Instrument (RAI) and data collected in structured interviews with the residents or the responsible nurse, respectively. Both data sets can be linked by a preassigned resident-ID. The MDS is a standardized resident assessment instrument provided by the participating NHs from which we will retrieve data on the following resident characteristics: age, sex, cognitive and functional capacity. The choice of outcome measures for the structured

interviews with residents was guided by the IMMPACT (Initiative on Methods, Measurement and Pain Assessment in Clinical Trials) recommendations for clinical trials in chronic pain (Turk et al., 2003). Furthermore, we aimed to include measures, which are appropriate for the use in the population of NH residents. With regard to the wide range of different levels of cognitive impairment in NH residents, we defined a cut-off for conducting resident interviews using the cognitive performance scale (CPS), which can be retrieved from the MDS. The CPS is based on a sum- score of multiple items of the MDS, ranging from 0= intact to 6= very severe cognitive impairment (Morris et al., 1994). Therefore, only residents with scores of three and less on the CPS will be considered for an interview. For all other residents we will interview the responsible care worker (RN or LPN) with an adapted list of items. An overview of the constructs and instruments categorized by CPS scores is shown in Table 3.

Chart review

Nursing documentation of the participating residents will be reviewed with regard to the following indicators: (I) Documentation of at least one comprehensive pain assessment within the last three months: yes/no (comprehensive pain assessment is defined as: besides information on pain intensity and pain location, at least three further aspects of the pain situation should be documented, e.g. quality of pain, pattern, psycho- social aspects, etc.); (II) Number of documented short form pain assessments within the last four weeks (short form pain assessment is defined as including at least information on pain location and intensity assessed before or after analgesic treatment).

CPS	Constructs	Instrument
CPS<4: no to mild cognitive impairment	Functional interference from pain	Brief Pain Inventory (Cleeland 1991)
	Pain intensity	Brief Pain Inventory (Cleeland 1991)
	Depressive symptoms	Geriatric Depression Scale (Yesavage et al., 1982)
	Independence in activities of daily living	Katz ADL (Bucks, Ashworth, Wilcock, & Siegfried, 1996)
	Quality of life	Quality of life - Alzheimer Disease (Logsdon, Gibbons, McCurry, & Teri, 1999)
	Satisfaction with pain management	Investigator- developed items
CPS≥4: severe cognitive impairment	Presence of pain	PAINAD (Warden et al., 2003)
	Depressive symptoms	Cornell Scale for Depression in Dementia (Alexopoulos, Abrams, Young, & Shamoian, 1988)
	Independence in activities of daily living	Katz ADL (Bucks et al., 1996)
	Quality of life	Quality of Life- Alzheimer Disease (Logsdon et al., 1999)
All	Age, sex, cognitive and functional capacity	Retrieved from the MDS

Table 2: Measurement on the resident level with regard to the CPS score (CPS: Cognitive Performance Scale; PAINAD: Pain Assessment in Advanced Dementia scale; MDS: Minimum Data Set)

Pain champions' questionnaire survey

Quantitative data of the pain champions will be assessed with monthly online questionnaire surveys consisting of different item groups: (a) personal information (socio-demographics); (b) general information concerning the ward (e.g. number of residents with pain); (c) report on tasks related to the role (e.g. number of contacts); (d) satisfaction with implementation (e.g. "How satisfied are you with the implementation of your role"); (e) feasibility of implementation (e.g. "How do you rate feasibility of implementing your role regarding time resources") and (g) self-

efficacy concerning capabilities related to the own role (e.g. “How confident are you in conducting a comprehensive pain assessment?”). Items concerning general information about the ward and quantity of tasks conducted will be assessed retrospectively for each month, other items except personal information will be assessed every other month.

Qualitative data collection

Focus groups

We plan to conduct focus groups with a sample of care workers at T1 and T2. Interview guidelines were developed using the TDF to identify potential barriers and facilitators to implementation (Cane et al., 2012). Further we plan to explore acceptability and feasibility of the intervention and implementation strategies from the perspective of the care workers. A convenience sample of 4- 6 care workers (RNs/ LPNs and NAs) will be recruited for each focus group. Focus groups discussions will be audio-recorded with the permission of the participants.

Individual interviews

We plan to conduct individual semi-structured interviews with all pain champions at T2, lasting about 60 minutes. Interview guidelines cover questions regarding acceptability and feasibility of the intervention and the role of the pain champion. Further we plan to explore potential barriers and facilitators to implementation based on the TDF similar to the focus groups.

Process evaluation

It is planned to evaluate implementation of the intervention using different measures and data sources. We are focusing on reach (proportion of people being in contact with the intervention), dose (quantity of the intervention implemented) and fidelity (intervention delivered as intended) of the intervention to evaluate feasibility (Moore et al., 2015). Also, we aim to explore acceptability of the intervention and the implementation strategies from the perspective of the care workers. An overview of the implementation outcomes and their measurement can be found in Table 4.

Outcome	Measurement	Data source	Time point
Reach	Organizational level: <ul style="list-style-type: none"> Attendance rate at training sessions 	Attendance sheets	Training sessions
	Individual level: <ul style="list-style-type: none"> Completion of training (part 1/ part 2 / both parts) Acquaintance with pain management policies (read completely/ partly/ just skimming/ not at all) Contact with pain champions (yes/ no) 	Care workers' questionnaire	T1
Dose	<ul style="list-style-type: none"> Number of contacts with the pain champion (based on resident situations) 	Care workers' questionnaire	T1, T2
	<ul style="list-style-type: none"> Quantity of activities related to the champion's role over the past 4 weeks 	Questionnaire for pain champions	monthly
Fidelity	<ul style="list-style-type: none"> Nursing documentation indicators 	Chart review	T0, T1, T2
	<ul style="list-style-type: none"> Self-reported behavior regarding core elements of the pain management policy 	Care workers' questionnaire	T2
Acceptability	Items/ questions related to acceptability of <ul style="list-style-type: none"> Pain management policies Training sessions Pain champions 	Care workers' questionnaire & Focus groups	T1, T2

Table 3: Measurement of implementation outcomes

Data analysis

Quantitative data

First, all data will be analysed descriptively to explore data distribution and summary statistics of the total sample and by NH. Further we will compare baseline data between NHs to identify significant differences according to the data structure. Secondly, we will explore effects of the intervention regarding care worker and resident outcomes using generalized linear mixed models

to account for the hierarchical data structure and repeated measurement points. Regarding the respective outcome, we will fit an additive model including the intervention and time of measurement as fixed effects and NH units and care workers or residents, respectively nested in NH units as random effects. The level of significance for all models is set to two-sided $\alpha = 0.05$. All analyses will be carried out using R statistical computing software (R Development Core Team, 2018).

Qualitative data

Focus groups will be conducted and analyzed following a mind mapping approach (Burgess-Allen & Owen-Smith, 2010). During the moderated discussion an assistant will add emerging topics and subtopics to a mind map, which at times will be summarized by the moderator and reviewed by the participants. After discussion, maps will be refined and organized with regard to domains of the TDF. After completion of all focus groups, maps will be integrated into a meta-map to gain an overview of the relevant barriers and facilitators to implementation. The audio- recorded interviews with pain champions will be transcribed verbatim and read several times for familiarization with the data. Subsequent identification and coding of meaningful extracts will be based on a predefined coding scheme, which builds on domains of the TDF. Further steps of analysis will follow the theoretical analysis approach described by Braun and Clarke (2006).

Data Integration

In this embedded design quantitative and qualitative data will be collected concurrently followed by a separate analysis. Findings of both strands will be merged in a next step. Qualitative data will assist to understand and expand on results of the quantitative strand.

Ethical considerations

This study protocol has been approved by the responsible cantonal ethics committees in October 2017 (EKNZ 2017-01466). Regarding the informed consent, different procedures have been applied: We obtained written informed consent from eligible residents, respectively their legally acceptable representative prior to the start of the study. In case of the care workers, informed consent to participate in the study is assumed by completing the questionnaire survey and submitting it to the researchers. Participants of the focus groups and pain champions will receive

a written study information and will be asked to give written consent to recording and further use of the anonymized interviews. All data collected in this study will be saved completely pseudonymised so it complies with local data protection laws.

Validity and Reliability

This study uses a mixed- methods study design combining data from different sources to provide comprehensive insights into the implementation processes. Furthermore, the concurrent data collection allows for data triangulation to account for threats to internal validity that might arise during implementation. Where possible this study considers validated scales for quantitative outcome evaluation. With regard to interrater- and intra-rater-reliability of the data collection at the resident level, research assistants received an intensive training from the first author to increase adherence to a standardized data collection protocol. Regarding the qualitative data collection, we seek to increase validity of data by member checking during focus groups. Additionally, data analysis and interpretation will be discussed and reflected with a group of researchers, who in parts are involved and not involved in the project.

5.4 DISCUSSION

This paper proposes an implementation intervention to improve pain management in Swiss NHs. Intervention research in unstable environments, such as NHs, experiences several challenges e.g. high turnover rates, leadership changes or other organizational restructuring processes which can be a threat for internal validity (Buckwalter et al., 2009). However, it is critical to test an intervention in clinical practice to evaluate its effectiveness. With the objective to determine the success of the implementation strategies simultaneously, this study uses an effectiveness-implementation hybrid design (Curran et al., 2012). To increase contextual fit of the implementation strategies we followed a participatory approach involving stakeholders from different levels in the development phase. With the combined use of two implementation frameworks (CFIR and TDF) we aim to comprehensively assess factors influencing implementation. Insights gained from this proposed study will inform potential adaptations to the intervention and implementation strategies.

Limitations

There are some limitations to the design of this study: the assessment of practice changes is limited to chart reviews of the nursing documentation and information on self-reported behavior. This kind of measurement does not reflect the actual practice but what is documented and subjectively reported. To gain a deeper understanding of the care workers' behavior in daily practice, it would be necessary to conduct observations in the NHs. However, due to logistical and financial constraints this approach is not feasible in this study. A further limitation to this study is the limited availability of validated scales in the context of care workers' behavior in pain management. To overcome this scarcity we had to develop several items building on existing measures from different contexts. Psychometric properties of these items have not yet been established, though. Another challenge specific to research in NH residents is the wide range of cognitive impairment in this population. This variability requires different outcome measures involving self-report or observations in residents with severe cognitive impairment, respectively. However, comparability between the outcome measures is not given, therefore resident outcomes have to be analyzed in two subgroups with relatively small sample sizes.

5.5 CONCLUSIONS

The proposed study aims to increase quality of life in NH residents by improving pain management in the participating NHs. Findings of this study will contribute to the understanding of behavior change in care workers regarding pain management practice. These insights can be used to inform the development of future implementation strategies in this field.

5.6 References

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Chapter 6

Pain management in nursing home residents: Findings from an effectiveness- implementation study

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6.1 Abstract

Objectives

To evaluate the effectiveness and implementation of a multilevel pain management intervention in nursing homes comprising a pain management guideline, care worker training and pain champions.

Design

An implementation science study using a quasi-experimental effectiveness-implementation (hybrid-II) design.

Setting

Four nursing homes in Switzerland.

Participants

All consenting long-term residents aged 65 years and older with pain at baseline (N=62) and all registered and licensed practical nurses (N=61).

Intervention

Implementation of a contextually adapted pain management guideline, interactive training workshops for all care workers and specifically trained pain champions.

Measurements

Interference from pain, worst and average pain intensity over the previous 24h; proxy ratings of pain with the Pain Assessment IN Advanced Dementia scale; Care workers' appraisal of the intervention's reach, acceptability and adoption.

Results

Pain-related outcomes improved for self-reporting residents (n=43) and residents with proxy-rating (n=19). Significant improvements of average pain from baseline to T1 ($P=.006$), and in worst pain from baseline to T1 ($P=.003$) and T2 ($P=.004$). No significant changes in interference from pain ($P=.18$). With regard to the implementation efforts, about 76% of care workers indicated to be familiar with the guideline; 70.4% agreed that the guideline is practical and matches their ideas of good pain assessment (75.9%) and treatment (79.7%).

Conclusion

Implementation of a multilevel pain management intervention did significantly improve average and worst pain intensity in nursing home residents. However, to effect clinical meaningful changes

in interference from pain, a more comprehensive approach involving other disciplines might be necessary.

Key words:

Pain management, nursing home, implementation study

6.2 Introduction

Pain is a prevalent symptom in nursing home (NH) residents. Affecting 40–85% of residents internationally (Hunnicutt, Ulbricht, Tjia, & Lapane, 2017; Takai, Yamamoto-Mitani, Okamoto, Koyama, & Honda, 2010) and roughly 60% in Switzerland (Sommerhalder et al., 2015), it has a serious impact on quality of life (Hemmingsson et al., 2018). Among other outcomes, under- or untreated pain interacts with depressive symptoms and limits functional capabilities, leading to increased care demands (Smith et al., 2016).

Pain management in NHs faces barriers on several levels, leading to insufficient assessment and treatment of residents' pain. Shortfalls in care workers' knowledge about geriatric pain management, combined with negative pain-related beliefs in both residents and care workers constitute some of the major difficulties in pain management (Kaasalainen et al., 2010; Martin, Williams, Hadjistavropoulos, Hadjistavropoulos, & MacLean, 2005). In addition, incapacity or reluctance of residents to report pain can hinder an appropriate pain assessment and management (Jones et al., 2006). Further challenges arise from the organizational level, high turnover rates among care workers can lead to a fluctuating pain management expertise and lack of stability in the care worker-resident relationship (Veal et al., 2018).

