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Improving caring quality for people with dementia in nursing homes using IPOS-Dem

SPICHIGER Frank

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UNIL | Université de Lausanne

Faculty of Biology and Medicine
Institute of Higher Education
and Research in Healthcare

Improving caring quality for people with dementia in nursing homes using IPOS-Dem

Thèse de doctorat ès sciences infirmières (PhD)

présentée à la

Faculté de biologie et de médecine
de l'Université de Lausanne

pour l'obtention du grade de Docteur ès sciences infirmières

par

Frank SPICHIGER

Jury

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Improving caring quality for people with dementia in nursing homes using IPOS-Dem

Lausanne, le 21 mai 2024

Pour le Doyen
De la Faculté de Biologie et de Médecine

Directrice de l'IUFRS

Vice-Directeur de l'Ecole Doctorale

Abstracts

Français

Être en mesure de dispenser des soins centrés sur la personne atteinte de démence avancée dans les établissements médico-sociaux (EMS) présente de nombreux défis. Dans les soins aux personnes atteintes de démence, le personnel de première ligne peut être confronté à des situations allant d'une gestion insuffisante des symptômes à une qualité de vie compromise. L'utilisation d'instruments d'évaluation systématique a été décrite comme un moyen d'améliorer potentiellement les soins centrés sur la personne et les soins aux personnes atteintes de démence. Cependant, en Suisse il n'existe pas à l'heure actuelle de mesures spécifiques pour la reconnaissance des symptômes chez les personnes atteintes de démence.

Cette thèse présente la traduction et les tests psychométriques d'une instrument d'évaluation développée pour évaluer les symptômes courants présentés par les personnes atteintes de démence. L'instrument - IPOS-Dem - (Integrated Palliative Care Outcome Scale for People with Dementia) a fait l'objet d'une traduction en six étapes et d'une adaptation culturelle aux établissements médico-sociaux de Suisse-alémanique grâce à l'utilisation de principes de lecture simplifiée. Toutefois, sa fiabilité inter-évaluation («inter-rating») parmi le personnel de première ligne s'est avérée sous-optimale, avec des valeurs kappa comprises entre 0.15 (IC 95 % : 0.08-0.22) et 0.38 (IC 95 % : 0.30-0.48). Bien que les scores IPOS-Dem global puissent répondre aux besoins de la recherche lorsque la moyenne est calculée sur deux mesures, leur application reste un élément central d'une intervention infirmière complexe testée dans le cadre d'un projet plus large. Les défis uniques posés par l'étude de ce contexte et les caractéristiques démographiques ont influencé la conception globale de ce projet et l'évaluation psychométrique subséquente de l'IPOS-Dem.

L'IPOS-Dem peut améliorer la prise en charge des personnes atteintes de démence et peut être recommandé à des fins de recherche. Pour la pratique clinique, le développement d'un guide pour aider à discerner les différents symptômes peut être recommandé.. Le développement et l'application d'outils tels que l'IPOS-Dem soulignent l'urgence mondiale d'améliorer les soins de la population atteinte de démence, qui connaît une croissance rapide. Les résultats de cette thèse posent non seulement les bases d'un amélioration futur de l'IPOS-Dem, mais soulignent également l'importance d'une évaluation rigoureuse des outils cliniques. La collaboration avec ProInfirmis et l'adoption de principes de langage simplifiée mettre en évidence le potentiel de démocratisation et d'amélioration de la communication dans le domaine des soins de santé, qui est cruciale pour les populations de patients vulnérables.

English

Delivering person-centred care to those with advanced dementia in nursing homes presents numerous challenges. When caring for people with dementia, frontline staff may face situations ranging from insufficient symptom management to a compromised quality of life. Using systematic assessment instruments have been described as ways for potentially enhancing person-centred care and caring for people with dementia. However, in Switzerland, specific symptom recognition measures for people with dementia remain unavailable, and their efficacy remains untested.

This thesis presents the translation and psychometric testing of a measure developed for assessing common symptoms in people with dementia. The Integrated Palliative Care Outcome Scale for People with Dementia (IPOS-Dem) underwent a six-step translation and cultural adaptation to Swiss-German nursing home settings through the use of easy-read principles. However, its inter-rating reliability among frontline staff was found to be suboptimal, with kappa values ranging between .15 (95% CI .08-.22) and .38 (95% CI .30-.48). Although aggregate IPOS-Dem scores might serve research needs when averaged across two measures, its application remains a central component of a complex nursing intervention trialled in a broader project. The unique challenges of researching this context and demographic influenced the overarching project's design and the subsequent psychometric evaluation of IPOS-Dem.

IPOS-Dem can improve caring for people with dementia and can be recommended for research purposes. For clinical practice, the development of a manual to help discern the different symptoms can be recommended. The development and application of tools like IPOS-Dem underscore the global urgency to enhance caring for the rapidly growing population of people with dementia. The insights from this thesis not only lay the groundwork for future refinement of IPOS-Dem, but also emphasise the importance of the rigorous evaluation of clinical tools. The collaboration with ProInfirmis and adoption of easy-read principles further highlight the potential to democratise and improve healthcare communication, which is crucial for vulnerable patient populations.

Disclaimer

This work has been submitted in partial fulfilment for the University of Lausanne requirements for the Degree of Doctor of Philosophy in Nursing under the regulations approved by the Faculty of Biology and Medicines' relevant board on 2015-04-21 and adopted by the direction on 2015-06-15.

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Thesis Type

This doctoral thesis is presented in seven chapters. Chapter 1 provides an introduction, objectives and hypothesis for the work. Chapter 2 presents a literature review on the research undertaken in nursing homes. Chapter 3 provides the overall framework for the project and elaborates on the materials and methods. The results are then presented as reproduced articles in chapters 4, 5 and 6. Finally, chapter 7 integrates and discusses the results and discussions from the chapters. Below, the publications are listed in the order they are presented in this thesis.

Article One

F. Spichiger, A. Keller-Senn, T. Volken, P. Larkin, and A. Koppitz, 'Integrated Palliative Outcome Scale for People with Dementia: easy language adaption and translation', Journal of Patient-Reported Outcomes, vol. 6, no. 1, p. 14, Feb. 2022, doi: 10.1186/s41687-022-00420-7.

Article Two

F. Spichiger, T. Volken, P. Larkin, A. A. Meichtry, and A. Koppitz, 'Inter-rating reliability of the Swiss easy-read integrated palliative care outcome scale for people with dementia', PLOS ONE, vol. 18, no. 8, p. e0286557, Aug. 2023, doi: 10.1371/journal.pone.0286557.

Article Three

F. Spichiger, A. L. Koppitz, S. D. Wolf-Linder, F. E. M. Murtagh, T. Volken, and P. Larkin, 'Improving caring quality for people with dementia in nursing homes using IPOS-Dem: A stepped-wedge cluster randomised controlled trial protocol', Journal of Advanced Nursing, Jul. 2021, doi: 10.1111/jan.14953.

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Contents

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Abbreviations

95% CI 95% confidence interval.

AACT Pressau et al.’s action, actor, context, target, time framework.

ACP Advanced care planning.

AG Canton of Agrovia.

Al. (Latin, et *al.*) Alii/aliae/alia [and *others* m/f/n].

APA American Psychological Association.

APN Advanced practice nurse.

BASEC Business Administration System for Ethics Committees.

BASEC-ID Business Administration System for Ethics Committees Identifier.

BE Canton of Bern.

BESA (German) Bewohner/-innen-Einstufungs-und-Abrechnungssystem [resident classification and billing system for care services provided].

BL Canton of Basel-Land.

BPSD Behavioural psychiatric symptoms of dementia.

BS Canton of Basel-Stadt.

BT1, BT2 Back translations one and two.

CASP Critical Appraisal Skills Programme.

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CHF Swiss Francs (1 CHF = 1.05 € [2024-02-20]).

CIFR Consolidated Framework for Implementation Research.

CINAHL Cumulative Index to Nursing and Allied Health Literature.

CONSORT Consolidated Standards of Reporting Trials.

COSMIN Consensus-Based Standards for the Selection of Health Status Measurement Instruments.

COVID-19 Coronavirus Disease 2019.

CV (Latin) Curriculum vitæ [vita].

D-Study Dependability study.

DCM Dementia Care Mapping.

DEEP Dementia Engagement and Empowerment Project.

DOI Digital object identifier.

DRKS (German) Deutsches Register klinischer Studien [German clinical trial registry].

DSM-5 Diagnostic and Statistical Manual of Mental Disorders, 5th Edition.

E.g. (Latin) Exempli gratia [for example].

E.v. (German) Eingetragener Verein [registered association].

eCRF Electronic case reporting form.

EMBASE Excerpta Medica dataBASE.

EOLD-CAD End-of Life in Dementia Comfort Assessment in Dying.

ERNA Improving Person-centred Dementia Care in Long-term Care Facilities: Development and Evaluation of a Family-based Framework via Patient and Public Involvement and Engagement.

ESAS-r Edmonton Symptom Assessment System revised.

EU European Union.

FAST Functional Assessment Staging Tool for Dementia.

FOPH Swiss federal office of public health.

FT1, FT2, and FT3 Forward translations one, two and three.

G-Study Generalisability study.

GCP Good clinical practice (training).

GLMM Generalised linear mixed-effects models.

GRRAS Guidelines for Reporting Reliability and Agreement Studies.

H0, H1 Null and alternative hypothesis.

HCA Health care assisstant.

HES-So (French) Haute Ecole Spécialisée de Suisse occidentale [University of applied sciences and arts of western Switzerland].

I.e. (Latin) Id est [that is].

ICC Intraclass correlations for reliability studies.

ICD-10 International Statistical Classification of Diseases and Related Health Problems 10th Revision.

ID Encoding identifiers.

IPOS Integrated Palliative Care Outcome Scale.

IPOS-Dem Integrated Palliative Care Outcome Scale for People with Dementia.

IQR Interquartile range.

JBI Joanna Briggs Institute.

Lmer linear mixed-effect method (a function call within the lme4 R package).

LTCF Long-term care facility.

LU Canton of Lucerne.

Max Maxiumum.

MDS Minimum data set.

Min Minimum.