Evidence-based guidelines for the management of geriatric pain have been available for a decade (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2002, 2009; Fischer, 2014), yet, their passive dissemination has not resulted in changes of NHs' pain management practice (Jablonski & Ersek, 2009). The body of evidence regarding effective interventions to improve pain management is limited in terms both of quantity and of methodological rigor. Some recent approaches, e.g., implementation of nurse practitioners, have yielded promising initial results concerning pain management practice and resident pain outcomes (Kaasalainen et al., 2016). With regard to the specific setting or country, introducing a nurse practitioner might not be a feasible strategy, though. In this regard, another study tested the formation of pain management teams involving clinical champions and opinion leaders to implement pain management algorithms. Despite a rigorous design, the authors could not show clinically significant changes in pain management practice, nor outcomes (Ersek et al., 2016; Ersek et al., 2012). However, it remains unclear how pain teams worked in daily practice or how they contributed to the overall implementation. In light of these shortcomings, innovative approaches

that increase our understanding of which strategies work how and why are urgently needed to improve the uptake of evidence-based pain management in NHs.

Implementation science seeks to facilitate the translation of knowledge from clinical trials to real-world settings, accounting for the influences of contextual factors (Peters, Adam, Alonge, Agyepong, & Tran, 2013). With regard to the NH setting, organizational challenges, including high turnover rates and low skill-grade mixes as well as barriers specific to pain management, such as care workers' shortcomings in pain management knowledge, call for contextually adapted intervention approaches (Cammer et al., 2014). A comprehensive analysis of the implementation context, hence, is a crucial first step for the selection and adaptation of appropriate implementation strategies (Powell et al., 2017). This study used the consolidated framework of implementation research (CFIR) to guide this contextual analysis and inform the planning and designing of implementation procedures (Damschroder et al., 2009). The CFIR provides a list of 39 factors that potentially influence implementation. The constructs were derived from a synthesis of several implementation theories and can be grouped into five domains: inner setting, outer setting, characteristics of individuals, the intervention and the process by which implementation is accomplished (Damschroder et al., 2009). To evaluate the success of implementation efforts, implementation outcomes, such as acceptability, reach and adoption of the intervention, constitute important indicators and hence, need to be assessed (Proctor et al., 2011).

The overall objective of this study was to evaluate the effectiveness and implementation outcomes of a pain management guideline using interactive training workshops of care workers and introduction of trained pain champions. We had two specific aims: (I) to test the effectiveness of a multilevel pain intervention in improving residents' self-reported and proxy-reported pain outcomes; and (II) to evaluate the utility of implementation strategies with regard to the intervention's reach, acceptability and adoption.

6.3 Methods

Design

An implementation science study using a quasi-experimental pre-post effectiveness-implementation (hybrid-II) design (Curran, Bauer, Mittman, Pyne, & Stetler, 2012).

Setting

This study is part of the larger ProQuaS study, which is embedded in a group of 25 privately-owned NHs in Switzerland's German-speaking region. In Switzerland the NH workforce comprises about 30% unqualified care workers, i.e. nursing aides (NAs), about 40% licensed practical nurses (LPNs), 30% registered nurses (RNs); currently only a fractional amount of nurses holds an advanced practice role at Master's level (Merçay, Burla, & Widmer, 2016). No standardized system of collaborations between physicians and NHs exists.

As indicated in Figure 1, in the first phase of the overall project we conducted a comprehensive contextual analysis in 20 NHs belonging to the group to gain a deeper understanding of the local barriers and facilitators to pain management (**Chapter 3**). Central findings were a lack of established routines (e.g. pain assessment, standardized documentation) due to missing guidelines and shortcomings in care workers' pain management knowledge. Based on the findings of the exploratory analysis, we adapted our intervention and implementation strategies to fit the contextual needs and resources.

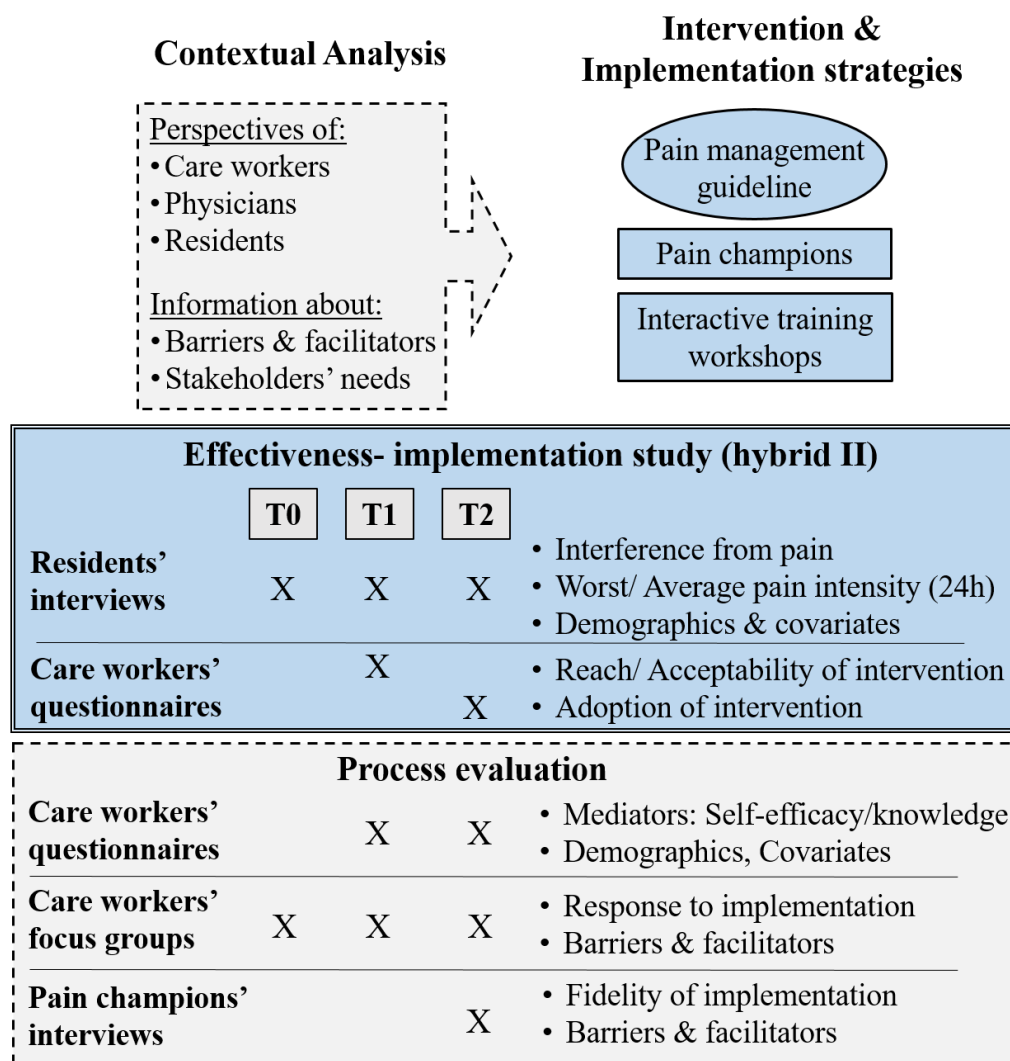


Figure 1: Overview of the ProQuaS study (dashed boxes not part of this manuscript)

Sample

This study was conducted in a convenience sample of four NHs acting as pilot institutions for the whole group (median bed count: 69; range: 47- 90). All residents who were >64 years and for whom written informed consent to participate was provided (either by the residents themselves or via proxy consent) were included. In addition to residents with a critical health status or terminal life situation with a presumed life expectancy of <3 months, short-term residents with an anticipated length of stay of <6 months were excluded. This paper only includes data of residents who reported pain at the baseline assessment.

For the care worker questionnaire survey, all RNs and LPNs were included if they worked in direct resident care, had been employed at least one month and were sufficiently fluent in German to understand the survey questions.

Intervention

The intervention and implementation strategies have been described in detail elsewhere (Brunkert, Ruppen, Simon, & Zúñiga, 2018). A facility pain management guideline was developed based on existing evidence-based guidelines and involvement of local stakeholders (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2009; Wulff et al., 2012).

The adapted guideline included the following core elements which are targeted in this study: (1) comprehensive pain assessment both of new residents (on admission) experiencing pain and of any residents with new or deteriorating pain situations; (2) use of the Pain Assessment IN Advanced Dementia Scale (PAINAD) (Warden, Hurley, & Volicer, 2003) for the observational assessment of pain in residents with severe cognitive impairment; (3) Routine pain assessment and re-evaluation; and (4) standardized documentation after pharmacological or non-pharmacological measures (Brunkert et al., 2018). Besides these core elements, the guideline comprised recommendations concerning the application of pharmaceutical and non-pharmaceutical approaches to pain management according to international guidelines (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2002, 2009).

Implementation strategies

In collaboration with an educational institute we provided interactive face-to-face training for all care workers according to their educational background. Workshops were based on the pain management guideline and comprised two sessions (2 hours each). Further, we recruited seven Pain champions (RNs or LPNs) from the staff of each participating NH ward and provided them with five days of interactive training focusing on pain assessment, treatment and coaching skills. Their tasks included regular educational booster sessions on pain management-related topics, monitoring and feedback of the residents' pain documentation, and providing guidance and practical support for care workers in resident pain situations. Further we conducted regular meetings with NHs' leadership and made adaptations of the context, e.g. documentation software.

A more detailed overview of the implementation strategies is described in the supplemental material.

Data collection

Residents' data were obtained from two sources: (1) routine data from the Resident Assessment Instrument–Minimum Data Set (RAI–MDS) provided by the participating NHs; and (2) structured interviews with the residents and responsible nurses by specially trained research assistants. Decisions concerning eligibility for a structured interview were made based on the cognitive performance scale (CPS), available from the RAI–MDS. Possible ratings ranged from 0= intact to 6= very severe cognitive impairment (Morris et al., 1994). Residents with a $CPS \geq 4$ were ineligible for structured interviews. Instead, their responsible care workers were interviewed (proxy reporting). Data were collected at baseline (T0), then three (T1) and six months (T2) after the start of the intervention. Care worker data were collected via questionnaire surveys three months after the start of the intervention. Overall, data collection was conducted from October 2017 until November 2018.

Variables and measurement

Resident outcomes. Functional interference from pain was assessed via a seven item scale from the Brief Pain Inventory (BPI) (Cleeland, 1991). Based on 11-point numeric rating scales (NRSs) (0= no interference - 10= interferes completely), the residents rated how, over the past 24 hours, pain has interfered with the following domains: general activity, mood, walking ability, normal work, relations with other people, sleep and enjoyment of life. For each resident's overall rating, a mean score was computed from all seven NRS ratings.

Worst and average pain intensity over the previous 24 hours were assessed with two BPI items, each of which asked the resident to rate his/her pain using an 11-point NRS (0= no pain - 10= pain as bad as you can imagine) (Cleeland, 1991). Acceptable measures of the BPI's validity and reliability were established both for the original scale and for the German translation (Budnick et al., 2016; Cleeland, 1991).

In residents with severe cognitive limitations, pain was assessed via a structured observation scale—the Pain Assessment in Advanced Dementia (PAINAD) scale (Warden et al., 2003). Trained research assistants observed each resident for two minutes during mobilization and

scored each of five aspects of his/her behavior (breathing, negative vocalization, facial expression, body language, and consolability) according to three categories: normal behavior (0); slightly indicating potential pain (1); and clearly indicating potential pain (2). With possible scores ranging from 0 – 10 points, a total of two and more points are supposed to indicate the presence of pain (Zwakhalen, van der Steen, & Najim, 2012). The German translation of the PAINAD shows strong psychometric properties (inter-rater reliability: $r = 0.8$; retest reliability: $r = 0.9$) (Schuler et al., 2007).

Descriptive characteristics. Depressive symptoms were assessed in residents able to self-report using the short form of the geriatric depression scale (Yesavage et al., 1982); proxy ratings used the Cornell Scale for Depression (Alexopoulos, Abrams, Young, & Shamoian, 1988). We further assessed independence in activities of daily living using the Katz ADL instrument (Bucks, Ashworth, Wilcock, & Siegfried, 1996). Each patient's CPS score, age and gender were obtained from the RAI-MDS.

Implementation outcomes. Adoption of the four core elements of the guideline was assessed in the third data collection (T2), using a two-step procedure. A first item assessed whether care workers experienced a situation which would require applying one of the core components, e.g., "Over the last three months, have you been responsible for the care of a resident with severe cognitive impairment". A second item assessed how frequently in these situations care workers have been applying the corresponding element on a four-point scale: never/ seldom (less than half of the situations)/ often (more than half of the situations)/ always. To construct a dichotomous indicator of adoption, we combined the answer options "never" and "seldom" = no adoption and "often" and "always" = adoption per core element.

In addition, we used four self-developed items in the care workers' questionnaire survey (T1) to assess reach (acquaintance with guideline) and acceptability of the pain management guideline (practicability of and accordance with guideline content and existing ideas of good pain assessment/management). Care workers were asked to rate each item on a 5-point Likert-type scale (range: completely disagree (0) to completely agree (4)). To report the items we combined the answer options "rather agree" and "completely agree."

Ethical considerations

This study was approved by the responsible cantonal ethics committees in October 2017 (EKNZ 2017-01466). Written informed consent was obtained from residents (if eligible) or their legally acceptable representatives by local study coordinators prior to the start of the study. For care workers, returning the completed questionnaire implied informed consent.

Sample size

Prior to the start of the study, we conducted a power analysis using the following assumptions: four participating nursing homes, an effect size of 0.2 in functional interference from pain based on prior studies (Drager et al., 2017) and an inter-participant correlation of 0.3. We assumed that for a power of 80%, we would need to include 180 participants in the final analysis. Since only four rather small nursing homes with less residents than anticipated participated, we were not able to meet the required number of residents.

Data analysis

Two resident subsamples were formed based on whether data were collected via self-report or by proxy-report. Based on these, descriptive statistics, such as means and proportions of the two samples were computed. To describe changes over time, we calculated absolute differences in means for each subsample and its corresponding outcome measures. For the self-report subsample, we also used linear mixed-effect models to determine changes in resident outcomes over time. Indicators for the measurement time points (T0, T1, T2) were added as fixed effects. To account for the nesting of the overall data structure, residents nested in their NHs and the repeated measurements of individuals, we added the NHs and individual residents' IDs as random effects. For outcomes on the care worker level we computed descriptive statistics. Statistical analyses were performed using R statistical computing software (R Development Core Team, 2018). Linear mixed models were computed using the LME4 package (Bates, Mächler, Bolker, & Walker, 2015). Statistical significance was assigned at the $P < .05$ level.

6.4 Results

At baseline, 62 residents were included in the study. Over the six-month study period, there was a dropout rate of 21%, mainly due to deaths ($n=9$); in one case, data collection was stopped at

the NH's request because the resident was ill (n=1). In the self-report subsample, some data were missing due to the residents' cognitive deterioration. Where this occurred, proxy reports (n=3) were used. Details concerning recruitment and retention can be found in Supplementary Figure S1. An overview of the residents' characteristics is shown in Table 1. The sample of included care workers (n=61) included 26 (43%) RNs and 35 (57%) LPNs; the overall survey response rate was 75%. At T2, overall 48 care workers (40% RNs, 60% LPNs) participated in the questionnaire survey (response rate= 59%).

	Participants able to self-report (n= 43)	Participants unable to self-report (n= 19)
	mean (SD)	mean (SD)
Age	87.1 (7.7)	87.4 (6.0)
Female n (%)	29 (67.4)	10 (52.6)
CPS	1.9 (1.2)	3.5 (1.4)
ADL	4.7 (1.7)	2.1 (1.8)
GDS	3.5 (2.3)	-
CSDD	-	10.7 (6.6)

Table 1: Baseline characteristics of study participants

Note. CPS: Cognitive Performance Scale (possible range: 0-6, higher number indicates more severe cognitive impairment); ADL: Activities of daily living (possible range: 0-6, higher number indicates higher ADL dependence) GDS: Geriatric Depression Scale (possible range: 0-15, higher number indicates higher probability of a depression); CSDD: Cornell Depression Scale (possible range: 0-18, higher number indicates higher probability of a depression)

Resident outcomes

Overall data indicated a decrease in all pain-related outcomes between baseline and T1/T2 in both samples (s. Table 2). In the self-report sample, functional interference from pain decreased from 2.8 at Baseline to 2.2 at T1 ($P = .18$), rebounding slightly to 2.4 at T2 ($P = .44$). Intensity of worst pain improved from 6.0 to 4.6 at T1 ($P = .003$) and 4.4 at T2 ($P = .004$), average pain improved

from 3.6 to 2.6 at T1 ($P = .006$) and 3.0 at T2 ($P = .16$). An overview of the coefficients for time indicators and confidence intervals of the random effects is provided in the supplementary material. In the proxy-report sample, the average PAINAD score decreased from 1.9 at baseline to 1.2 at T1 and 1.1 at T2. Table 2 provides an overview of descriptive changes in both samples. In Figure 2, an overall decreasing trend can be observed in all NHs for both samples, with two exceptions: the NH A's average pain intensity rose above the baseline value of 2.8 to 3, and NH B's mean interference from pain climbed above the baseline value of 2.7 to 3.1. However, 95% confidence intervals (CI) of the NH random effects' variance components indicate no significant differences between facilities.

	Baseline (T0)	T1	T2
	mean (SD)	mean (SD)	mean (SD)
		Δ T0	Δ T0
Self- report	n= 43	n= 40	n=37
Interference from pain (possible range: 0-10)	2.8 (2.5)	2.2 (2.1) -0.6	2.4 (2.5) -0.4
Intensity of worst pain (possible range: 0-10)	6.0 (2.6)	4.6 (2.8) -1.4	4.4 (2.7) -1.6
Intensity of average pain (possible range: 0-10)	3.6 (2.3)	2.6 (1.6) -1	3.0 (2.1) -0.6
Proxy- report	n= 19	n= 15	n= 12
PAINAD (possible range: 0-10)	1.9 (2.7)	1.2 (1.5) -0.7	1.1 (1.9) -0.8

Table 2: Descriptive changes in resident outcomes

Note. Δ T0: absolute difference to baseline; PAINAD: Pain Assessment IN Advanced Dementia Scale

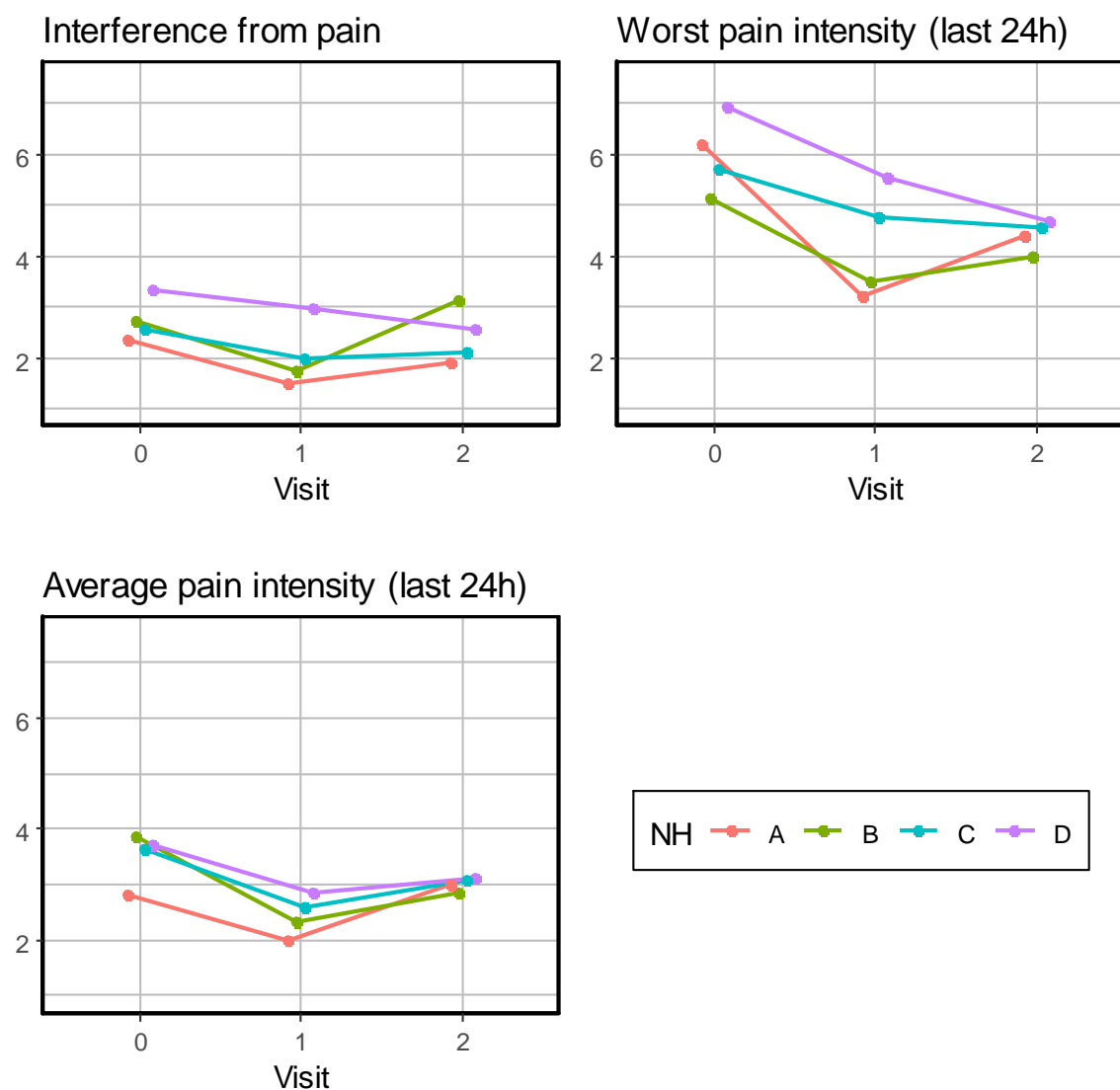


Figure 2: Overview of changes over time by nursing home

Implementation outcomes

Of the 61 participating care workers, 76.4% (CI: 62.7- 86.3) indicated familiarity with the pain management guideline (=reach of intervention). Regarding the intervention's acceptability, 70.4% (56.2- 81.6) agreed that implementing the pain management guideline into daily practice was practical. Moreover, 75.9% (62.1- 86.1) agreed that the content of the pain management guideline accorded with their ideas of good pain assessment and pain management practice (79.7%, 70.9- 90.7). An overview of the self-reported adoption is depicted in Table 3 (below).

Guideline components (n)*		%
I	Comprehensive assessment: new resident (n=36)	44.4
	Comprehensive assessment: new pain (n=33)	54.5
II	PAINAD: Observational tool (n= 29)	48.3
III	Pharmacological treatment: Reassessment (n=41)	73.2
	Nonpharmacological treatment: Reassessment (n= 38)	50.0
IV	Pharmacological treatment: Documentation (n=41)	68.3
	Nonpharmacological treatment: Documentation (n= 38)	44.7

Table 3: *Care workers' self-reported adoption of the different guideline components at T2*

Note. (*) number of respondents who experienced relevant situation corresponding to the item

6.5 Discussion

The implementation of a pain management guideline supported by interactive training workshops and trained pain champions showed partly significant improvements in NH residents' pain-related outcomes. Intensity of average pain (24h) decreased significantly from baseline to three months ($P=.006$); and intensity of worst pain decreased from baseline to three ($P=.003$) and six months ($P=.004$). However, changes in interference from pain were not statistically significant (T1: $P=.18$ / T2: $P=.44$). In residents unable to self-report, proxy-reported PAINAD scores decreased from baseline to T1 and T2. Results from the care worker questionnaire indicate that the intervention was perceived as acceptable. The intervention's reach, operationalized as familiarity with the guideline, was fair: 76% of all care workers indicated a reasonable knowledge of the guideline. The self-reported adoption of guideline components ranged from 44.4 to 73.2%.

Unlike similar studies in the field of NH pain management, and despite our small sample size, this study showed significant changes in pain-related outcomes (Drager et al., 2017; Ersek et al., 2016; Hadjistavropoulos, Kaasalainen, Williams, & Zacharias, 2014; Kaasalainen et al., 2012). Chronic pain is common in NH residents; therefore, improving psychosocial and functional interference from pain is highly relevant to the affected residents' quality of life. Similar to our findings, a cluster-randomized controlled study that comprised training of NH care workers and

general physicians showed a slight (non-significant) decrease in residents' interference from pain (Drager et al., 2017). In light of the complexity of chronic pain situations, decreasing interference from pain might require a more comprehensive approach. Previous research has shown that the experience of functional impairment due to pain is strongly associated with perceived self-efficacy; depression, on the other hand, is known to rather increase interference from pain (Adams et al., 2018; Jackson, Wang, Wang, & Fan, 2014). NH care workers need to be aware of how pain can influence psychosocial and physical functioning and vice versa. Moreover, where possible, they should foster residents' self-efficacy to deal with their pain. A multimodal approach involving physical therapists, psychotherapists and/or pain specialists might be necessary.

Overall, with regard to the implementation of pain management guidelines our experiences from this study highlight that NH administrators should carefully plan and prepare the undertaking. Besides training care workers in pain assessment and treatment, it is imperative to implement a sustainable educational structure that provides continuous opportunities for staff to strengthen their knowledge and skills. To directly support care workers, a staff member particularly trained in pain management can be a helpful resource and role model. Testing complex interventions in a real-world setting is challenging due to influencing factors' potential to disrupt internal validity. In this regard, it is crucial to distinguish between an intervention's effectiveness and the success of the implementation efforts. Implementation efforts in this study have been challenged by high turnover in NH staff and leadership, as well as competing interests due to concurrent organizational changes.

Developing effective strategies to achieve sustainable changes in NH practice therefore remains a central issue for future research (Drager et al., 2017; Jones et al., 2004). In this regard, it is important to evaluate interventions beyond their effect on patient outcomes. Our implementation outcomes gave us important insights on the implementation efforts. On the one hand, the majority of care workers were familiar with the guideline and perceived it as acceptable. One explanation for this positive finding might be the close involvement of all directors of nursing to adapt the existing guidelines to fit the Swiss context. It has been recognized that stakeholders' perceptions both of an intervention's source and of its adaptability factor crucially in implementation success (Damschroder et al., 2009; Rogers, 2003). On the other hand, our findings

showed that the self-reported adoption of the guideline varied considerably between components which might have had implications for the overall effectiveness.

This study's strengths include its comprehensive development approach which was informed by a contextual analysis involving all relevant stakeholders, particularly care workers, NH administrators, physicians and residents (see Figure 1). A further strength lies in the concurrent evaluation of effectiveness and implementation efforts using a hybrid study design. The forthcoming process evaluation will help to shed light upon the underlying mechanisms and processes of implementation.

In addition to its strengths, this study's limitations need to be recognized. For one, the non-randomized, uncontrolled study design might limit the validity of our findings. For another, because of restricted financial and logistical resources, the sample was limited to four NHs, resulting in 62 participating residents. Considering the heavy burden of data collection, as we did not want to exclude half of the NHs from the intervention, we decided against a control group. Another aspect that requires critical evaluation is the limited information on actual pain management behavior. Although we were unable to conduct observations in the participating NHs to assess changes in staff pain management practices, our process evaluation's preliminary findings indicate positive developments over the course of the implementation period e.g., increased awareness towards pain in residents, particularly in residents with dementia (forthcoming).