MIDOS Minimal Documentation System for Palliative care.

MRC (The United Kingdoms') Medical Research Council.

MRC framework MRC guidance on the development and evaluation of complex interventions.

N Number (…of participants, nursing homes, records).

NA Not applicable.

NOSGER Nurse Observation Scale for Geriatric Patients.

PACE Palliative Care for Older People (trans-European research project).

PACOP Palliative Aged Care Oucomes Programme.

PICOT Population, intervention, context, outcome, type.

PhD (Latin) Philosophiae doctor [philosophical doctorate].

PID Pain Intervention in Dementia.

PLAISIR (French) Planification Informatisée des Soins Infirmiers Requis [Computerized care needs planning].

POS Palliative Care Outcome Scale.

PPIE Patient and public involvement and engagement.

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

PREM Patient-reported experience measure.

PROM Patient-related outcome measure.

PWD People with dementia.

QOD-LTC Quality of Dying in Long-Term Care.

RAI-NH Resident Assessment Instrument for nursing homes.

RCT Randomised controlled trial.

REDCap Research electronic data capture.

RN Registered nurse.

RR Risk ratio.

SD Standard deviation.

SH Canton of Schaffhausen.

SMD Standardised mean difference.

SO Canton of Solothurn.

SPIRIT Standard Protocol Items: Recommendations for Interventional Trials.

SRAN Swiss Research Agenda for Nursing.

SW-CRT Stepped-wedge cluster randomised trial.

STI Serial trial intervention.

TG Canton of Thurgau.

TIDieR Template for Intervention Description and Replication.

UAS University of applied science.

UK The United Kingdom of Great Britain and Northern Ireland.

UR Canton of Uri.

USA United States of America.

VS Canton of Wallis.

WHO World Health Organisation.

z.B. (German) Zum Beispiel [for example / e.g.].

Preface

My entry into academic work started with my Masters in Nursing Science at the Zurich University of Applied Science. With wonderfully supportive colleagues, I have worked in inpatient hospice and palliative care (mainly for people with carcinogenic disease) for nearly a decade until 2021. My experience as an advanced nurse practitioner working with other healthcare professionals and people with care needs shaped my perception of interdisciplinary work. Together with my supervisors, my experience and collaborative engagement led to this project. I owe a profound debt of gratitude to my supervisors, Philip Larkin and Andrea Koppitz. As clinician-academics, their support and commitment to fostering a growth mindset have been instrumental in navigating the challenges of the overarching trial and thesis during and after COVID-19. Their empowering approach has consistently encouraged me to figure out all the different ways of conceptualising, conducting, reflecting and communicating research while striving for excellence.

Along the way, I have had additional support through the University of Lausanne, the University Hospital of the Canton of Vaud and my team at the HES-SO, School of Health Fribourg. My gratitude is extended especially to Silvia Alvarado, Mathieu Bernard, Alexander Bischof, Derek Christie, Anita Keller-Senn, Stephanie Kipfer, François Moser and Eve Rubli-Truchard.

A lot of people and colleagues helped with discussions and reflections during the entire process; I want to especially highlight the invaluable exchange with Claudia Bausewein, Andreas Büscher, Martin Dichter, Vera Logan, André Meichtry, Fliss Murtagh, Martin Nagl-Cupal, Sandra Bartolomeu Pires, Thomas Volken, our team leads and my group at the European Academic Nursing Society summer school(s).

This also extends to friends and family, who were a source of inspiration and respite during these years in which human history has been speeding along at an increased pace. Namely, my significant other Sarah Allenspach and her family were always there to help (considerably in piloting and testing our eCRFs on different devices). My parents, Hildegard Schlösser and Hans-Ruedi Spichiger, provided interdisciplinary insights at any time. Many friends (patiently) endured and gave feedback on my pitches and ramblings.

Also—last but not least—a big thank you to the clinical partners, family members and people with dementia who agreed to work with me on this project and continue to collaborate. Some people rightfully dubbed ‘Clinical Champions’ are named in the acknowledgements in the respective paper Chapter 5. However, those are only a fraction of the frontline staff and people involved who were (and still are) a part of this endeavour.

Acknowledgements

This doctoral thesis focused on the translation, adaptation, and psychometric testing of the Integrated Palliative Care Outcome Scale for Dementia (IPOS-Dem) for the Swiss-German nursing home context within the framework of a comprehensive trial. The thesis owes its depth and rigour to the collective efforts and expertise of numerous esteemed collaborators and participants.

Pain Intervention in Dementia (PID) Project

I sincerely thank the team behind the PID project, which ran in 2017 and significantly informed the person profile component of the overarching trial intervention. Special acknowledgement goes to Thomas Volken for his analytical expertise and Andrea Koppitz for her leadership in study design and overall project administration. In this quasi-experiment, I was an intervention nurse visiting the nursing homes for a 'proto-person profile' focused on pain. I helped with the data curation and analysis, working closely with our methodologist and statistician, Thomas Volken. The final article was first authored by me and finally submitted for publication in the fall of 2022 [1].

Overarching Trial

The protocol for the overarching clinical trial of monthly IPOS-Dem assessment and subsequent person profiles was made possible through the collaboration with Andrea Koppitz, Fliss E. M. Murtagh, Philip Larkin, Susanne De Wolf-Linder, and Thomas Volken. Their roles in conceptualisation, supervision, formal analysis, and methodology have been fundamental to the project's success. A protocol similar to the publication [2] was submitted to the Cantonal Ethics committee by Andrea Koppitz and colleagues at the Zurich UAS in 2019. Recruitment and consent was mainly a collaborative effort by Andrea Koppitz, our clinical sites and myself. Data capture was hosted on the REDCap instance run by the Data Acquisition Unit at the HES-So Valais. Entry forms and quality checks were programmed and tested by me with the help of two clinical champions. The introductory and follow-up training, as described in Chapter 6, were provided by me and Andrea. Scheduling of the person profile visits and training was determined with the clinical champions and me. The main data analysis started in the fall of 2023 in parallel to the finalisation of this thesis. I wrangled the data to a presentable shape for the sociodemographics tables of the final report; further analysis and model selection using mixed-effect models was done by me under close supervision by Thomas' successor and colleague André Meichtry and in discussion with Andrea Koppitz. The final publication is currently a 60% draft, and we plan to have it edited and finalised with our patient and public involvement group. Additionally, the participation and support of the people with dementia and their family members have provided essential insights and perspectives, enriching the research. The engagement and commitment of the frontline staff in the nursing homes have been pivotal to this study. Their willingness to participate and contribute their expertise and time have been fundamental to the research's success. I wish to express my sincere appreciation to the clinical champions who played a critical role in this project: A. Beqiri, R. Benz, M. Bonaconsa, A. Brunner, A. Conti, M. Deflorin, D. Deubelbeiss, L. Ebener, S. Egger, E. Eichinger, D. Elmer, A. Ermler, M. Fuhrer, C. Grichting, M. Havarneanu, H. Hettich, E. Hoffmann, E. Imgrueth, R. Juchli, I. Juric, K. Knöpfli, S. Kuonen, F. Laich, H. Meiser, N. Mergime, B. Michel, C. Ming, F. Müller, C. Niederer, G. Parkes, P. Piguet, A. Repesa, C. Ritz, B. Santer, A. Schallenberg, C. Schweiger, M. Spitz, and R. Strunck for their invaluable contributions and dedication.

Translation and Adaptation

The translation and adaptation phase was crucial for ensuring the IPOS-Dem's applicability in the nursing home context. I am grateful for the collaborative manuscript drafting and substantial intellectual contributions from Anita Keller-Senn, Thomas Volken, Andrea Koppitz, Philip Larkin, and colleagues. During each stage, many informal experts in their own right contributed to the process.

Psychometric Testing of IPOS

Inter-rating reliability

The psychometric testing of IPOS involved critical contributions from Thomas Volken, André Meichtry, Philip Larkin, and Andrea Koppitz in conceptualisation, formal analysis, methodology, validation, supervision, and manuscript review. Their expertise and guidance have been instrumental in the success of this thesis.

Internal consistency and structure

A publication on the analysis of the internal consistency and structure of the Swiss Easy-read IPOS-Dem is underway. Here, I was supervised by André Meichtry, Philip Larkin and Andrea Koppitz. Along the way, I had insightful discussions on IPOS and Palliative Aged Care (research) with experts in the field like our colleagues at the University of Wollongong running PACOP, Margareth Wallhagen, Lieve van den Block, Walter Sermeus, Thomas von Achterberg and Fliss Murtagh.

The collaborative efforts and unique contributions of each person across and beyond these projects have enriched this research and been a cornerstone of my academic and professional development. The interdisciplinary approach and community engagement underscores the complexity and collaborative nature required in our field.

1 Introduction

1.1 Dementia

Dementia is an umbrella term for a group of diseases that display progressive loss of functioning in daily life because of cognitive decline [3]. People with dementia have limited options for disease-modifying treatment [3], which means that they are at risk for serious health-related suffering [4]. The standard definition put forward by the German Network for Quality in Dementia Care for dementia as an 'impairment of memory, learning and speech' [5] [p. 89] is the common denominator between the ICD-10 and DSM-5 diagnostic criteria. Staff in nursing homes and carers of people living with dementia in more advanced stages, however, define and experience dementia by the behaviour of people living with dementia [5].

Livingstone et al. [3] projected the incidence of dementia will increase from 50 million people today to 152 million people in 2050 worldwide. Between 13.4% and 70–80% of people living in European nursing homes have dementia [6, p. 7], yet the nursing home sector globally and locally suffers from a severe workforce crisis [7], [6], [8].

Relevant guidelines on healthcare for people with dementia issued by the Swiss federal office for public health lack specific recommendations for assessment and screening, which are fundamental components for care planning for frontline staff [9]. The German guidelines on dementia care point to the Nurse Observation Scale for Geriatric Patients, a scale for staff to rate behaviour, mood and functional deficits [10], [11]. Neither of the instruments recommended in these guidelines encourage a narrative or person-centred approach, which are integral to quality of care and nonmedical care in people with dementia [5]. However, healthcare staff in nursing homes need such an approach to enable meaningful care goal-setting for people with dementia and their families [5], [12]. The plethora of assessment instruments and methods [9], [13] may lack the necessary sensitivity to the context of nursing homes, overburdening staff with their variety [14].

1.1.1 Dementia Care

People with dementia present with a wide variety of healthcare needs that can be subject to periodic changes [15]. The instability of their disease trajectory is compounded by high multimorbidity [4]. Multimorbidity, which is the presence of multiple diseases, further complicates the predictability of the disease trajectory by additional signs and symptoms, treatments and side effects.

Contemporary dementia care models and research aim to be person-centred [7], [16], [17]. Person-centred care prioritises people and their self-identified needs and values. The holistic identification and nurturing of these individual needs is theorised to contribute to the realisation of psychosocial needs of people with dementia [16]. Addressing people with dementias' psychological and social needs may be a prerequisite to identifying and evaluating all other needs or concerns [5]. A person-centred care approach and a certain familiarity between the carer and person with dementia may also be critical for adequate symptom management and the navigation of communication difficulties or challenging behaviour [5].

Several authors described the care needs of people with dementia living in nursing homes. Estabrooks [18] pointed out that psychiatric symptoms are alarmingly high in people with dementia in their last year of life. Koppitz et al. [19] noted that impaired mobility, sleep problems and pain were the most prevalent. Research has focused on physical symptoms like pain but described other needs superficially, lacking person-centred outcome measures [7]. The complexity of the setting and population poses an enormous challenge for both frontline staff [20] and researchers to identify needs and concerns [21], [22].

The literature has shown that interventions and policy change primarily targeting pain assessment and management in people with dementia and older people living in nursing homes returned hardly any conclusive or sustainable results [12]. Research targeting behavioural psychiatric symptoms of dementia (BPSD) has been inconclusive because multimorbidity and communication often obscure pathogenesis [12]. Especially at the end of life, people with dementia may present with complete care dependence, be bedridden and lose their ability to communicate verbally [15]. Contemporary guidance advises against pharmacological management of BPSD, but the nonpharmacological management of BPSD is a highly demanding process requiring exemplary communication skills [12]. Watt [12] further indicated that, despite flawless medical management, clinicians sometimes have to expect BPSD to persist.

1.2 Nursing Homes

Nursing Homes are complex environments [21], [23] where care for people with dementia, mainly older people, is provided. The term nursing homes is used here to refer to residential long-term care homes, where medical, nursing and social services are provided. Alzheimer Europe [6] estimated that the number of older people moving into nursing homes will increase by 30% over the next 40 years. However, determining the number of people with dementia living in nursing homes is challenging because many people with cognitive impairment are never formally diagnosed [24], [25]. Data from Froggatt et al. [26] suggested that between 13.4% and 80% of nursing home residents in Europe live with dementia. For Switzerland, the 2014 estimate was 60%, with higher prevalence in the francophone regions [27].

Over the past 20 years, a differentiation between nursing and care homes waned in Switzerland because of a) the increase in complexity of healthcare needs in older people, b) an increase in demands for broader service choice and c) a decrease in funding [28]. Therefore, people living with dementia reside in all types of long-term care settings. Nonetheless, Swiss nursing homes are provided for and controlled at a communal government level. Local governance has led to heterogeneous service provision, which is sometimes mitigated by cantonal guidance or programmes. All three types of care facilities described by Froggatt et al. [26] can be found in Switzerland: facilities that have medical and staff on site all the time, facilities that have external providers for medical care and facilities that only rely on healthcare assistants on site. There are, however, similarities that apply to a majority of Swiss nursing homes. On average, registered nurses comprise 30% of the staff mix and cover care at the site 24 hours a day, 7 days a week [8]. Most of the registered nurses care is provided in collaboration with healthcare assistants [8]. Healthcare assistants interns and trainees, in turn, make up, on average, 70% of the staff mix [8]. The registered nurse monitors the nursing process and medical management and then delegates some or most direct care activities. Swiss registered nurses in nursing homes are sometimes involved with quality and innovation processes [8].

1.2.1 Dementia Demographics

The number of people aged 65 and older is increasing in most of the EU region [29]. Over the next 30 years, a quarter of the population will be aged over 65 [29]. The difficulties mentioned above in estimating the numbers for people with dementia living in nursing homes also hold true for the estimation at the population level. Looking at biomarkers for Alzheimer's disease, which is the most common form of dementia, Gustavsson estimated that between 327 and 525 million people live with dementia worldwide [24]. Although many have asymptomatic stages of Alzheimer's disease, this corresponds to one-fifth of the world's population aged 50 and older. For Europe, the projected increase in the number of people with dementia is from 11.4 million today to 18.8 million in 2050 [25]. This means that 3% of the total population in Europe in 2050 will live with dementia [25].

According to Alzheimer Europe [6] and the WHO [7], workforce capacity and patient choice can impact the quality of care in nursing homes. On the other hand, issues have been identified with the responsiveness to and recognition of the wishes and preferences of people living with dementia; this has been identified as a core process of person-centredness, which is further discussed in Section 1.3.2.

1.2.2 Dementia Care in Switzerland

In 2013, Switzerland started to develop a national strategy for dementia care [30]. The initial report by Ecoplan [30] highlighted the lack of knowledge about the quality of life of people with dementia living in Swiss nursing homes. Furthermore, the quality of care and staff's capacity to deliver high-quality care has not been assessed [30].

In 2015, Sommerhalder et al. [28] looked at the quality of life of people living in 52 Swiss nursing homes. Although the overall quality of life and quality of care was rated good or very good, person-centred care was highlighted as an area of improvement. The Swiss Federal Office of Public Health suggested again in its 2020 report [31] that data on the quality of care for Swiss nursing homes were still scarce but advised the Swiss Federal Council to act on the tariffs and policy primarily. No further inquiry into the quality of care and quality improvement was discussed [31].

A systematic and comprehensive assessment of 118 Swiss nursing homes' quality of care was analysed in the 2018 study by Zúñiga et al. [8]. The quality of care was operationalised by the established quality control and tariff systems with four indicators for quality of care: malnutrition, pain, polymedication and use of restraints. These, however, represent the quality of care in nursing homes on a rather abstract and distant level. Furthermore, the quality indicators do not consider any issues highlighted by international evidence regarding the benefits of person-centred care [3], [7], [17], [6]. In addition, the quality of life and care of people with advanced dementia are not reported systematically in Switzerland.

1.2.3 Swiss Nursing Homes Quality Management

Swiss nursing homes have implemented routine assessments and quality control processes [32]. However, related procedures and policies appear to prevent timely and relevant monitoring of people with dementia [32]. Two-thirds of the frontline staff engaged in care for people with dementia are not formally permitted to document their observations and interactions in routine assessments [33], [34], which may lead to a deficit in their capacity to highlight necessary changes in care plans and quality improvement at an institutional level. Person-centred care in nursing homes is a collaborative task [14], [35]. The staff work in different roles and relations with varying skill levels and relationships with people with dementia and their family [31]. The diverse knowledge of staff members is best shared systematically to develop person-centred care plans that align with the needs and values of the person with dementia [35]. There should be clear communication between the involved actors, especially among those providing care to people with dementia (frontline staff), their family members and the people with dementia. Miscommunication between staff and people with dementia, between staff or with family members is a barrier to person-centred care for people with dementia [36], [37].

1.2.4 Contextual Factors in Dementia Care Research

Physical, spiritual and psychosocial care needs are prevalent in people with advanced dementia. Aside from the unpredictable disease trajectory, symptom management in nursing homes is complicated by the setting and demanding communication and caring skills. According to Kupeli [38], nursing homes are business driven, focusing on profit instead of care quality, with demanding workloads for frontline staff, limited time and high numbers of low-skilled frontline staff. Some nursing homes must make referrals in a complex network to communicate and arrange health and social care. Additionally, there are hints at excessive documentation and scrutiny in the UK [38] and in Switzerland [39]. Research, practice and intervention development must reflect the documentation burden when planning data collection for experimental studies. To resolve this proposed gap in quality care provision, Kupeli and other authors have called for efficient reporting and documentation systems [38], [39].

Nursing homes in Switzerland are ill-equipped for experimental research and systematic practice development. Compared with university hospitals, research in nursing homes is often confined to routine data evaluation, management surveys and a few very select experimental studies. When researching people with dementia living in nursing homes, the research, mainly in cross-sectional studies, has usually focused on three outcomes: BPSD, pain management and hospital admissions.

An intervention that aims to support the frontline staff in nursing homes with needs assessment and reflection may improve subsequent symptom management in people with dementia, ultimately making care more person centred. According to Ellis-Smith et al. [40], this should enable frontline staff to optimise the nursing process, giving them an independent voice. Using and further developing a clinical instrument all frontline staff can use with a proxy-patient perspective helps develop an evidence base for planning and furthering person-centred care for people with dementia in nursing homes.

1.3 Definitions and Core Concepts

Previous work has defined the central elements of the present thesis and further elaborated upon them. The Integrated Palliative Care Outcome Scale for People with Dementia (IPOS-Dem) is introduced in the following paragraphs. Furthermore, there is an introduction to person-centred care and an introduction to the theory at its core: caring [41]. Both concepts are essential to the overall purposes of the intervention, which are introduced in Chapter 3 and further operationalised in Chapter 6.

1.3.1 IPOS and IPOS-Dem

Patient-reported symptom measures have spread rapidly in palliative care, from the Canadian Edmonton Symptom Assessment System to the Palliative Care Outcome Scale (POS). In the new millennium, the POS was developed to become more of a clinical and holistic instrument. Therefore, for further development, the Integrated Palliative Outcome Scale (IPOS) was introduced [42] The IPOS is a successful instrument used in research and clinical practice, with multiple language versions for its original palliative care target population [43]. It was later adapted to reflect the needs of specific disease groups. One of the latest disease-specific IPOS versions is the Integrated Palliative Outcome Scale for People with Dementia (IPOS-Dem). IPOS-Dem was developed to assess the most frequent distressing symptoms and concerns of people with dementia by caregiver staff to facilitate symptom detection and treatment. Ellis-Smith et al. [44] developed the instrument for the nursing home context and established its feasibility and mechanisms of action when introduced into practice [40]. IPOS-Dem is an instrument for the proxy assessment of people with dementia by frontline staff and family members and can help its users look at the frequent needs and concerns of people with dementia. The scale begins with an open question and transitions into a questionnaire with 26 symptoms/concerns. Its introduction into care home practice in three pilot nursing homes near London showed promising results [40]. IPOS-Dem comes with a handbook explaining its use and suggesting the completion of IPOS-Dem for a person with dementia at least every month [40]. The present thesis builds upon the IPOS-Dem programme theory developed by Ellis-Smith et al. [40], as illustrated in Figure 1.