A further limitation is the use of different outcome measures in residents with and without the ability to self-report, hindering direct comparison between the two groups. Furthermore, data collection in residents was conducted by trained research assistants with little acquaintance of the residents. The PAINAD scale can be administered without extensive knowledge of the person, however, previous studies established considerable floor effects (Sanford, 2016).

6.6 Conclusions

This study used an implementation science approach to develop and evaluate contextually adapted intervention and implementation strategies to improve pain management in nursing homes. On the one hand, we could show partially significant improvement in residents' pain-related outcomes, on the other hand care workers were mostly familiar with the guideline and

perceived it acceptable, however, self-reported adoption of the guideline varied between components.

Future work should focus on developing implementation strategies to withstand contextual barriers such as high turnover, low skill-grade mix and limited knowledge to improve uptake of new practices in NHs. Tackling changes in pain management practice is of particular concern, since undertreated or unrecognized pain remains widespread in NH residents.

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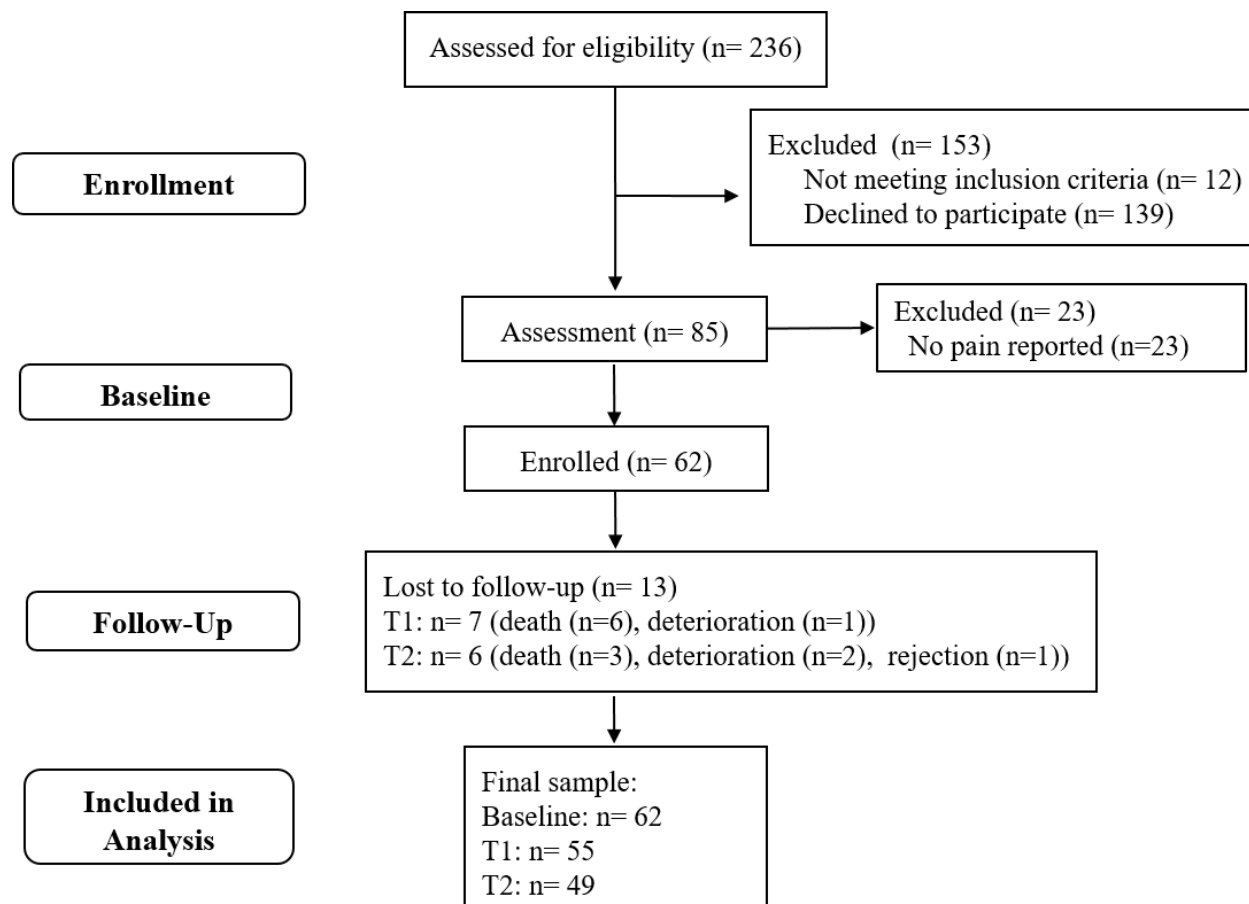
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Supplemental figure S1: Flow diagram of participant recruitment and retention



Supplemental Table 1: Overview of implementation strategies

Implementation strategy	Operationalization	Timing
Interactive training workshops	<ul style="list-style-type: none"> - 2x 2h face to face training/ education according to job level (RNs & LPNs/ nursing assistants) - Interactive workshops conducted by educational institute - Content according to pain management guideline, i.e. pain assessment and treatment 	Before T0
Pain champion	<ul style="list-style-type: none"> - Recruitment of 1-2 care workers (RNs or LPNs) from each NH - 5x 8 h interactive training focusing on pain assessment, treatment and coaching skills - Management of NH group grants NHs additional 0.1 FTE per pain champion to conduct tasks related to the role - Provision of material for educational booster sessions - Quarterly meetings with all pain champions and researchers to reflect on implementation experiences and extend training content 	Before T0
	<u>Role of pain champions:</u> <ul style="list-style-type: none"> - Conduct regular educational booster sessions - Monitor residents' documentation and provide individual feedback - Provide guidance and practical support in complex resident pain situations 	After T0

Meetings with NHs' leadership	<ul style="list-style-type: none">- Preparatory meetings with NH leadership prior to implementation- Collaborative agreement between NHs and research institute- Ongoing telephone support as needed- Quarterly sounding board meetings involving leadership of each participating NH, administrative leadership of NH group and researchers to discuss local barriers and progress of implementation	Before T0 Between T0- T2
Adaptations of the environmental context	<ul style="list-style-type: none">- Adaptations of the resident documentation software (e.g. pain assessment form)- Provision of guideline on each ward in paper form and intranet- Distribution of assessment tools (e.g. cardboard VAS scales)	After T0

Supplementary Table S2: Coefficients for time indicators and confidence intervals of the random effects for different outcome measures of the self-report subsample

	Interference pain (average)	from (pain previous 24h)	Worst intensity (pain previous 24h)	Average intensity (pain previous 24h)
	β (CI)		β (CI)	β (CI)
Fixed effects:				
T1	-0.5 (-1.3, 0.2)		-1.4 (-2.2, -0.5)*	-1.1 (-1.8, -0.3)*
T2	-0.3 (-1.1, 0.5)		-1.3 (-2.2, -0.4)*	-0.5 (-1.3, 0.2)
Random effect:				
NH (CI)	(0, 1)		(0, 1)	(0, 0.7)

Table 3: Coefficients for time indicators and confidence intervals of the random effects for different outcome measures

Note. * $p < 0.01$; T1: time indicator, three months after start; T2: time indicator, six months after start; NH: nursing home; CI: confidence interval

Chapter 7

Understanding the implementation of a pain management intervention in Swiss nursing homes: a process evaluation

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7.1 Abstract

Background

Underutilization of evidence-based pain management in nursing homes is common. Evidence towards effective approaches to improve adoption of evidence-based practices in nursing homes is limited. To get a better understanding of the challenges in the implementation process of a pain management guideline, this study explored the underlying mechanisms of the implementation strategies, care worker training workshops and the introduction of trained pain champions, using behavioral theory.

Methods

We conducted a process evaluation alongside an implementation- effectiveness study which was conducted in a convenience sample of four Swiss nursing homes. Implementation strategies were developed based on an a priori contextual analysis in the participating homes and then specified into behavior change techniques. On the basis of this, we developed a conceptual framework describing hypotheses concerning the underlying mechanisms of change.

Care workers' questionnaire surveys were conducted at baseline (n=136), after three (n= 99) and six months (n=83) to assess self-efficacy in pain management and self-reported guideline adoption. We computed linear mixed-effect models to assess changes over time in self-efficacy and logistic regressions to assess associations between self-efficacy and guideline adoption.

Results

Overall, there was a significant increase in self-efficacy after three and six months ($p<0.001$). Self-reported adoption of guideline components ranged between 44% and 73% depending on the component. We found significant associations between self-efficacy and adoption of two guideline components, i.e. performing a comprehensive pain assessment and using an observational pain assessment tool in cognitively impaired residents.

Conclusions

Our findings highlight the importance of continuous commitment of an implementation facilitator, e.g., a pain champion, within an organization. With regard to persistent implementation challenges, a theory-based conceptual framework can contribute to the overall understanding.

Keywords: Implementation study, Process evaluation, Nursing home, Pain management

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Conflict of interest

No conflict of interest has been declared by the authors.

7.2 Introduction

Implementation of evidence-based interventions in health care organizations has been recognized to be a challenging endeavor (Grimshaw, Eccles, Lavis, Hill, & Squires, 2012). To increase the uptake of new practices, current literature emphasizes the need to systematically select and tailor implementation strategies with regard to needs of the implementation context (Powell et al., 2019). An a priori contextual analysis to identify barriers and facilitators to the new practice, hence, is a pivotal first step to inform the development of appropriate implementation strategies (Powell et al., 2017). Although there is some evidence that strategies tailored to determinants are more likely to change practice (Baker et al., 2010), little is known about the mechanisms of how implementation strategies affect change in practice (Lewis et al., 2018; Powell et al., 2019).

One approach to understand mechanisms of change in a specific context can be a process evaluation (Moore et al., 2015). Crucial steps of this evaluation are specification of the implementation strategies with regard to their active components and the generation of hypothesized mechanisms of change based on a program theory (Lewis et al., 2018). To date, implementation science literature is vastly lacking theory about underlying mechanisms of implementation efforts (Williams, 2016). Advances have been made in the field of behavior change, though. In a current synthesis of 277 behavior change interventions, identified behavior change techniques were linked to mechanisms of actions based on constructs of behavioral theory (Carey et al., 2018). The most frequently identified mechanism “Beliefs about Capabilities”, originates from Bandura’s theory of Self- Efficacy (Bandura, 1977). The theory describes “mastery experience”, “vicarious experience”, and “verbal persuasion” as strategies to improve self-efficacy, which can be translated into behavior change techniques (Carey et al., 2018). Implementation strategies that incorporate these behavior change techniques, e.g., modeling, monitoring and feedback on the behavior, hence might be able to increase self-efficacy related to the intended behavior. This study reports the process evaluation of an implementation study that used interactive training workshops and the introduction of pain champions to facilitate the adoption of pain management guidelines in nursing homes (NHs).

In the field of nursing home care, pain management is a critical topic with an established knowledge to practice gap (Jablonski & Ersek, 2009). Although international guidelines for

geriatric pain management are available, their adoption into daily practice of NHs is often inadequate (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2009). Internationally, between 40–85% of NH residents report pain (Hunnicutt, Ulbricht, Tjia, & Lapane, 2017; Takai, Yamamoto-Mitani, Okamoto, Koyama, & Honda, 2010). Insufficient pain management can result in severe consequences for NH residents' health and quality of life (Smith et al., 2016). Residents with cognitive impairment are at particular risk for unrecognized and undertreated pain due to their inability of communicating pain (Fain et al., 2017).

In a first phase of this project we conducted a comprehensive analysis of the implementation context to identify determinants of behavior change with regard to pain management practice (**Chapter 3**). Based on these findings we developed and tested a multilevel intervention to improve pain management in NH residents (**Chapter 5**). The overall aim of this study was to gain an understanding of the processes and mechanisms related to the implementation of a multilevel pain management intervention in Swiss NHs. Our specific aims were, to determine changes in care workers' self-efficacy in pain management, to describe care workers' self-reported adoption of the pain management guideline and to assess associations of self-efficacy and adoption.

7.3 Methods

Conceptual model

In the planning phase of this study we developed a conceptual model, hypothesizing how our implementation strategies might affect change in pain management practice. To underpin our hypothesis we defined the active components of the strategies using the behavior change taxonomy (Michie et al., 2013). With regard to the central strategies, training workshops and pain champions we hypothesized that 'demonstration of the behavior', 'verbal persuasion about capability' and 'feedback on the behavior' would increase self-efficacy as suggested by Bandura's theory of self-efficacy (Bandura, 1977). With regard to his theory, we further hypothesized that the increased self-efficacy in pain management would result in the adoption of the guideline in daily practice. However, in light of the multilevel influences of contextual factors in implementation processes, it needs to be acknowledged that the linearity of our conceptual model depicts a simplified assumption about actual mechanisms and processes.