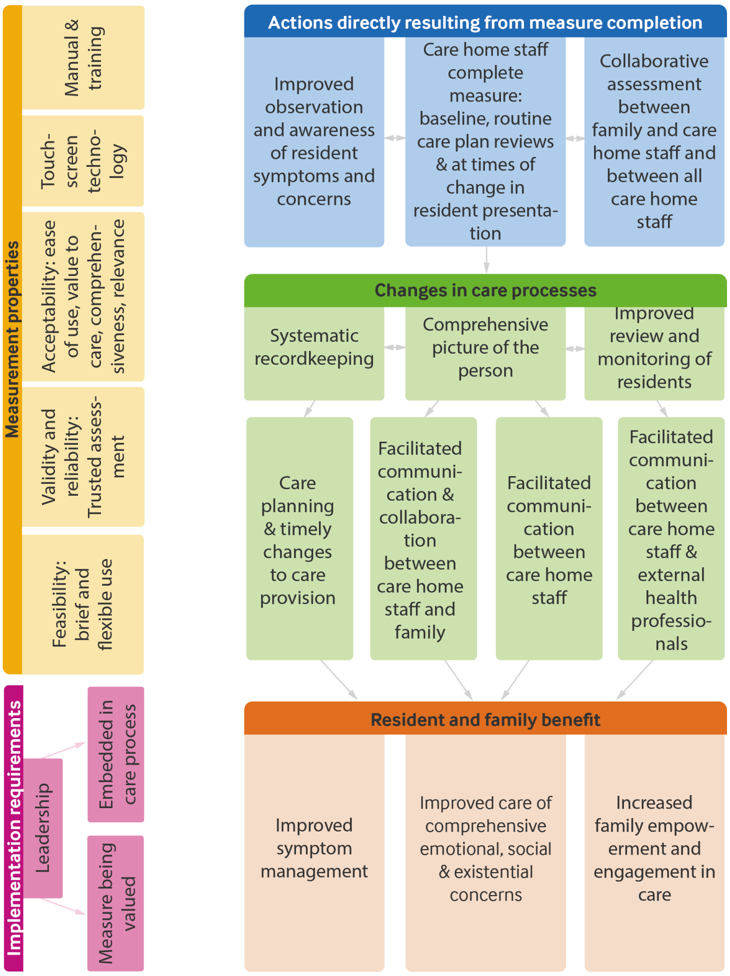

Figure 1: IPOS-Dem Programme Theory

Adapted from C. Ellis-Smith, I. J. Higginson, B. A. Daveson, L. A. Henson, and C. J. Evans, 'How can a measure improve assessment and management of symptoms and concerns for people with dementia in care homes? A mixed-methods feasibility and process evaluation of IPOS-Dem', PLoS One, vol. 13, no. 7, p. e0200240, 2018, doi: 10.1371/journal.pone.0200240. Published with a CC-BY 4.0 license.

1.3.1.1 How IPOS-Dem Changes Care Processes in Nursing Homes

Ellis-Smith et al. demonstrated that the systematic keeping of records and repeated evaluation resulted in timely care plan reviews, improved observation and a new way of collaboration between family members and frontline staff [40].

Using IPOS-Dem improved staff observation and awareness of the needs and concerns of the person with dementia.

This, in turn, made staff more aware of what could affect the person with dementia. According to Ellis-Smith et al. [40], the participants reflected deeper on the possible needs and concerns of the people they cared for by having to fill out IPOS-Dem. Family members suggested it may also have value as a tool to train less experienced frontline staff.

IPOS-Dem Encouraged Collaborative Assessment between all Carers.

Frontline staff seemed interested in knowing the person with dementia, which extended to familiarisation with that person's values and beliefs. Therefore, they consulted among themselves and with the family members to fill any gaps in knowledge about the person with dementia. When completing IPOS-Dem, frontline staff started to discuss some questions to resolve insecurities or out of curiosity. Hence, IPOS-Dem can act as a prompt for discussions, learning and reflections among the care team. This finding corresponds with the result of Bolt et al. [45] that frontline staff in nursing homes are especially keen to learn more about symptom assessment and management and involving family members. Their preferred support mode is peer-to-peer learning, joint case discussions, expert advice and on-the-job coaching [45]. Therefore, when designing an intervention for nursing homes, it should facilitate communication among frontline staff, regardless of the level of experience and educational background.

The Comprehensiveness of the Assessment.

The usual care in a Swiss nursing home involves writing sessions for the frontline staff, which is frequently done in prose structured by the preplanned functional tasks completed for or with a person with dementia during the shift. This structure ‘hides’ the needs and concerns of people with dementia beneath their functional abilities. The comprehensive assessment to plan these care tasks is only taken routinely every half a year. Frontline staff, however, have an ambiguous relation to this narrative report. On the one hand, they value the flexibility of their narration. On the other hand, they are burdened by the amount of paperwork in their daily routines. This is also reflected in work by Ellis-Smith et al. [40]. However, frontline staff produce care plans routinely and use narrative notes about care episodes. The IPOS-Dem struck them with its comprehensiveness while still being very concise to gain an overview of people with dementia’s symptoms and concerns. They contrasted the quick look at the scored IPOS-Dem questions with the need to read through lengthy case notes.

Systematic Records.

The argument about the comprehensiveness of IPOS-Dem above continues with its new way of routine record keeping. In the pilot nursing homes [40], IPOS-Dem turned out to be a more efficient way to record, show and reflect on the people with dementia’s situations over time.

Review and Monitoring of People with Dementia.

One outcome of Ellis-Smith’s study showed that IPOS-Dem records, especially its standardised and systematic storage, helped monitor people with dementia [40]. The frontline staff suggested that they could detect problems earlier and quickly understand changes in behavioural patterns because of their access to an archive of IPOS-Dem assessments for the person with dementia.

Care Provision and Planning.

IPOS-Dem informed the care planning in the pilot nursing homes. Because IPOS-Dem identifies symptoms early but also helps with communication among the frontline staff, there must be an emphasis on addressing the identified needs and concerns. As explained above and regarding comprehensiveness, one of the care home managers in the study by Ellis-Smith et al. [40] highlighted that care plans are written but not always followed through.

Communication with Family members.

Staff turnover takes its toll on person-centred care and interaction with family members in nursing homes. Ellis-Smith et al. [40] further described the challenges expressed by staff when communicating with family members. The frontline staff interviewed for the study seemed to lack confidence, were concerned about causing distress to family members, and were unsure about giving information or answering questions.

There were hints of unclear role definitions regarding communication between managers and frontline staff. With access to the systematic IPOS-Dem records, the family expressed benefits in receiving and accessing information. A shift pattern of three to four shifts is usual in Swiss nursing homes, where frontline staff can leave hand over to the next team, especially in the evening or on weekends; the number of available registered nurses may be drastically reduced (however this can vary from one nursing home to another). These fluctuations in availability make it difficult to access information or communicate with the frontline staff for family members.
IPOS-Dem helped frontline staff returning from time off to get a quick refresh on the people with dementia's changes regarding their concerns and needs. Nurses with more experience in the setting saw a heightened sensitivity to concerns by getting reports of needs and concerns observed by junior staff more frequently. The more experienced nurses saw themselves as better equipped to supervise junior staff through the use of IPOS-Dem.

Communication with Other Health Professionals.

Many nursing homes rely on external healthcare providers. Here, the same issues are apparent when it comes to contact with family members. Staff turnover, shift work and a lack of shared written reports impede collaboration. Ellis-Smith et al. [40] reported that IPOS-Dem may support communication with care providers outside the nursing homes.

1.3.1.2 Benefits to People with Dementia and their Family Members

Symptom Management.

According to Ellis-Smith et al. [40], the needs and concerns identified with IPOS-Dem were addressed promptly in the pilot study.

Providing Holistic Care.

The pilot nursing homes in Ellis-Smith et al.'s study [40] highlighted the comprehensiveness of IPOS-Dem. This may help identify physical symptoms, spiritual, psychosocial, practical or concerns people with dementia may suffer from.

Engagement and Shared Decision-Making.

Some pilot nursing homes highlighted the benefit of IPOS-Dem in empowering people with dementia's family members. Family members may be better informed, as detailed in the care process change descriptions above; this also helps family members evaluate if actions have been taken to address their or the patient's needs and concerns.

1.3.2 Person-Centred Care

Kitwood developed the person-centred care approach for people with dementia, which is a mode of care delivery that is superior to a task or behaviour-based practice in nursing homes. Person-centred care contrasts with conventional dementia care practice. Frontline staff in nursing homes regularly assume people with dementia are dependent and lack autonomy [16]. Consequently, frontline staff focus on the people with dementia's loss of functioning and mainly compensate for cognitive decline instead of fostering their skills and capacities [16]. In addition, the prevailing paradigm extends to normalising BPSD, attributing these to dementia instead of the care context [16]. The foundational model invites frontline staff to think about interactions with people with dementia to respect and nurture their personhood.

The model was later developed further for nursing by McCormack and McCance [41], as illustrated in Figure 2.