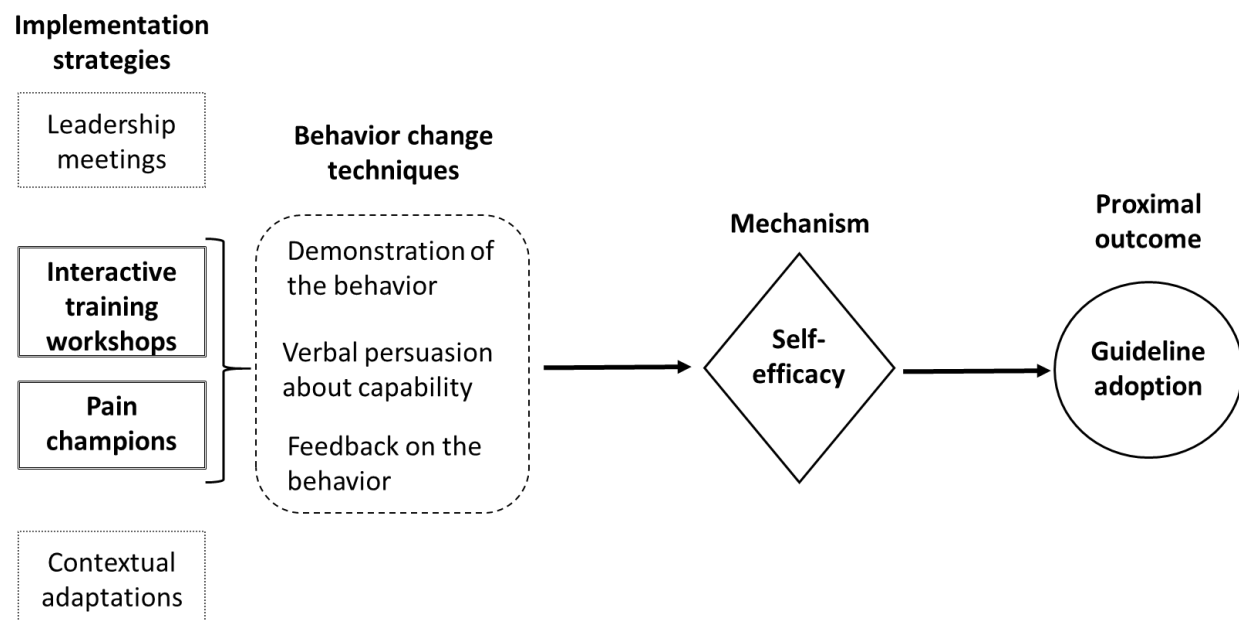


Figure 1: Conceptual model

Design

A process evaluation using quantitative data from care workers participating in an implementation-effectiveness study (hybrid II) to improve pain management in NHs.

Sample/ Setting

This study is part of a larger implementation study which was conducted in a convenience sample of four NHs located in the German-speaking part of Switzerland. All institutions belong to a privately- owned NH group, which is part of a large European operator of long-term care facilities.

Intervention

A protocol for this study describing the intervention and implementation strategies in more detail was published previously (Chapter 5). We developed a pain management guideline based on international recommendations for the management of geriatric pain as in Switzerland currently no national guideline for the management of geriatric pain are available (Abdulla et al., 2013; American Geriatric Society Panel on Persistent Pain in Older Persons, 2009; Fischer, 2014). The final guideline was adapted to the local context in collaboration with the participating NHs. An overview of the core components targeted in this study, is displayed in Table (below).

#	Core component	Description	Scope of practice
I	Comprehensive pain assessment	Fill in pain assessment form on admission of new residents with pain	RNs, LPNs
		Fill in pain assessment form for residents with new or deteriorating pain situations	RNs, LPNs
II	Use of the Pain Assessment in Advanced Dementia Scale (PAINAD) (Warden, Hurley, & Volicer, 2003)	Observational pain assessment tool to be only used in residents with severe cognitive impairment	Mainly RNs, LPNs
III	Routine pain assessment and re-evaluation	Use of standardized instrument, e.g. visual analogue scale to assess pain intensity, pain location and quality before and after pharmacological or non-pharmacological interventions	RNs, LPNs, nursing assistants
IV	Standardized documentation	Documentation of pain assessments results before and after pharmacological or non-pharmacological interventions	RNs, LPNs, nursing assistants

Table 1: Core components of the pain management guideline

Implementation strategies

The implementation strategies have been developed based on a comprehensive contextual analysis involving perspectives of multiple stakeholders (**Chapter 3/4**). An overview of the implementation strategies is displayed in Table 2. We itemized the overall implementation strategies into discrete strategies according to the Expert Recommendations for Implementing Change (ERIC) (Powell et al., 2015). Further, we determined corresponding behavior change techniques and their hypothesized mechanisms of change (Michie et al., 2013).

Implement ation strategy	Discrete strategies	Operationalization	Behavior change techniques	Hypothesized mechanism
Interactive training workshops	<ul style="list-style-type: none"> - Conduct educational meetings - Work with educational institutions - Make training dynamic 	<ul style="list-style-type: none"> - 2x 2h face to face training/ education according to job level (RNs & LPNs/ nursing assistants) - Interactive workshops conducted by educational institute - Content according to pain management guideline, i.e. pain assessment and treatment 	<ul style="list-style-type: none"> - Information about health consequences 	<ul style="list-style-type: none"> - Knowledge gain - Awareness building
			<ul style="list-style-type: none"> - Instructions on how to perform the behavior - Demonstration of the behavior - Verbal persuasion about capability 	<ul style="list-style-type: none"> - Increase in self-efficacy
Pain champion (PC)	<ul style="list-style-type: none"> - Identify and prepare champions - Use train-the-trainer strategies - Revise professional roles 	<ul style="list-style-type: none"> - Recruitment of 1-2 care workers (RNs or LPNs) from each NH - 5x 8 h interactive training focusing on pain assessment, treatment and coaching skills - NH groups' management grants 10% of regular working time for champions' role 	<ul style="list-style-type: none"> - Information about health consequences 	<ul style="list-style-type: none"> - Knowledge gain - Awareness building
			<ul style="list-style-type: none"> - Instructions on how to perform the behavior - Demonstration of the behavior 	<ul style="list-style-type: none"> - Increase in self-efficacy

	<ul style="list-style-type: none"> - Capture and share local knowledge - Organize clinician implementation team meetings - Develop/distribute educational material - Conduct ongoing training 	<ul style="list-style-type: none"> - Quarterly meetings with all PCs and researchers to reflect on implementation experiences and extend training content - Provision of material for educational booster sessions <p><u>Role PC:</u></p> <ul style="list-style-type: none"> - Conduct regular educational booster sessions - Monitor residents' documentation and provide individual feedback - Provide guidance and practical support in complex resident pain situations 	<ul style="list-style-type: none"> - Behavioral practice/rehearsal - Review behavior goals - Review outcome goals - Discrepancy between current behavior and goal - Feedback on behavior - Verbal persuasion about capability 	
			- Social support	- Social influences
Meetings with NHs' leadership	<ul style="list-style-type: none"> - Mandate change - Obtain formal commitments - Use advisory boards and workgroups 	<ul style="list-style-type: none"> - Preparatory meetings with NH leadership prior to implementation and ongoing telephone support - Collaborative agreement between NHs and research institute - Quarterly sounding board meetings involving leadership of each 	- Restructuring the physical/social environment	- Environmental context and resources

	<ul style="list-style-type: none"> - Involve executive boards - Capture and share local knowledge - Provide ongoing consultation 	participating NH, administrative leadership of NH group and researchers to discuss local barriers and progress of implementation		
Adaptations of the environmental context	<ul style="list-style-type: none"> - Change record systems - Develop educational materials - Distribute educational materials 	<ul style="list-style-type: none"> - Adaptations of the resident documentation software (e.g. pain assessment form) - Provision of guideline on each ward in paper form and intranet - Distribution of assessment tools (e.g. cardboard VAS scales) 	- Restructuring the physical environment	- Environmental context and resources

Table 2: Overview of implementation strategies

Sampling and data collection

For our quantitative data collection we included care workers from all educational backgrounds, i.e. registered nurses (RNs), licensed practical nurses (LPNs) and nursing aides (NAs) who worked in direct resident care, had been employed for at least one month and were sufficiently fluent of German to understand the survey questions. We conducted a questionnaire survey collecting data at baseline (T0), three (T1) and six months (T2) after start of the intervention, lasting from November 2017 to November 2018. Local coordinators (e.g., director of nursing) were responsible for distributing questionnaires in the NHs. Participation was voluntary and anonymous. A pre-stamped envelope was provided with each questionnaire to ensure confidentiality.

Variables and measurement

Self- efficacy in pain management was assessed at all data collection points with a self- developed 13-item scale. At the time of data collection, no measure assessing this construct was available. In developing the scale we followed guidance on creating self-efficacy scales (Bandura, 2006). Care workers were asked to rate items assessing how confident they feel in tasks related to pain management, e.g. pain assessment, documentation and non- pharmacological treatment on an 11- point rating scale (0= not confident at all - 100= very confident). For evaluation a mean score of all 13 items was calculated.

Guideline adoption with regard to the four core components of the guideline was assessed in the third data collection (T2), using a two-step procedure. A first item assessed whether care workers experienced a situation which would require applying one of the core components, e.g., “Over the last three months, have you been responsible for the care of a resident with severe cognitive impairment?”. A second item assessed how frequently in these situations care workers have been applying the corresponding component on a four- point scale: never/ seldom (less than half of the situations)/ often (more than half of the situations)/ always. To construct a dichotomous indicator of adherence to the component, we combined the answer options “never” and “seldom” = no adherence and “often” and “always” = adherence.

Further items of the care workers’ questionnaire assessing sociodemographic data comprise age, sex, educational level (RN/LPN or nursing assistant), years of work experience, tenure in NH, and working percentages.

Data analysis

Descriptive statistics were computed to explore means, medians, distribution and confidence intervals of the data. To determine changes in self-efficacy over time we used unadjusted linear mixed-effect models. Indicators for the time of data collection (T0, T1, T2) were added as fixed effects. To account for the nested data structure, care workers nested in NHs and the repeated measures of individuals, we added the NHs and individual IDs as random effects. We conducted a sensitivity analysis based on a sample of care workers who have been participating in all three data collections.

To describe the self-reported pain management behavior we built different sub-samples per core component, considering only data from respondents who indicated to have experienced relevant situations corresponding to the core component. Further, for the indicators “comprehensive pain assessment” and “use of PAINAD”, we excluded data from nursing assistants since these components are not part of their scope of practice. In a next step, we determined associations between adherence to guideline components and self-efficacy items by calculating several simple logistic regressions based on these sub-samples.

Statistical analysis was performed using R statistical computing software (R Development Core Team, 2018). Linear mixed-models were computed with the LME4 package (Bates, Mächler, Bolker, & Walker, 2015). Statistical significance was assigned at the $P < .05$ level.

Ethical considerations

We received ethical approval for this study from the responsible ethics committee (EKNZ 2017-01466). For the questionnaire survey, informed consent was implied by returning the questionnaire.

7.4 Results

Sample size of care workers differed between the three waves of data collection due to care worker turnover and partial decline of response rates, resulting in 136 respondents at baseline (average response rate: 84%), 99 respondents at T1 (69 %) and 83 respondents at T2 (59 %). A sub-sample of 41 care workers participated at all time points. An overview of the different sample characteristics is displayed in Table 3.

	Baseline (n= 136)	T1 (n=117)	T2 (n=83)	Sub-sample (n=41)
Age mean (SD)	37.7 (13.9)	38.0 (13.5)	36.9 (13.1)	36.9 (13.4)
Female n (%)	110 (83.3)	97 (84.3)	69 (83.1)	35 (86.4)

RNs n (%)	29 (21.8)	24 (23.1)	17 (20.7)	9 (22.0)
LPNs n (%)	36 (27.1)	27 (26.0)	25 (30.5)	10 (24.4)
Nursing aides n (%)	52 (39.8)	51 (49.0)	31 (37.8)	15 (36.6)
Other personnel n (%)	15 (11.3)	13 (11.3)	9 (11.0)	7 (17.0)
Work experience mean (SD)	11.2 (10.5)	11.2 (9.9)	10.5 (9.9)	10.9 (10.3)
Tenure in NH mean (SD)	3.3 (4.9)	3.2 (3.9)	3.0 (4.0)	2.8 (4.1)

Table 3: Characteristics of care workers at all three data collection points

Note. RN= registered nurse, LPN= licensed practical nurse

Changes of self- efficacy in pain management

Overall, there was an increase of self- efficacy between baseline and T1/T2 for all educational levels. In LPNs and RNs the mean score of self-efficacy increased from 69.6 (SD 14.6) at baseline to 74.2 (SD 15.2) at T1 and 76.8 (SD 14.7) at T2. In nursing assistants the mean score changed from 64.3 (SD 15.1) at baseline to 72.4 (SD 12.1) and 69.2 (SD 12.4) at T2.

	Self- efficacy	
	β (CI)	
	A	B
	n=337	n= 123
T1	8.84 (6.08 - 11.58)***	11.28 (7.67 - 14.89)***
T2	9.39 (6.24 – 12.49)***	10.17 (6.56 - 13.78)***

Table 4: Coefficients of the linear mixed-models for self-efficacy mean score

*Note. A=sample includes all care workers irrespective of participation, B=sub-sample of care workers that participated in all three data collections, * $p<0.05$, ** $p<0.01$ *** $p<0.001$*

Self-reported pain management behavior

Self-reported adherence to guideline components ranged between 44% and 73% depending on the component. In Table 5, an overview of care workers' adherence to core components of the guideline is displayed. Sample sizes vary between the components, since they depend on the number of care workers who experienced a corresponding situation.

We found significant associations between care workers' adherence to core component I (conducting a comprehensive assessment) and II (using PAINAD scale) and corresponding self-efficacy items. However, we have not found significant associations between the other two core components and corresponding self-efficacy items. An overview of the associations is displayed in Table 6.

		RN & LPN (n=48)	Nursing assistants (n=32)	Overall (n=83)**
Guideline components (n)*		%	%	%
I	Comprehensive assessment: new resident (n=36)	44.4	x	x
	Comprehensive assessment: new pain (n=33)	54.5	x	x
II	PAINAD: Observational tool (n= 29)	48.3	x	x
III	Pharmacol. treatment: Reassessment (n=62)	73.2	45.0	64.5
	Non-pharmacol. treatment: Reassessment (n=65)	50.0	50.0	50.8
	Pharmacol. treatment: Documentation (n=62)	68.3	60.0	66.2
IV	Non-pharmacol. treatment: Documentation (n=65)	44.7	50.0	47.7

Table 5: Self-reported adherence to guideline;

Note. () number of respondents who experienced relevant situation corresponding to the item; (**) missing observations on educational level: 3*

	I Comprehensive Assessment OR (CI)	II Use of PAINAD OR (CI)	III Re-evaluation OR (CI)	IV Documentation OR (CI)
How confident are you				
..to systematically interview residents about their pain	1.10* (1.03- 1.17)		1.00 (0.97 -1.04)	
...to differentiate between different sources of residents' pain?	1.07* (1.01- 1.14)			
...to recognize when residents with dementia are in pain?		1.05* (1.00- 1.1)	1.02 (0.98- 1.05)	
... to use an observational pain scale for pain assessment in residents with dementia (e.g., PAINAD)?	1.07* (1.02- 1.13)	1.05* (1.00- 1.09)	1.01 (0.99- 1.04)	
...to use a standardized scale for residents' self- report of pain?	1.14* (1.03- 1.25)		1.01 (0.98- 1.04)	
...to document the relevant information about residents' pain situations completely?				1.02 (0.98- 1.05)

Table 6: Associations between self- efficacy items and self- reported adoption of core elements

Note. OR= odds ratio, CI= confidence interval; * $p < 0.05$

7.5 Discussion

The current study found that interactive training workshops and introduction of a trained pain champion could significantly increase self-efficacy related to pain management in care workers. Overall, about half of the care workers reported to adhere to the guideline components ‘conducting a comprehensive assessment’ and ‘use of PAINAD’. In comparison, between half to two thirds of care workers indicated to document routine pain assessment and to re-assess pain after a pain alleviating measure -adoption was lower in nursing assistants and with regard to nonpharmacological measure. Furthermore, we could show significant associations between care workers’ self-efficacy and adoption of two core components: ‘conducting a comprehensive assessment’ and ‘use of PAINAD’, however there was no significant relation with the components ‘documentation’ and ‘re-evaluation’.

This study was the first to look at the implementation of a pain management guideline in NHs using a behavioral perspective. In general, effects of previous studies in this field were mixed (Herman, Johnson, Ritchie, & Parmelee, 2009; Knopp-Sihota, Patel, & Estabrooks, 2016), yet most evaluation approaches did not allow to differentiate between the effectiveness of the intervention and utility of implementation strategies. Much of the previous research was based on quality improvement approaches and did not integrate further theoretical underpinning. The majority of studies dealing with pain management in NHs assessed pain related outcomes on the resident level, additionally, most studies evaluated process measures based on the residents’ documentation. To some degree these measures can be informative, however they are only crude indicators of the changes occurring on the level of care workers.

The pain management guideline implemented in this study consists of a set of several recommended actions to assess and treat pain. Pain assessment in NH residents depicts a challenge for care workers since pain is a highly subjective symptom and the ability to self- report pain is often limited in residents. The use of a comprehensive pain assessment at admission or the onset of pain is therefore crucial to gain an understanding of the biopsychosocial and spiritual dimensions of the residents’ pain (Abdulla et al., 2013; Hadjistavropoulos et al., 2007). Furthermore, to facilitate the recognition and assessment of pain in residents with severe cognitive impairment, the use of observational assessment tools is essential (American Geriatric Society

Panel on Persistent Pain in Older Persons, 2002). However, both types of assessment require certain clinical competencies that are not part of the basic nursing education, and hence necessitate additional training, particularly in licensed practical nurses. With regard to the low rate of adoption of these components, one possible explanation might be a need for further training of clinical competencies. In comparison, the two other components ‘documentation’ and ‘re-evaluation’ require less advanced competencies, however, with regard to their regular performance, other factors, such as memory or motivation, play an important role.

In this regard, a recent systematic review and meta-analysis highlighted the potential influence of habits on healthcare professional behavior (Potthoff et al., 2019). Habits can be defined as “a process by which a stimulus generates an impulse to act as a result of a learned stimulus-response association” (Gardner, 2015, p. 280). Implementation strategies aiming to sustainably improve the adoption of a new guideline, hence, should consider the aspect of habit formation in care workers. Regular prompts or cues to perform the behavior, for example in team meetings, help care workers to remember the behavior, e.g. documentation, use of PAINAD. On the other hand, feedback on the performance of the behavior based on the documentation or general observations can be a further measure to support behavior change in this context. Therefore, ongoing commitment of a person responsible for pain management, e.g. a pain champion, is a crucial component to achieve sustainable practice change. From informal conversations with pain champions involved in our study, we know that due to organizational reasons not all of them were able to adhere to the intended role related tasks, such as booster sessions. This lacking fidelity might have had implications regarding the adoption of guideline components. In a forthcoming qualitative paper we will explore barriers and facilitators to the implementation based on interviews with pain champions and focus group discussions with care workers.

This was the first study in the field of pain management in NHs to use behavioral theory to gain an understanding of the underlying implementation processes and mechanisms. A clear strength of this study was the systematic specification of our implementation strategies into behavior change techniques. The specification allowed the generation of hypotheses with the aim to increase our understanding of the underlying mechanisms. Furthermore, clear definitions of implementation strategies enhance the comparability of studies and thus facilitate the generation

of transferable knowledge. Besides its strengths, there are also some limitations to this study. First of all, this study was based on a quasi-experimental, uncontrolled design limiting our ability to draw direct conclusions about the effectiveness of our implementation strategies. This is further complicated by the fact that we were only able to collect data concerning the guideline adoption after six months. Secondly, the study was based on care workers' self-reports of behavior which might have introduced bias due to care workers' ability of recalling behavior or by social desirability. A further aspect in this regard is the risk of common method bias, since data analyzed in this study solely stem from care workers' questionnaire surveys (Podsakoff, MacKenzie, Lee, & Podsakoff, 2003). A more objective appraisal of the care workers' behavior would have been the use of participant observations based on behavior checklists. Additional data gained through observations could then have been used to validate care workers' self-reports. However due to logistical constraints we were not able to incorporate further data collections.

7.6 Conclusions

The purpose of this current study was to explore the underlying mechanisms related to the implementation of a pain management guideline in Swiss NHs using training workshops of care workers and trained pain champions. Despite a significant increase in care workers' self-efficacy in pain management, adoption of pain management guideline components was not optimal. Our findings highlight that continuous commitment of pain champions or similar implementation facilitators is pivotal to the embedding of new routines in care workers' practice. Future studies in the field of pain management in NHs should make use of behavioral theory to understand and tackle implementation challenges. Increasing the adoption of evidence-based pain management guidelines in NHs remains of crucial importance to improve management of residents' pain and ultimately their quality of life.

7.7 References

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Chapter 8

Synthesis and Discussion

In this final chapter the results of the five studies of this dissertation (Chapter 3 to 7) are synthesized and key findings are discussed. Furthermore, methodological strengths and limitations of the dissertation are presented. The last sections of this chapter suggest implications for research and practice.

8.1 Key findings

In the first phase of ProQuaS, we conducted a contextual analysis to gain an overview of facilitating and hindering factors of pain management in the participating NHs. Our findings indicated shortcomings in care workers' knowledge and skills in pain management, particularly with regard to pain assessment and the use of standardized assessment instruments. Non-pharmacological measures were rarely used for residents' pain management. Furthermore, most care teams were generally lacking established routines regarding pain management. At that time, no facility guideline concerning pain management was available in most NHs- this absence had implications for care workers' motivation to conduct a comprehensive pain assessment or to apply non-pharmacological measures (**Chapter 3**).

In addition to these findings, our interviews with residents indicated that some perceive that care workers are not always taking them seriously. Residents reported to have experienced situations where care workers did not respond adequately to their needs- resulting in a tendency to no longer address their pain management concerns with care workers (**Chapter 4**). These findings corroborated our prior results, highlighting the need to focus on improving care workers' attitudes and knowledge about pain to enable a person-centered pain management (**Chapter 3**).

In collaboration with several stakeholders from the participating NHs, we adapted international recommendations for the management of geriatric pain to fit the Swiss NH context. Based on our findings of the contextual analysis, we developed and conducted training workshops for care workers and an in-depth training for the pain champions, who were recruited from the participating NHs in pain management and coaching skills (**Chapter 5**).

In the second phase of ProQuaS, we then implemented and evaluated the multilevel pain management intervention in a subsample of four NHs. With regard to the effectiveness we could show improvement of all pain-related resident outcomes. In a self-report subsample of 43 residents with pain at baseline, worst and average intensity of pain after three and six months, respectively,

improved significantly. Changes in interference from pain, however were not significant (**Chapter 6**).

With regard to the utility of our implementation strategies, we could show a significant increase of care workers' self-efficacy in pain management after the intervention. Furthermore, there were significant associations between self-efficacy and care workers' adherence to two core components of the guideline ('conducting a comprehensive pain assessment' and 'using PAINAD scale') (**Chapter 7**).

8.2 Contextual analysis

Implementation science aims to facilitate the translation of knowledge generated in clinical trials to real world settings. Having an understanding of stakeholders' needs as well as barriers and facilitators to implementation, is an important prerequisite for implementation success (Powell et al., 2017). To date, there are no specific recommendation how to conduct a contextual analysis, however several implementation frameworks provide guidance for the assessment of contextual factors (Damschroder et al., 2009; Rycroft-Malone, 2004). The contextual analysis in ProQuaS was guided by the CFIR, with a particular focus on influencing factors related to the domains 'outer setting' (patient needs and resources), 'inner setting' (structural characteristics, readiness for implementation) and 'characteristics of the individuals' (knowledge and beliefs about the intervention) (Damschroder et al., 2009). To gain a comprehensive overview of barriers and facilitators to pain management, we incorporated the perspectives of care workers, residents and physicians (unpublished data). The following two sub-chapters will discuss our findings of Chapters 3 and 4 with regard to the barriers and facilitators of evidence-based pain management on the one hand and the contextual needs, such as organizational capacity and organizational readiness for implementation on the other hand.

8.2.1 Barriers and facilitators to evidence-based pain management

As described in **Chapter 1**, a wide range of barriers related to pain management have been reported in the literature. However, with regard to implementing new practices, knowledge of the local contextual factors and needs is key. The central part of our analysis focused on care workers'

perceptions of barriers to pain management (**Chapter 3**). For the collection of quantitative data we used a list of single barrier items which has been used in previous studies investigating pain management in nursing homes (Jones et al., 2004; Kaasalainen et al., 2010). Findings of these studies indicate mainly resident-related barriers, i.e. residents' inability to report pain and reluctance to report pain. Care workers in our study also indicated that residents' reluctance to report pain is the most problematic issue with regard to pain management. However, the two newly- added items regarding nonpharmacological treatment (lacking availability and application) have also been rated among the most problematic. Since we adapted the original list to the Swiss NH setting, our results cannot directly be compared with previous studies. Therefore it remains unknown, whether the perception of underutilization of non-pharmacological treatment is unique to our convenience sample. The majority of NHs in our sample were newly opened (less than two years) which might have had implications for the lacking infrastructure. On the other hand, low utilization of nonpharmacological measures in NH residents has been reported in previous studies. For example, a cross-sectional study looking at MDS data from long term care institutions in seven European countries showed that only 39% of NH residents with pain received nonpharmacological measures (Lukas et al., 2013). As discussed in Chapter 4, the low application of nonpharmacological measures might be related to care workers perceived or actual lack of time leading to implicit rationing of care. It has been shown, that psychosocial, emotional and/or educational resident needs are at particular risk of implicit rationing (Jones, Hamilton, & Murry, 2015). Further hindering factors that have been discussed in the literature are limited knowledge on the application and lacking reimbursement of nonpharmacological measures (Tarzian & Hoffmann, 2005). Overall, the low number of utilization clearly indicates a need to improve the use of non-pharmacological measure in NHs. In particular with regard to the increased prevalence of chronic pain in NH residents and high risk of adverse events related to pharmacological approaches (Els et al., 2017).

In addition to the care workers' perspective, we were also looking into residents' and physicians' perception of barriers and facilitators of pain management. The qualitative interviews with residents (**Chapter 4**) and our interviews with physicians (unpublished data) indicated concerns about care workers' lacking skills and competence with regard to pain management. Residents often did not feel taken seriously by care workers and hence stated to address their pain

management requests directly with physicians. Furthermore, physicians noted that combined with broad disparities in training, high proportions of nurses with little care experience, language barriers and low levels of professional competencies would hinder professional pain management (unpublished data). These findings corroborate previous literature that points out shortcomings in care workers knowledge in pain management (Jones et al., 2004; Zwakhalen, Hamers, Peijnenburg, & Berger, 2007). Although the aspect of care workers' pain management competence was emphasized by residents and physicians, no similar concerns were raised by care workers. This divergent perception of care workers might be related to the "illusion of explanatory-depth" a common phenomenon which has previously been described in the literature (Rozenblit & Keil, 2002). Based on the perception to have a deeper understanding of a concept than one actually does, self- assessment can be positively biased (Eva, Cunningham, Reiter, Keane, & Norman, 2004). Due to inadequate training in pain management, many care workers have limited knowledge on what constitutes best practice, therefore they might tend to overestimate their actual knowledge and behavior. One approach to deal with these biased perceptions in NH practice is the use of audit and feedback of the behavior. Drawing attention to discrepancies between actual behavior and the target behavior by providing feedback has been shown to be an efficient strategy in changing health care personnel's behavior (Ivers et al., 2012).

Besides a considerable quantity of barriers to pain management, residents, care workers and physicians also reported some facilitating factors. One aspect all stakeholders agreed upon was the value of a close relationship between resident and care worker. On the one hand, residents expressed the wish for being taken seriously in their perception of pain (**Chapter 4**). On the other hand, care workers and physicians accorded, that knowledge of the resident's biography and needs are crucial to facilitate appropriate pain management (**Chapter 3**). Patient- centered care is central tenet of care in nursing homes enabling

A further aspect that was positively emphasized by care workers and physicians was the value of joint residents' visits and ward rounds to directly discuss resident situations (unpublished data). With regard to the lack of an institutional physician in most participating NHs, joint ward rounds can foster the inter-professional collaboration and communication. However, since some physicians are only responsible for very few residents, this approach might not be feasible.