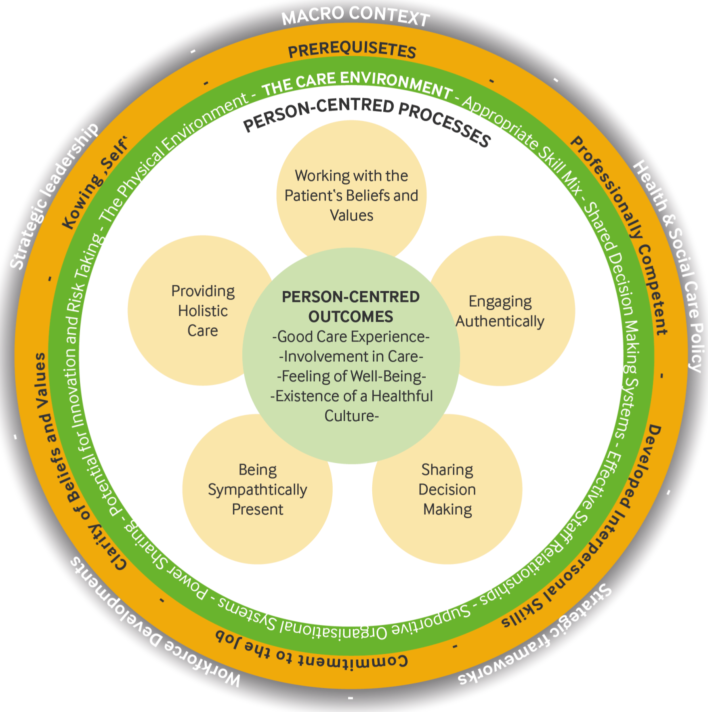

Figure 2: The Person-centred Care Framework

Reprinted from B. McCormack, T. McCance, and B. McCormack, Eds., Person-centred practice in nursing and health care: theory and practice, Second edition. Chichester, West Sussex ; Ames, Iowa: John Wiley & Sons Inc, 2016. Copyright (2016) with permission from WILEY

The person-centred care framework has four constructs: prerequisites, the care environment, person-centred processes and expected outcomes. Usually, to think about decisions and develop a shared vision or practice development, one moves through the constructs from the outermost to innermost 'expected outcomes'.

The person-centred care framework's 'prerequisite' construct focuses on the nurse's attributes. Nurse's attributes describe a broad set, from self-realisation, professional skills and competence to commitment and interpersonal communication.

The care environment relates to the context that care is delivered within. It has a significant impact on the operationalisation of the framework. In the best case, the environment can be most conducive to facilitating person-centred approaches, and in the worst case, it is limiting person-centred processes. Empirically, it was shown that the workplace culture, quality of nursing leadership and openness to the multiperspective evaluation of quality are vital characteristics that are necessary to align the environment construct with person-centred care.

The construct of person-centred processes focuses on the care delivery activities in each interaction. This construct has five activities that structure it further. The five process activities are *working with the persons' beliefs and values*, *engagement*, *providing for holistic needs*, *shared decision-making* and *compassionate presence*. These processes map onto caring, which is defined in the next section [41].

According to the person-centred care model, person-centred care outcomes are satisfaction with care, involvement with respect, feeling of well-being and creating a therapeutic culture.

1.4 Quality of Life, Quality of Care and Caring Quality

Quality of life is a central construct to measure the outcomes of caring and has been shown to improve in people with dementia if care is person centred [46], [47]. In people with advanced dementia living in nursing homes, quality of life reflects adaption to all domains of life affected by dementia (and comorbidities) [48]. In the present thesis, quality of life in people with advanced dementia living in nursing homes follows the definition proposed by Ettema et al. as a "multidimensional evaluation of the person-environment system of the individual, in terms of adaption to the perceived consequences of dementia." [48, p. 366].

The environment of people with advanced dementia living in nursing homes contributing to the quality of care, which was reduced to four indicators by Zúñiga et al. [8] as detailed above. A broader conceptualisation [49] of quality of care for people with dementia living in nursing homes mainly focuses on three parts: a) maintaining independence, b) protection from harm and burden and c) support for specific needs. Both approaches somewhat cover objective aspects of quality of life but are missing the relational part of nursing practice [5].

The person-centred processes construct of the person-centred care model introduced above is mainly informed by caring theories from nursing science [41]. Nurses establish caring relationships with the people they care for. Caring is considered the moral imperative and ethical foundation of nursing [50]. During caring, nurses stop performing instrumental tasks and introduce conscious and intentional forms of 'being' with the persons they care for. In other words, caring could be described as a universal existential skill all human beings may access. Nurses, however, use caring professionally by promoting quality of life through assistance in maintaining human connection and concerns. Benner and Wrubel concluded that these essential human connections encourage people to *'weather illness'* [51, p. 52].

Shared decision-making is the second person-centred care process mapping to Benner's conceptualisation of caring [41]. Shared decision-making is generally conceptualised as an approach to providing healthcare where both the care recipient and their caregiver are actively involved in making decisions. Shared decision-making is based on a partnership between both parties, where each contributes their own knowledge, skills, and experience to develop a plan of action that is beneficial for the care recipient. This approach acknowledges that not all decisions are made by the caregiver alone and that the care recipient also has valuable knowledge to contribute.

For shared decision-making to be successful, it is necessary for both parties to have a good therapeutic relationship. This means that there must be mutual respect between both parties and honesty in communication so that the care recipient can feel comfortable expressing their opinion and be heard. It is also important for both parties to recognise that each has different perspectives on providing care best.

In day-to-day interactions, frontline staff engage in shared decision-making by 'being with' and 'doing with' the care recipient. Under optimal circumstances, this would involve listening carefully to what the care recipient has to say and understanding their needs and preferences. Essential here is that nurses greatly rely on engagement through fundamental nursing care activities to enhance daily living. Therefore the care recipients can express themselves, feel valued and have ownership over their own life.

Trust between both parties is essential for shared decision-making to be successful [35]. The trust between the caregiver and care recipient must be reciprocal: the caregiver must trust the care recipient's abilities while also earning the trust of the care recipient through respect, empathy and understanding. This trust allows for open dialogue between both parties, where ideas can be expressed freely without fear of judgement or criticism.

The tasks and actions involved in shared decision-making are dynamic and can change depending on the individual needs of the care recipient [35]. For example, if a care recipient is feeling anxious or overwhelmed, they may need more time or assistance with certain tasks. It is up to both parties to discuss these needs openly so that they can come up with an action plan that works best for them.

Shared decision-making, can involve identifying creative solutions or activities that will help meet the care recipient's individual needs. Individual approaches to give and receive care can, for example, range from precise observation for subtle paraverbal cues in movement and focus during assisted eating to suggesting to take a walk outside together when one feels emotionally overwhelmed. This allows for more individualised care interactions that can help improve the quality of life for the care recipient [35]. The role of the care recipient in shared decision-making is very important to ensure that their individual needs are met. Explicating their values and beliefs can be helpful to efficiently identify approaches and actions; however, this is a demanding, higher-order thinking process that is hard to access, especially during a health crisis or when the patient has impaired cognitive abilities.

In some cases, it may be necessary for the professional or lay caregivers to take a more active role in leading by focusing on certain actions to prevent risk or insecurity for the care recipient. This could involve setting boundaries or providing guidance on how best to handle certain situations or tasks [35]. However, this should not be done without involving the care recipient to ensure the recipient can still have input on how best to provide their own care. In dementia care, this facet of caring very frequently has to be proxied through prior communication, written statements or involving family members.

In addition, it is important for both parties to negotiate with each other to maintain a real partnership between them [35]. Negotiating real caring partnerships means that communication should be open and honest so that both parties can feel comfortable expressing their opinions without fear of judgement or criticism. The negotiation of caring also means recognising that the parties involved have different perspectives on how best to provide care for the care recipient and establishing a plan of action that works the best for them.

Shared decision-making is an important approach to providing dementia care because it allows for mutual respect between the involved parties, as well as open dialogue about how best to provide individualised care interactions that meet each person’s unique needs. It is essential that those involved maintain trust in their relationship so that ideas can be expressed freely without fear of judgement or criticism. Additionally, mutual negotiation is important for maintaining a real partnership between them so that they can come up with a plan of action that works best for them. Overall, shared decision-making is an essential part of providing dementia care because it allows for more individualised interactions between the involved parties, which can help improve the quality of life for those living with dementia.

Furthermore, caring quality is closely linked to the individual’s quality of life [49]. Because caring is a way of entering, sharing and exploring the world of people in need and a way of producing mutual understanding, it is essentially person-centred [41]. According to Benner [52], the development of caring practices in frontline nursing staff is driven by practical experience. Frontline staff develop narrative knowledge about the individual’s illness experience, the disease and what these mean to the person they care for [50]. The narrative understanding in caring is only achieved by an ‘active’ presence in the situations that frontline staff share with the people they provide care to. Central to Benner’s later work was the development of nursing practice [52], [53], where she asserted that improving and continuously developing caring practice, independently of the nurses’ prior education, is driven by encouraging the individual to reflect on their perceptions and later share their reflections and perceptions.

1.5 Gaps in Current Knowledge and Understanding

IPOS-Dem provides a readily available instrument that is able to capture people with dementia’s needs and concerns [44]. It has, however, not been adapted and translated to the Swiss-German nursing home context. Besides the established intricacies of Swiss nursing homes introduced in Section 1.2.2 above, there may be a need for translating IPOS-Dem to produce a measurement instrument as inclusive as possible for frontline staff, family members and people with dementia. Switzerland is a four-language state, where French, German, Italian and Romansh are used for written and spoken communication [54]. German-speaking Switzerland, however, finds itself in a special situation linguists call diglossia: Swiss standard German is spoken by Swiss-Germans only on request and is understood by the majority of people living in the Swiss-German region. It is much more accessible to other people speaking German, but subtle differences compared with standard German remain [55]. In contrast to the Allemenic dialects spoken in Austria, Germany and northern Italy, Swiss-Germans use a variety of Allemenic dialects in nearly all day-to-day interactions [55] (find more about the rationale for this in Appendix 8.I. Furthermore, although the psychometric properties of the general IPOS have been reported by Murtagh et al. [42], the psychometric properties of IPOS-Dem have not been extensively explored beyond face validity [40].

The context of nursing homes presents a space that comes with the complexity and challenges of conducting effective research. More work on the theory developed for IPOS-Dem introduced above should be undertaken to test its assumptions and ability to contribute and develop person-centred care for people with dementia living in nursing homes.

1.5.1 Questions and Objectives

- How can IPOS-Dem be adapted for the Swiss-German nursing home context?
- What are the psychometric properties of the IPOS-Dem instrument?
- Can the routine use of IPOS-Dem be further enhanced through an additional, person-centred intervention component, and how can the effectiveness be investigated?

For the present thesis, there are three aims. The first is to culturally adapt and translate IPOS-Dem for use in the Swiss-German nursing home context. The second is to psychometrically test the adapted IPOS-Dem instrument. The third is to develop a study to evaluate the effectiveness of a person-centred intervention based on IPOS-Dem as assessed by frontline staff and family members to improve person-centred care for people with dementia in nursing homes.

1.5.1.1 Hypothesis for Question One

H0: The German IPOS-Dem can be used as-is for all frontline staff and family members in Swiss-German nursing homes. *H1:* The German IPOS-Dem will need extensive adaption for use with all frontline staff and family members in Swiss-German nursing homes.

1.5.1.2 Hypothesis for Question Two

Regarding IPOS-Dem individual item inter-rating reliability among frontline staff *H0:* The agreement between two independent ratings at baseline for each item will occur randomly. *H1:* The Swiss IPOS-Dem will show at least fair Fleiss' Kappa ($\kappa_w \geq .2$, by Landis and Koch's criteria [56]) for all scaled items between two independent ratings at baseline.

1.6 Design

The objectives were investigated in two phases. The translation and adaption and IPOS-Dem psychometric properties were investigated during the first phase. Phase one was conducted before and during the first four months of the trial phase. The trial phase—phase two—was a trial of a person-centred complex intervention with two active components.

The design of the overall study is described in detail in Chapter 6. This trial was designed as a stepped-wedge experiment with a closed cohort of people with dementia. For this type of trial, a stepped-wedge cluster randomised trial (SW-CRT), the participating nursing homes were randomised on a cluster level, that is, each nursing home as a whole was assigned to a different cross-over time from the control to the intervention condition. Each nursing home collected data with IPOS-Dem monthly for 15 months. By applying this design instead of a standard randomised controlled trial, practical issues and ethical concerns can be addressed. Applying this design, the nursing homes could enrol in the trial at differing absolute time points. All people with dementia who were participating were exposed to the intervention condition for at least half a year in the design proposed. The issues and benefits of an SW-CRT design are discussed further in Chapter 6.

1.7 Thesis Structure

This is a thesis by publication. The thesis consists of eight chapters presented in three main parts. In the first part, three chapters provide an overview of the current research and the rationale and foundations for the thesis. The second part contains the published research papers associated with this thesis [57], [58], [2]. The last part provides a critical appraisal of the findings in context. And considers its implications for policy and practice and its grounding in nursing science. Strategies for further research in the field are also discussed. The data collection for the trial the present thesis is embedded in was completed in Spring 2023. Analysis regarding the endpoints described in Chapter 6 are ongoing but do not form part of the thesis project. The three papers [57], [58], [2] presented are parts of the ongoing research project and an intervention development outlined in Chapter 3.

This introductory Chapter 1 has presented the rationale for the study and its main content. It has also introduced the problem and explained the importance of the current study based on the significance of the problem. Chapter 1 has provided an overview of the main definitions of the concepts used and the current theory in nursing science relevant for further discussion.

Chapter 2 presents recent research in nursing homes and the knowledge gained from this that is relative to the project and discussion of the thesis.

Chapter 3 outlines the methodological and philosophical underpinning the project. In this chapter, a distinction is made between prior work undertaken by the candidate, some of which influenced this thesis and the specific contributions presented in this thesis. This thesis is positioned as a subset of a broader project in which contributions from other researchers have been incorporated.

Chapter 4 describes how the IPOS-Dem needs and concerns assessment instrument was adapted to the Swiss nursing home context [57]. Furthermore, Chapter 4 details the rationale for using easy-read principles in clinical communication.

Chapter 5 presents one aspect of IPOS-Dem's psychometric validity [58], covering the second research question.

To answer the third research question, the development and conduct of a trial are reported in Chapter 6 [2]. In Chapter 6, the research design to investigate the intervention development is elaborated and presented in a published peer-reviewed research protocol [2].

The overall results and development process are discussed in Chapter 7 to frame the findings and conclusions in current nursing research and complex intervention development in general. Chapter 7 also discusses the results of current policy and practice and its implications for nursing practice and nursing science. Chapter 7 closes with a summary of the main findings while providing an outlook on further research and implications for clinical practice.

2 Person-Centred Care for People with Dementia: Umbrella Review

This chapter presents an overarching review of the literature on person-centred care (PCC) after the second revision of McCormack and McCance's framework (introduced in Section 1.3.2) in nursing homes. It provides an overall synthesis of quantitative and qualitative evidence on interventions, quality improvement and research conducted more generally with and for people with dementia living in nursing homes and their formal and informal carers. This is approached with an umbrella review following the Joanna Briggs Institute (JBI) manual and materials for conducting umbrella reviews [59]. Due to the high number of systematic reviews and meta-analyses available on the context, as detailed below, an umbrella review has been chosen as the most appropriate method to provide a comprehensive overview. [60], [59]. The results of this review further informed the development and testing of a complex intervention aimed at facilitating communication between frontline staff and family members regarding the symptoms, concerns and goals of care for people with dementia in Swiss nursing homes. This chapter's background section will primarily focus on the significant growth in publications in the field and relevant concepts of PCC for frontline staff's interactions with people living with dementia. In this chapter, the Methods section will describe the umbrella review process, detailing the search strategy, inclusion and exclusion criteria, along with data extraction process. The Results section will present the key findings, trends and gaps in knowledge identified from the reviewed literature. The chapter will conclude with a Discussion section, which will analyse the implications of these findings for practice, and future research, which will provide a foundation for the subsequent chapters of the present thesis.

2.1 Background

PCC, as described by seminal authors McCormack and McCance, is defined as the following:

> '… an approach to practice established through the formation and fostering of healthful relationships between all care providers, service users and others significant to them in their lives. It is underpinned by values of respect for persons, individual right to self-determination, mutual respect and understanding. It is enabled by cultures of empowerment that foster continuous approaches to practice development' [17, p. 20].

PCC has been endorsed by clinicians, the public, researchers and public health institutions [17]. PCC is built around values like the self-determination and autonomy of the care recipients [17]. In dementia care, there is evidence that, if care is organised along PCC in nursing homes, it may improve the quality of life in people with dementia [61]. Furthermore PCC is known to reduce the agitation, neuropsychiatric symptoms and depression of people with dementia living in nursing homes [62]–[64]. Frontline staff can benefit from decreased job strain when working with PCC [65].

The WHO has challenged decision-makers focusing on PCC to let go of disease-focused service planning and instead reflect on the needs of communities and citizens.

With the 2017 representation (see Chapter 1, Figure 2) of the PCC framework, McCormack and McCance expanded on the nursing-centric model based on theories of caring [41] and work by Kitwood et al. [17]. In their elaboration on the PCC framework introduced in Chapter 1, McCormack and McCance put forward the importance of culture and context. Their discussion emphasised practice development with a whole system approach to achieve person-centred outcomes and processes. According to the logic of the PCC framework, this means first analysing and influencing the macro context, like rethinking strategic leadership, policy and workforce development.

Most healthcare professionals working in Swiss nursing homes are not registered nurses with tertiary degrees, but most often, they are health and social care workers with various educational backgrounds [8]. There is wide variability in the preparation of frontline staff without tertiary degrees in Swiss nursing homes. This can range from fundamental care instructions over a number of days to up to three years of vocational training [8]. Experience is also variable from those with many years of experience to interns working in the settings for only a couple of weeks. The heterogeneity of the workforce population in Swiss nursing homes is further complicated by varying degrees of language competency and professional backgrounds, with frontline staff frequently having migratory backgrounds and, therefore, varied levels of education [66].

Following the precept of McCormack and McCance's PCC framework, frontline staff should engage in the five person-centred processes outlined by McCormack et al. [17], which aim to realise person-centred outcomes. However, it is currently unclear if and how Swiss nursing homes have adopted PCC as their primary model of care. In Table 1, the definitions of the five PCC care processes according to McCormack et al. [17] are provided.

Table 1: Definitions for the Person-Centred Care Processes.

Person-Centred Care Process	**Definition**
Working with the patient's beliefs and values:	Having a clear picture of what the patient values about their life and how they make sense of what is happening from their individual perspective, psychosocial context and social role.
Sharing decision-making:	The facilitation of involvement in decision-making by patients and others significant to them by considering values, experience, concerns and future aspirations.
Engaging authentically:	The connectedness of the practitioner with a patient and others significant to them, determined by knowledge of the person, clarity of beliefs and values, knowledge of self and professional expertise.
Being sympathetically present:	An engagement that recognises the uniqueness and value of the individual by appropriately responding to cues that maximise coping resources through the recognition of important agendas in their life.
Providing holistic care:	The provision of treatment and care that pays attention to the whole person through the integration of physiological, psychological, sociocultural, developmental and spiritual dimensions of persons.

With the ageing population, significant research has engaged in understanding and improving residential long-term care for people with dementia, a line of research that has particularly increased over the past 40 years. Figure 3 illustrates the absolute number of publications with five keywords.