In addition to barriers and facilitators that focus mainly on the role of care workers in the pain management process (Chapter 3 and 4), we also explored the influence of organizational factors on pain management during our regular sounding board meetings (unpublished data). One central aspect was the absence of institutional pain management guidelines in most of the NHs. Having no established guideline in place can be a major barrier to evidence- based pain management due to different levels of knowledge and experience in care workers. Furthermore, until the beginning of ProQuaS, no standardized documentation software was implemented in the NHs belonging to the Senevita group. Each NH used a different version with different features, thus hindering consistent documentation across NHs. The absence of standardization in combination with lacking guidance on the content and timing of documentation by means of a facility guideline lead to uncertainty of the care workers with regard to documentation of pain situations.

In the following paragraphs, methodological aspects of the contextual analysis will be discussed. In addition to practical challenges related to the subjective illusion, the objective assessment of knowledge and attitudes to pain management also constitutes a challenge to researcher. A range of surveys and tools to assess knowledge and attitudes to pain in older people has been developed in the context of different studies (Douglas, Haydon, & Wollin, 2016; Fetherstonhaugh, Lewis, McAuliffe, & Bauer, 2016; Long, 2013). However, it is unclear whether the assessment of attitudes using questionnaire surveys provides a valid summary of actual beliefs. On the one hand, a potential influence of social desirability in filling out questionnaire surveys needs to be considered. On the other hand, many of the negative beliefs and prejudices towards older people's pain might be unconscious and only show in the behavior. To uncover some of these beliefs in ProQuaS, we conducted focus group discussions with care workers to talk about pain management on the wards. The aspect of social desirability might also have influenced some care workers to only report positive examples, however we tried to create a confidential atmosphere to encourage participants to share perceptions about current pain management practice. A further possibility to explore prevalent beliefs towards pain in older people could be to conduct participant observations. The use of observational methods could have strengthen the overall design of our contextual analysis by providing insights into the day to day behavior of care workers from the perspective of an external person (Adler & Adler, 1994). However, conducting participant observations is a time

consuming data collection method, which we were not able to include within the context of ProQuaS due to insufficient time and personnel resources.

With regard to the assessment of care workers' perceptions of barriers to pain management, our methodological approach using a "pre-determined" set of items might also have benefited from a more explorative approach. The barrier items used in **Chapter 3** depict very broad statements, making it impossible to understand the reasoning behind the choice of answers. E.g. care workers who rated the item "residents' reluctance to report pain" as problematic, might have limited knowledge in assessing pain in residents, have negative beliefs towards pain in older people themselves or just presume, that residents always need to take an active part in the care worker-resident relationship. As mentioned earlier, we conducted focus groups with care workers to gain a deeper understanding of their perceptions about barriers and facilitators of pain management to account for this limitation.

However, a different approach to gain more in-depth knowledge from a questionnaire survey, could be the use of behavioral theory in developing survey items. So far, barrier items have been derived from previous studies and practice, thereby mainly reflecting the perspective of practitioners (Jones et al., 2004). Yet, to be able to address the perceived barriers, it is key to understand the underlying reasoning that influences the care workers' behavior. To strengthen the theoretical underpinning of questionnaire items in future studies, constructs of behavior change theory, e.g. the Theoretical Domains Framework (TDF), could be used for development (Cane, O'Connor, & Michie, 2012). The TDF has been used in previous studies to analyze the behavior of health care staff in the context of implementation projects (Curran et al., 2013; Huijg et al., 2014). Based on care workers' reasoning in preliminary focus groups, specific items addressing domains of the TDF, such as 'beliefs about consequences' or 'memory, attention and decision processes' could be used to identify the relevant determinants of behavior.

8.2.2 Organizational capacity and readiness for implementation

Implementing new practices in health care organizations is a complex endeavor with regard to the increased demand of financial, time and personnel resources. NHs considering to embed a new practice should therefore deliberate about whether they have sufficient capacities disposable at that moment. The study context of ProQuaS did not allow to select NHs in terms of organizational capacity. All NHs associated with the Senevita group were invited to participate, however the

decision about implementation in the second part was made in a ‘top-down’ approach by the overall management of the group. Of the original sample of six NHs that started in the second phase of ProQuaS, two NHs dropped out due to major organizational changes leading to a scarcity of resources for the project. Because of the limited overall time schedule we were not able to recruit new NHs. Future implementation studies planning to collaborate with NHs should therefore consider to over-recruit institutions, to ensure a sufficient sample size. Further measures to avoid withdrawal of NHs, respectively to ensure implementation capacity, can be the application of selection criteria, such as high commitment of leadership to the implementation project, no planned structural changes at the same time and low staff turnover.

In addition to the organizational capacity, the concept of organizational readiness for implementation also plays an important role for implementation success (Weiner, 2009). Organizational readiness can be defined as “the extent to which organizational members are psychologically and behaviorally prepared to implement organizational change” (Weiner, Amick, & Lee, 2008, p. 3). Based on this definition Weiner et al. highlight the two constructs ‘change commitment’ and ‘change efficacy’. The first refers to the collective motivation of employees to implement change (“we want to change”), whereas the second refers to the perceived capacity of the team to implement change (“we can implement the change”) (Weiner, 2009).

It has been recommended that the construct of organizational readiness for implementation should be assessed after making the decision to commit to the implementation (Weiner et al., 2008). Based on the level of readiness it might be necessary to initially consider strategies that increase the organizations’ readiness for the implementation, e.g. leadership training, knowledge and resource management (Williams, 2011). In the light of the top-down approach in ProQuaS and potential other implementation projects, organizational readiness and particularly change commitment can be a crucial issue. Several implementation theories highlight the importance of a positive implementation climate to foster the adoption of a new practice (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004; Rogers, 2003). As opposed to interventions that were internally developed, interventions that were externally developed, respectively decided, might experience less commitment of the employees. There are several potential explanations for this disparity, beginning with a low tension for change, i.e. a shared perception that the current practice needs change (Damschroder et al., 2009). Internally developed projects frequently arise from current or

past practice issues or resident situations- hence, the immediate benefit of the practice change might be more apparent for care workers. For externally developed projects it is therefore essential to increase the tension for this specific change. Potential strategies in the case of pain management could be the provision of current numbers of residents with under- or untreated pain as one example. A further related aspect that might limit employees' commitment to change can be the relative priority, i.e. the perceived importance of the new practice in the light of concurrent changes (Damschroder et al., 2009). In health care organizations and particular in NHs, regular changes are ubiquitous, differing individual priorities hence can reduce commitment to pursue a specific change.

With regard to the overall approach of ProQuaS, the preparatory contextual analysis in the first part provided us with a general overview of all 20 NHs belonging to the Senevita group at that point. The regular sounding board meetings with several stakeholders of the different NHs allowed us to gain additional insights to understand the overall structures and processes of the Senevita group. However, a more focused approach collaborating more closely with NHs intending to implement the pain management intervention might have allowed us to be more specific in the preparation of our implementation processes. On the one hand, early collaboration with NHs allows to apply preparatory strategies to increase readiness for implementation as discussed earlier in this chapter, e.g., supporting internal training of ward managers to facilitate implementation. On the other hand, closer collaboration with the final sample of NHs from the beginning can facilitate the selection and adaption of implementation strategies to better fit with their needs and capacities. For example, more time could be spent to develop the champions' role within the NHs together with the leadership and the care teams on the wards. Furthermore, involving potential pain champions early in the development of their training curriculum can be an opportunity to increase the program's fit to the champions' actual educational needs. Future implementation projects should therefore start as early as possible to collaborate with NHs that express intentions to participate in the implementation project.

8.3 Implementation of evidence-based pain management

8.3.1 Investigating pain management in nursing homes

Generally, conducting intervention research in NH residents is a challenging undertaking on several levels, yet the topic of pain management adds a further layer of complexity. NH residents constitute a frail subgroup of the general population; deteriorations of physical conditions and cognitive capabilities, hence, are very common. The increased vulnerability can pose a challenge to the feasibility of conducting trials in this population. First, with regard to the recruitment, the residents' physical and psychological condition can hinder participation. In addition, the partial limited ability to provide informed consent due to cognitive impairment raises ethical concerns (Lipsitz, Pluchino, & Wright, 1987). Second, due to the increased morbidity and mortality of NH residents, high attrition rates and challenges in retention and treatment adherence are very common (Lam et al., 2018).

Nevertheless, one aim of ProQuaS was to assess the effectiveness of our intervention in improving resident-related pain outcomes (**Chapter 6**). Cognitive impairment of NH residents constitutes a limiting factor to obtain self-report. Evaluation of pain in people with severe cognitive impairment hence requires special attention. In ProQuaS we decided to use the Pain Assessment in Advanced Dementia (PAINAD) scale to assess pain in residents unable to self-report because of its ease of use and high inter-rater reliability (Warden, Hurley, & Volicer, 2003). However, using PAINAD as outcome measure was problematic in two ways: first, there is only limited evidence for the cutoff value of 2/10 to indicate probable pain (Zwakhalen, van der Steen, & Najim, 2012). Secondly, PAINAD provides only information about the presence of pain yet not about pain intensity. Similar limitations apply to the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC), a widely used tool for pain assessment in clinical practice (Fuchs-Lacelle & Hadjistavropoulos, 2004). The Mobilization–Observation–Behaviour–Intensity–Dementia (MOBID-2) pain scale, on the other hand, provides a proxy-rating of pain intensity based on a comprehensive physical assessment and observation (Husebo, Strand, Moe-Nilssen, Husebo, & Ljunggren, 2010). However, using MOBID-2 in the context of an intervention study requires highly trained research staff to perform the physical assessment and ideally

acquaintance with the resident over a longer period of time, which we could not provide in our setting.

Besides the general challenge of assessing pain objectively, the different levels of cognition in NH residents pose an additional challenge to the evaluation. Different outcome measures might be necessary in residents with severe and mild to no cognitive impairment, calling for a split sample. Other intervention studies in NHs therefore decided to use a proxy-reported pain intensity measure, e.g., the Iowa Pain Thermometer, as primary outcome for all residents (Ersek et al., 2016). However, with regard to the ‘gold standard’ of using a self-report assessment, this approach also has its limitations. A more comprehensive evaluation approach was applied in a Canadian study, here the researcher used four assessment instruments with each resident, two self-report tools and two observational tools (Kaasalainen et al., 2016). It remains unclear though, how self-report was obtained from residents with severe cognitive impairment, since there were no exclusion criteria in this regard. In the light of these methodological challenges, it becomes clear that the evaluation of pain outcomes in NH research requires compromises, as no ideal approach exists. Despite advances in the development of observational pain measures, pain assessment still poses a challenge for both, health care staff and researcher and therefore remains a priority for future research (Kaasalainen et al., 2017).

With regard to the complexity related to pain it is not surprising that the amount of intervention studies in this field is comparably low. As described in **Chapter 1**, a range of evidence-based guidelines for the management of geriatric pain exist. However, the level of evidence in these guidelines is moderate to low (American Geriatric Society Panel on Persistent Pain in Older Persons, 2002, 2009; Fischer, 2014). With regard to the pharmacological measures, only a fraction of efficacy and effectiveness studies has been conducted in the population of older people, even less in people with dementia or other cognitive impairments, therefore, much of the recommendations were directly translated from younger study populations (Abdulla et al., 2013). In the light of the changed pharmacokinetics and -dynamics due to older age and the high prevalence of comorbidities, equal effectiveness of the pharmacological measures cannot be assumed, though (Brahma, Wahlang, Marak, & Ch Sangma, 2013).

Despite the many challenges to conduct research in older people, in particular in NH residents, it is important to include this population in future trials. Above all, the field of non-pharmacological

interventions could benefit from further intervention studies to increase the rather limited body of evidence. Current reviews on nonpharmacological interventions in older people could show partial effectiveness of several approaches, e.g. acupuncture and exercise, however, the authors also pointed out severe methodological limitations of the included studies (Park & Hughes, 2012; Pu, Moyle, Jones, & Todorovic, 2018).

8.3.2 Implementing new practices

A central concern of implementation research is to investigate what, how and why programs work in real world settings (Peters, Adam, Alonge, Agyepong, & Tran, 2013). Creating an understanding of the factors that influence the implementation process facilitates the translation of knowledge to other settings. According to the CFIR, the implementation process can be divided into four components: ‘planning’, ‘engaging’, ‘executing’ and ‘reflecting and evaluating’ (Damschroder et al., 2009).

Although we collected and analyzed data concerning all four components in ProQuaS, this dissertation is limited to data presented in Chapters 3- 7. The following two sections therefore only discuss the aspects of ‘planning’ and ‘engaging’ with regard to the ProQuaS project. A forthcoming process evaluation will look deeper into the influences of contextual factors on the overall implementation process using a mixed-methods design.

Planning

As discussed in the previous chapters, a contextual analysis conducted in the planning phase of a project provides information on prevalent barriers and facilitators to the planned implementation. Based on this information, a crucial next step is the development of a program theory that describes how changes in practice might be achieved (Moore et al., 2015). There are different approaches to develop a program theory, e.g., by means of a logic model or conceptual framework. They have in common that they clearly define inputs, processes, outputs and outcomes of the program (Kellogg Foundation, 2004). To be able to test and refine the program theory it should ideally be based on existing theories (Moore et al., 2015).