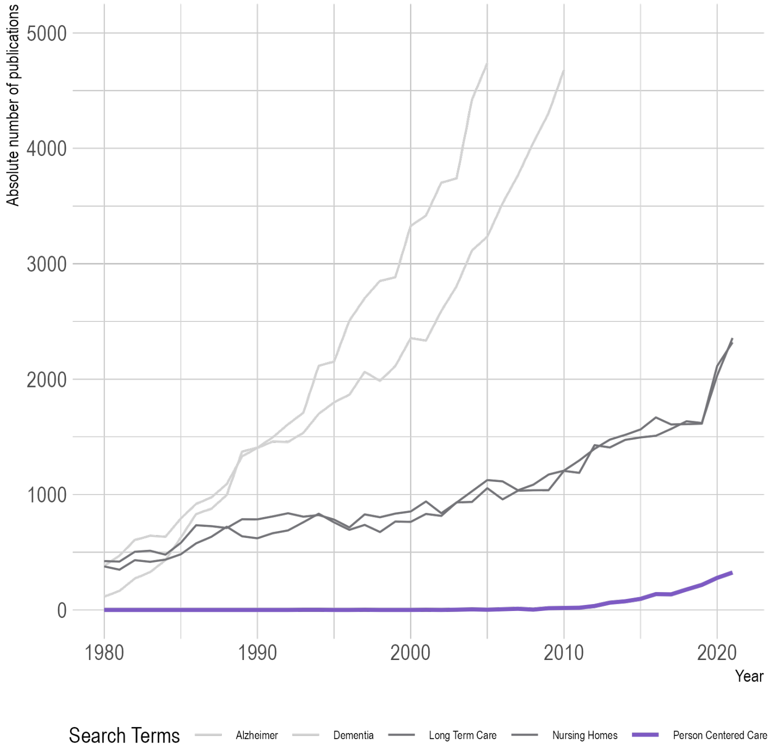

Figure 3: PubMed Publications on 'Dementia', 'Nursing Homes' or 'Person-centred care' in Absolute Numbers

Two figures illustrate the academic interest in PCC and provide evidence as to the rationale for conducting an umbrella review. The keywords in Figure 3 and Figure 4 were used to illustrate the interest in PCC, dementia and nursing home research since the instalment of PubMed. The keywords were compared with a common and innocuous keyword (i.e., 'banana') following Dalmaijer's method to produce meaningful plots to gauge trends in academic interest [67]. The relative interest in dementia and nursing homes seems to have dropped in 1995, as shown in Figure 4. Some authors attribute this decline to the 1995 national nursing home survey in the United States [68]. PCC yearly publications broke double-digits on PubMed in 2006 after being established as one of the fundamental pillars of healthcare in the WHO's World health-report [69]. Publications on PCC crossed 100 per year in 2014, four years after McCormac and McCance's publication of their framework for person-centred nursing and one year before the WHO published their first interim report on the global strategy and definition of PCC [70].

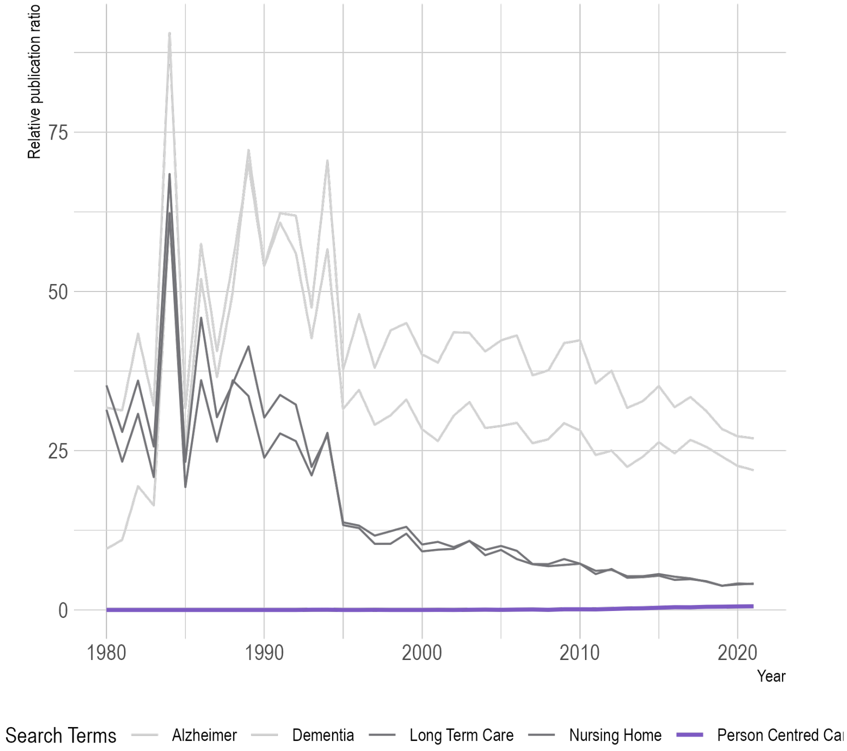

Figure 4: PubMed Publications on ’Dementia’, ’Nursing Homes’ or ’Caring’ Scaled to a Common and Innocuous Keyword.

2.1.1 Review Question

This review provides an overview of the literature from 2017-01-01, the year the represented PCC framework was published, to 2022-08-01, guided by the following questions:

- What evidence exists that describes the interventions contributing to the person-centred processes for people with dementia living in nursing homes?
- What are the recommendations for further research on interventions contributing to PCC processes for people with dementia living in nursing homes?

2.2 Methods

2.2.1 Search Strategy and Inclusion Criteria

CINAHL, Cochrane, Embase, APA PsycNet, PubMed and Web of Science were searched on 2022-07-15. The search was conducted using the following search terms: dementia (and synonyms), nursing home (and synonyms) caring (and subconcepts/synonyms), nurses (and synonyms). The search strategies were adapted to the different databases and applied Boolean operators to link synonyms and terms Appendix 8.II. The available toggles in the database user interfaces were used to limit the results to reviews from 2017 to 2022.

All reference lists of eligible publications (after title and abstract screening) were hand-searched for additional reviews published after 2017.

The inclusion criteria for this review are described below along the population, intervention, context, outcome and type (PICOT) approach for reporting inclusion criteria [71].

2.2.1.1 Types of participants

The review includes studies that involve people with dementia living in nursing homes; their dementia stage was not deemed critical to selection. Studies primarily involving healthcare staff or family members caring for the above population in nursing homes were also included. Studies that did not explicitly mention the involvement of frontline staff were excluded.

2.2.1.2 Interventions/phenomena of interest

Studies of interventions aiming to improve quality of life and person-centredness or contribute to care processes, as introduced by Table 1 in Section 2.1, were included. Studies of interventions that only aimed to improve cognitive function, particular skills and behaviours of people with dementia or were mainly directed at medication stewardship were excluded.

2.2.1.3 Outcomes

Regarding the outcomes, a thorough search for evidence across four levels, as per the PCC framework, was conducted: people with dementia, family members, frontline staff and organisation level.

For people with dementia living in nursing homes, the studies addressed the following: quality of life, quality of care, quality of dying or well-being.

For the family members, studies looking at family member satisfaction, skills, self-efficacy, knowledge, engagement or involvement were included.

On the frontline staff level, the outcomes included the following: staff engagement, staff communication, staff skills, self-efficacy, knowledge, staff resilience or burnout.

On a provision or institution level, descriptions of one or multiple PCC processes and descriptions of factors or experiences of one of the named populations above were also included.

2.2.1.4 Context

Included as well were studies from nursing homes. The definition of Nursing homes internationally can vary widely; most of the institutional nursing home settings exclusively house older people and can have varying degrees of support by varying staff skills and grade mixes.

2.2.1.5 Types of studies

As an umbrella review, the units of analysis were research syntheses. The studies included in this review were syntheses of existing empirical research studies, that is, systematic reviews and meta-analyses. Reviews without primary research as their main source of evidence have been excluded.

2.2.2 Data Collection and Analysis

The author reviewed all titles and abstracts obtained from the search described above with Rayyan® [72]. The title and abstract review were conducted alongside the inclusion criteria stated in Section 2.1. The standardised extraction form for umbrella reviews recommended by the JBI was used. Additionally, each article's recommendations for further research were retrieved. After data extraction, every review was assessed using the JBI critical appraisal instrument for Systematic Reviews and Research Syntheses. The categorised sections were analysed by content analysis, allocating the sections into one of the PCC model domains. The studies were processed using ATLAS.ti 23© [73]. ATLAS.ti is software designed to support qualitative data analysis; it was used to categorise the study contents with PCC processes and label relevant passages for later citation. Furthermore, ATLAS.ti was used to produce descriptive tables of categories and visualise code-document networks to facilitate narrative reporting. Data from the previous steps were summarised in tables and are further illustrated with quotations from the included articles that are presented in the next section.

2.3 Results

2.3.1 Review Process

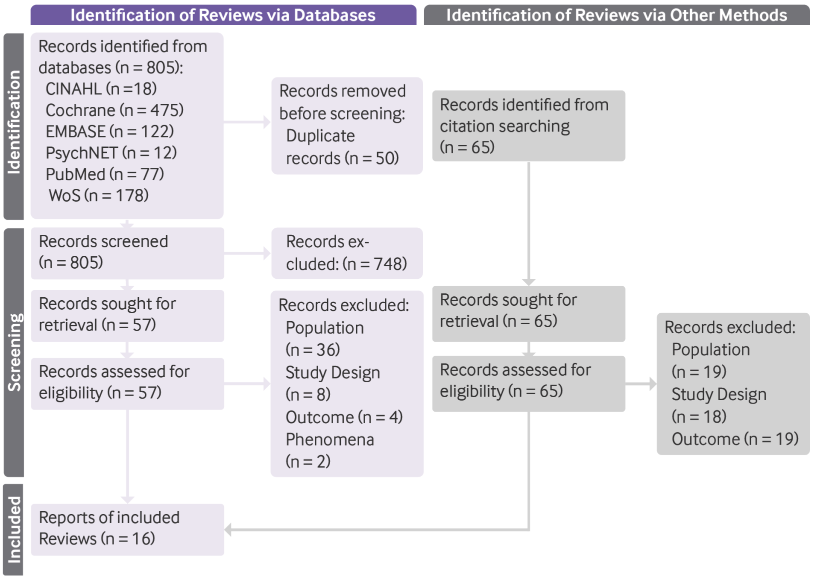

Figure 5: PRISMA Flow Diagram Showing Report Identification and Reasons for Exclusion.

Abbreviations: *Cumulative Index to Nursing and Allied Health (CINAHL), Excerpta Medica Database (EMBASE), number (n), Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)*

As shown in Figure 5, 805 records were screened after duplicates were removed (n = 50). Out of the total, 57 of the records entered the full-text review process. Reference tracking led to 65 additional records, which were all full-text reviewed.

Two-thirds (55 out of 122) of the assessed studies were excluded because of the population being studied. For example, records were excluded when the people with dementia were studied in hospital settings or a comorbidity was in focus. Scoping reviews and review protocols were the main reason studies were excluded based on their design during eligibility assessment (26 of 122). Ineligible outcomes in the excluded studies (n = 22) were recruitment strategies for clinical research and studies promoting pharmaceutical stewardship. A study on physical environmental design and one on simulated presence were excluded based on the phenomena studied. Finally, 16 records were included for the review.