A range of theories dealing with behavior change on an individual level, including the theory of planned behavior or the social cognitive theory, exist (Ajzen, 1991; Bandura, 1977). However,

implementation of new practices in healthcare organizations, requires changes on multiple levels. Yet, the body of literature providing so called general implementation theories is limited (Nilsen, 2015). One theory, the normalization process theory proposes a model to understand processes of embedding and sustaining new practices in a social context (May & Finch, 2009). The theory constitutes four central concepts, ‘coherence’, ‘cognitive participation’, ‘reflective action’ and ‘reflexive monitoring’ that emphasize the importance of interactions in the social context and their dynamics over time in implementation and sustainability processes (May et al., 2009). The theory uses a sociologists’ perspective to provide an understanding of the implementation process in one specific context. However, the theory is limited in its capability to translate this knowledge into other contexts. Since there is a huge diversity of implementation contexts, understanding how specific contextual factors, e.g. organizational readiness, influence implementation of an intervention might be more relevant to inform future implementation projects. Depending on the intervention and the context where it is going to be implemented, the use of several theories and frameworks might thus be indicated (Birken et al., 2017; Nilsen, 2015).

The conceptual framework of ProQuaS uses constructs of the CFIR and TDF allowing us to incorporate influencing factors on the level of individual adopters and the inner and outer setting of the implementation context (**Chapter 5**). In addition, we used Bandura’s theory of self-efficacy as theoretical base for our hypothesized program theory (Bandura, 1977). According to his theory, ‘mastery experience’ (positive experience with conducting the intended behavior), ‘vicarious experience’ (modeling), ‘verbal persuasion’ and the ‘emotional/physiological state’ can influence the level of self- efficacy (Bandura, 1977). Since our central implementation strategies, care worker training and introduction pain champions make use of vicarious and mastery experience and verbal persuasion (**Chapter 7**), we assumed that we could increase care workers’ self-efficacy in pain management. In **Chapter 7** we could confirm this hypothesis, moreover, we could show associations of self-efficacy with the adherence to some of the guideline components.

In general, research concerning the underlying mechanisms of implementation strategies is still in its infancies- however, increasing our understanding of how implementation strategies work in real world, will move forward the field of implementation science (Lewis et al., 2018; Williams, 2016). In the field of pain management in NHs, implementation science principles have rarely been considered, so far only few studies reported the use of implementation frameworks

(Abrahamson, DeCrane, Mueller, Davila, & Arling, 2015; Hadjistavropoulos et al., 2016). However, no study provided a conceptual framework or testable hypotheses how their intervention and implementation strategies might work. Our approach in ProQuaS therefore gives an example how implementation science can increase our understanding of the complexities related to the implementation of new practices.

Engaging

A vital aspect with regard to the implementation process is the engagement of key persons in the implementation context (Damschroder et al., 2009). A Cochrane review that examined the effect of engaging local opinion leaders on compliance to the implemented practice showed that compliance increased by 12 % (Flodgren et al., 2011). A local opinion leader can be defined as an individual that holds an “influential position in their system’s communication”, the influence is not related to the formal position or role, but rather to the interconnectedness and social status of the person (Flodgren et al., 2011, p. 3). There is some conceptual ambiguity between the terms opinion leaders and champions, however, both roles have in common that they can influence behavior by changing current norms in the team (Thompson, Estabrooks, & Degner, 2006). A recent systematic review exploring the use of champions in NH quality improvement studies highlighted the importance of champions in facilitating implementation (Woo, Milworm, & Dowding, 2017).

With regard to pain management in NH, only four studies reported the use of champions as part of their implementation strategies. In three studies the designated champion was a clinical nurse specialist (CNS) or nurse practitioner (NP) that was already employed at the facilities before the study (Hadjistavropoulos et al., 2016; Kaasalainen et al., 2012; Kaasalainen et al., 2016). Another study described the formation of a pain management team that “comprised clinical champions and opinion leaders from multiple disciplines”, however, it remains unclear which training and role the clinical champions had before the implementation and how they contributed to the overall success of the implementation (Ersek et al., 2012, p. 637).

The three studies that used a CNS or NP as part of their implementation strategy agreed that the advanced training of CNSs and NPs combined with their unique position in the inter-professional healthcare team make them ideal candidates for leading change efforts (Hadjistavropoulos et al.,

2016; Kaasalainen et al., 2015; Kaasalainen et al., 2016). In contrast to the NH setting of Canada, where the abovementioned studies were conducted, the number of CNSs and NPs in the Swiss NHs is insignificant (Maier & Busse, 2017). In light of these structural shortcomings, our approach to identify and train pain champions from the existing staff in NHs was an inevitable adaptation. Overall, the type of strategies used by champions in the study of Kaasalainen et al. (2012), such as care worker training in pain management, phasing in use of pain management guideline, provision of reminders, audit and feedback based on the residents' documentation, are similar to our approach in ProQuaS (**Chapter 5**). However, due to limited reporting of the study, several aspects of the overall implementation strategy remain unclear. First, there is no information about the preparation of the champions for this specific project. Second, fidelity and dose of the strategies used by pain champions have not been reported (Kaasalainen et al., 2015).

With regard to the four NHs participating in ProQuaS, we could see an apparent variation in the pain champions' use of these strategies. Contextual factors of the four NHs and individual factors, such as professional experiences and functional roles of the pain champions might play a role and will be further explored in the forthcoming process evaluation (unpublished data). Based on our findings we will formulate recommendations for NHs that face similar staffing situations with no NPs or CNS being available. Another aspect that should be further explored in this regard, is the central role of middle managers, e.g. ward manager or director of nursing in the translation of knowledge in NHs and how these persons can be supported (Birken et al., 2018).

One aspect that hinders comparability of many studies in the field of NHs, is a lack of clarity in the reporting of the preparation and training of champions (Woo et al., 2017). To be able to translate knowledge from other contexts, future studies should also describe the context where the study was conducted. Particularly with regard to the use of champions, huge variations between health care settings can exist. Generally, to increase our understanding of what works how and why, it is central that future studies in pain management clearly describe their intervention and implementation strategies using appropriate reporting guidelines, e.g. Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014) or Standards for Reporting Implementation Studies (StaRI) Statement (Pinnock et al., 2017).

8.4 Strengths and limitations of methods

This chapter will discuss strengths and limitations of methods used in ProQuaS in addition to methodological aspects that have been comprehensively discussed in the previous chapters. This thesis was embedded in the ProQuaS study, the first study in Switzerland to examine pain management in NHs from an implementation science perspective. The comprehensive contextual analysis guided by the Consolidated Framework of Implementation Research helped us to gain an understanding of barriers and facilitators to pain management. Overall, the use of behavioral theory in the development and evaluation of ProQuaS contributed significantly to the understanding of underlying mechanisms and processes. The knowledge gained through our approach can be translated to other implementation projects in Switzerland and internationally.

A further strength of ProQuaS was the close collaboration with a group of stakeholders in regular sounding board meetings throughout the project. The opportunity to exchange with people working in different positions at the participating NHs enabled us to customize our implementation strategies to the contextual needs. Collaboration with stakeholders to facilitate the implementation processes is a central tenet of implementation science (Damschroder et al., 2009).

With regard to the data collection, a further strength of ProQuaS was the mixed-method approach in both parts of the project. The combination of quantitative and qualitative data provided comprehensive insights into the implementation context and its stakeholders and enabled the triangulation of different perspectives.

Besides the clear strengths there are also some limitations to ProQuaS. Overall, many limitations stem from logistical and practical reasons related to the funding situation and the project's embedment within the nursing home group:

(1) The decision to use a pre-post design with no control group was motivated by practical reasons, since we did not want to exclude NHs from receiving the intervention. One approach to increase statistical power and not exclude NHs from receiving the intervention would have been a repeated measure design with additional pre-implementation measures. With this approach, NHs would have acted as their own control group, however due to limited time resources, a prolonged pre-implementation data collection phase has not been possible;

(2) The overall sample size of NHs participating in the second part of the study was relatively small. The original sample of six NHs was further decreased by two NHs withdrawing from participation due to organizational reasons. Despite limited statistical power of the quantitative results, our comprehensive evaluation approach incorporating quantitative and qualitative data provided us with thorough information on the implementation processes. With regard to the implementation science approach in ProQuaS, gaining an understanding of underlying mechanisms and the influence of contextual factors is key for the translation of knowledge.

(3) The convenience sample of NHs participating in the second part of the project might not represent the ideal NHs to start an implementation project with regard to the organizational capacities. Our findings might have been different in NHs with better financial, time and personnel capacities. However, despite many parallel changes in the participating NHs we could still complete the project in four NHs. Information on contextual factors collected throughout the implementation will help us to gain a deeper understanding of the barriers and facilitators to implementation in a forthcoming process evaluation. With regard to the high demand of time and personnel resources related to the implementation of new practices, NHs should consider carefully the timing and necessary capacities to fully engage in a planned project.

8.5 Implications for research

ProQuaS was the first study in the field of pain management in NHs that builds on implementation science principles. In addition to the forthcoming process evaluation that will provide further insights into the implementation processes, there is a need for further research.

With ProQuaS we could show that despite limited resources a comprehensive evaluation can provide valuable information for future projects. To further increase our understanding of the challenges related to implementation of new practices in NHs, the use of implementation science hence is pivotal. Fostering the use of implementation science principles in NH research requires several measures.

First, there is a need to develop reliable and pragmatic tools to measure implementation outcomes. With regard to limited time and funding resources, it is worthwhile to improve methods for data collection and to increase efficiency of methods that use readily available data. As one example,

future studies could investigate time-saving observational methods to assess fidelity of complex interventions. Also, the use of advanced data-science methods, such as machine learning to review the electronic resident documentation could be considered in future projects.

Secondly, there is a huge potential to use the electronic resident documentation as part of implementation strategies that focus on audit and feedback. However, to be able to make reliable conclusions on basis of the documentation, in a first step, documentation of pain assessment and management needs to be standardized. Based on the experiences from ProQuaS and other studies, the aspect of documentation is an intervention in itself that needs further study (Kaasalainen et al., 2017).

Thirdly, to increase our understanding of how implementation strategies work in different contexts it is necessary to look at their underlying mechanisms and the influence of contextual factors. Cluster- randomized controlled trials or stepped-wedge designs are needed to establish effectiveness of interventions and implementation strategies in organizational settings. However, to increase our understanding of mechanisms and processes, further information on the context and the adopters needs to be assessed and analyzed. Although there are statistical approaches to look into multilevel mediation models, there has been limited application in the context of implementation science projects. Future research should therefore look into methodological approaches to account for the multilevel influences in implementation processes.

Furthermore, there are also conceptual limitations to linear approaches to causality in the field of implementation science. Health care organizations in general and NHs in specific have been described as complex adaptive systems, emphasizing the non-linearity of processes and interactions (Anderson, Issel, & McDaniel Jr, 2003). There are first approaches to incorporate the perspective of complexity science in implementation research (Braithwaite, Churruca, Long, Ellis, & Herkes, 2018). However this development is still in its infancies and further research is needed to weave the idea of complexity science into applicable models for context analysis and evaluation. Lastly, in addition to the aspect of embedding new practices, it is important to also look at sustainability of these practices over time. Due to the funding situation or other logistical reasons, most studies are limited to a follow-up period of six to 12 months. With regard to the high turnover and the commonness of organizational changes in NHs, sustainability of the change efforts needs

to be evaluated as well. Particularly with regard to scaling-up effective interventions, future studies should establish factors contributing to the sustainability of implementation efforts.

8.6 Implications for practice

In ProQuaS and other studies the central importance of pain management knowledge and attitudes towards pain for an efficient pain management could be shown. Hence, improving care workers' understanding of the biopsychosocial and spiritual dimensions of residents' pain is a key element for ultimately improving pain management. Furthermore, we could show that in addition to training of knowledge and skills in pain management, the formation of habits is essential to sustain a newly learned behavior (**Chapter 7**). However, facilitating care workers to develop new habits requires measures that go beyond the provision of a single training. To become a routine, it is necessary that a behavior is frequently repeated, external cues or prompts can help to remember the behavior in the first place. Therefore, regular booster sessions should be integrated into team meetings or in individual conversations.

From our experiences in ProQuaS we learned that organizational readiness for change is an important aspect with regard to the implementation of new practices. In some NHs it might therefore be beneficial to invest in certain preparatory strategies, e.g. leadership training on the ward level, to achieve a higher level of readiness before actually starting with the implementation of a new practice. On the other hand, pain management is a central topic which touches upon several aspects within NH practice. Improving pain management by means of a practice development project hence can have spill-over effects to other aspects of nursing care such as communication in the inter-professional healthcare team and patient-centered care.

In addition to this, the experiences from ProQuaS and other studies show that high turnover can act as a barrier to establish sustainable knowledge. Besides strategies to tackle turnover in the first instance, it is vital that NHs have unlimited access to training resources to enable them to improve pain management. One strategy to achieve sustainable knowledge within the NHs is the 'train the trainer' principle. Comparable to ProQuaS, NHs could identify champions from their staff which are then trained in educational institutions. Based on experiences with ProQuaS, training should be conducted by pain specialists with a focus on the comprehensive assessment, pharmacological

and nonpharmacological measures. To enable continuous education for the champions and other staff, access to online resources and tool kits to facilitate implementation of pain management should be provided by educational institutions.

8.7 Conclusions

It has been recognized that pain management in NHs is often suboptimal – factors contributing to this deficit are manifold. Advancing pain management in NHs is of crucial importance with regard to the residents' quality of life. In the light of previous literature, improving pain management seems a discouraging undertaking, since only few approaches could show improvements. To respond to the previous challenges, ProQuaS used an innovative approach based on implementation science principles. In the first step, we conducted a comprehensive analysis of the context on the basis of an implementation framework. The additional use of behavioral theory helped to increase our understanding of barriers to pain management and enabled us to customize our implementation strategies accordingly. Following implementation, in the second step, we could show improvements in pain-related resident outcomes and significantly increased levels of care workers' self-efficacy in pain management.

Overall, this dissertation contributes to a comprehensive understanding of pain management in NHs by disentangling some of the underlying complexities using theoretical frameworks. Due to the rich description of contextual factors, knowledge gained in ProQuaS can be translated to future implementation projects in Switzerland and internationally.

8.8 References

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