2.3.2 Study Characteristics

Of the included reviews, most were published in 2017 [74], [46], [75], [76]. They covered primary studies published from 1992 [77] to 2021 [78]. Machiels et al. and Tsai et al. [76], [79] had the lowest number of records in their reviews with six studies, while Morris [80] reviewed evidence from 38 studies. Overall, the reviews considered 245 research projects, with 26 projects overlapping between the reviews. The countries where the studies informing the included reviews were undertaken are illustrated in Figure 6. Figure 6 also shows that the majority of primary studies originated from the USA (n = 55), the UK (n = 39) and Australia (n = 33). Three Swiss studies were reviewed in the included reviews [81]–[83].

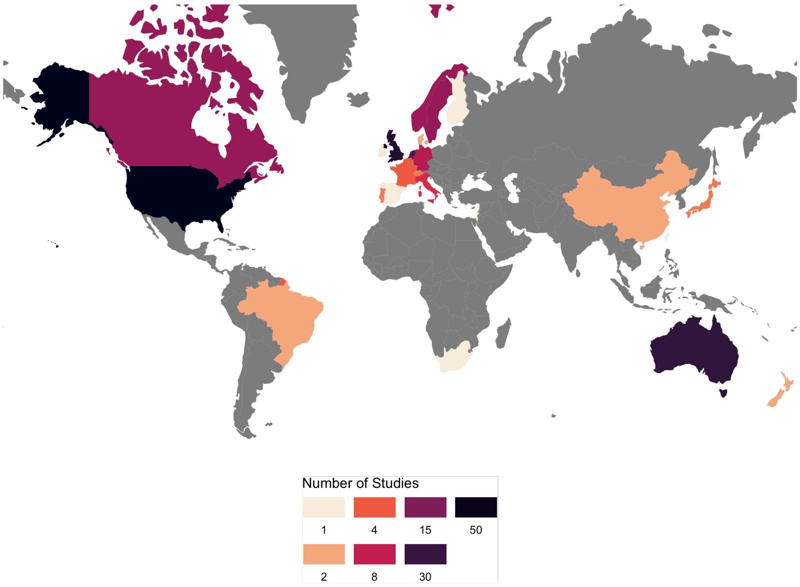

Figure 6: Countries where the Research Projects (n = 245) Included in the Identified Reviews Were Conducted.

Three reviews included studies not primarily undertaken in nursing homes [46], [80], [84]. These three reviews also included reports of projects undertaken with people with dementia in their homes and hospitals.

2.3.2.1 Methodology

All studies were designated as 'systematic review' by their authors. The analysis methods for the five meta-analyses conducted [85], [77], [86], [46], [79] applied fixed effects models in two studies and random effects models in three studies. Only one [46] out of the five meta-analyses also reported publication bias. Narrative approaches were also frequently used and complemented by meta-analysis in all studies. The authors employed a variety of methods with very detailed descriptions and citing specific subvariants of analytic frameworks in a few cases [85], [80], [78] and broad descriptions in the others [87].

2.3.2.2 Approaches

Literature Searches in the Reviews

Databases specific to dementia, such as the Cochrane collaboration's ALOIS, were surprisingly underused. A few reviews did not search the identified studies' reference lists for further studies [84].

Quality Appraisal Instruments Used in the Reviews

Ma et al. were the only authors to exclude three studies because of quality concerns [88]. Backhaus et al. [89] did not report or undertake quality appraisal. Despite low ratings in several instances highlighting the scarcity of primary evidence in the field. Quality appraisal was conducted with the Cochrane Risk of bias tool [85], [80]. The relevant Critical Appraisal Skills Programme (CASP) checklist was used frequently [87], [78], [75], as was referring to the JBI suite of instruments [90], [88], [79] for quality appraisal. Two meta-analysis followed up their appraisal by using the Grading of Recommendations Assessment, Development and Evaluation system [91], [79]. The qualitative studies most frequently omitted detailing the relationship between researchers and participants [78], [80], [87], [88], [90]. The experimental studies often showed issues with participant and assessor blinding, attrition and sampling strategies [46], [77], [80], [84], [86], [85].

2.3.3 Quality Appraisal

Quality appraisal for the 16 reviews was performed, and the results are presented in Table 2. Three reviews had to be excluded because of unfulfilled criteria for less than 60% of the applicable JBI Critical Appraisal Checklist for Systematic Reviews items.

Although the research objective(s) were stated in every study, only four explicitly added review questions [79], [85], [84], [90]. Search strategies and inclusion criteria were developed to a point that their reporting was clear and nonproblematic. Three reviews omitted popular databases without a clear rationale for doing so [84], [74], [76].

Machiels et al. [76] used an outdated quality appraisal instrument. Most reviews did not undertake independent appraisals of quality [74], [86], [87], [76], [80], [78], [92]. One review [78] made a point of working around this issue by comparing a subset of records appraisals between two independent researchers to subsequently argue for a single-person quality assessment. Furthermore, 8 of the 16 studies [85], [86], [74], [88], [76], [80], [78], [92] provided limited descriptions of their data extraction processes. Numeric publication bias assessment is only possible in meta-analysis, so it was mostly scored as not applicable (NA) in this respect. Many meta-analysis, however, also refrained from undertaking this type of analysis without providing reasons for doing so.

Nearly a quarter of the papers did not provide recommendations for policy and practice at all, instead focusing on strengths, limitations and further research [86], [87], [80], [92]. This fraction was lower for recommendations for further research, with only two reviews not offering any suggestions [74], [88].

Table 2: JBI Critical Appraisal Checklist for Systematic Reviews Ratings (Full Score = 11) for the Included Reviews.

Authors	**Date**	**NAs**	**Score**	**Overall Appraisal**
Abbott, Noren, Whear *et al.*	2019	0	8	Include
Backhaus, Hoeck, de Vries *et al.*	2020	3	7	Include
Birkenhäger-Gillesse, Boudewijn, Achterberg *et al.*	2018	0	9	Include
Costello, Walsh, Cooper *et al.*	2019	0	7	Include
Gonella, Mitchell, Bavelaar *et al.*	2022	1	10	Include
Kim & Park	2017	0	10	Include
Kormelnick, Janus, Smalbrugge *et al.*	2021	2	8	Include
Ma, Zhao, Wan *et al.*	2020	2	6	Include
Morris, Horne, McEvoy *et al.*	2018	2	6	Include
O'Donnell, Holland & Swarbrick	2022	1	7	Include
Rees, Tuijt, Burton *et al.*	2019	1	9	Include
Tsai, Browne & Inder	2021	2	9	Include
Walsh, Dennehy, Sinnott *et al.*	2017	1	9	Include
Holst & Skär	2017	2	5	Exclude
Machiels, Metzelthin, Hamers *et al.*	2017	1	4	Exclude
Sawan, Jeon & Chen	2018	2	5	Exclude

2.3.4 Description of Included Reviews

The included reports can be grouped into four thematic groups: working with neuropsychiatric symptoms, PCC, working with family members and other reviews. The reports are summarised narratively below, with further details on the reports available within Table 20 in Appendix 8.III.

2.3.4.1 Working with Neuropsychiatric Symptoms

Five of the thirteen reviewed studies focused on neuropsychiatric symptoms and ways to work with these symptoms. Birkenhäger-Gilesse [77] looked at psychosocial interventions for neuropsychiatric symptoms and the administration of antipsychotic medication in people with dementia. They presented a meta-analysis of 11 randomised controlled trials (RCTs). Psychosocial interventions, where attention to a culture change component was reported, substantially reduced the rate of antipsychotics administered (risk ratio [RR] 0.65, 95% confidence interval [CI] 0.57 to 0.73), with educational programmes proving less effective regarding antipsychotic prescribing (RR 1.50, 95% CI 0.49 to 4.64).
The remaining four reviews looked at behavioural challenges and neuropsychiatric symptoms, exploring more the context than the effects of various interventions. Kormelinck et al. [87] undertook a systematic review, applying thematic analysis to 15 studies and framing previous research using the Consolidated Framework for Implementation Research (CIFR) [93]. The included studies implemented complex interventions targeting neuropsychiatric symptoms and pharmacological management in nursing homes. They highlighted that strong leadership and support are critical to success. Kormelinck et al. [87] also emphasised nonpharmacological interventions for managing neuropsychiatric symptoms. However, suboptimal implementation of these complex interventions often limits their effectiveness. In addition, these authors emphasised how contextual factors hinder care processes in nursing homes, such as frequent changes in organisation structures, high staff turnover, perceived work and time pressures and involvement in several projects at one time.
The complexity of nursing homes was also taken up by Walsh et al. [75]. Their review concluded that medication prescribing in people with dementia involves interactions between numerous stakeholders, the nursing home organisation and external care collaborators. They synthesised 18 studies identifying five main themes that influence decision-making. The themes described included the following: organisational capacity, individual’s professional capability, communication and collaboration, attitudes and rules and standards. The developed model shows that an effective decrease in inappropriate prescribing can occur when all stakeholders come together to discuss and work as equal and empowered partners.
Ma et al. [88] reported that frontline staff in nursing homes have many misconceptions about antipsychotic administration for patients with dementia. The systematic review of 10 qualitative studies using content analysis emphasised the need for changes in the organisational climates. Providing relevant employee education may be of great value in addressing knowledge and practice. The complexity of behaviour that challenges the frontline staff results in many barriers to reducing the use of antipsychotics in patients with dementia, as detailed in this review.
Similarly, O’Donnell et al. [78] analysed the methods employed by frontline staff to control challenging behaviour in dementia. They conceptualised the comprehension of pharmacological and nonpharmacological techniques with a three-stage thematic synthesis of 34 qualitative studies. O’Donnell et al. concluded that social malignancy is still widespread. Kitwood defined social malignancy as frontline staff and family member behaviours that dehumanise and devalue people with dementia [16]. In this sense, frontline staff knowingly described psychotropic medicines as a ‘quick fix’ to handle challenging behaviour or to finish clinical shifts on time, according to O’Donnell et al. The review again highlighted the contextual limitations in nursing homes, such as the exclusion of people with dementia from participating in PCC because of insufficient staffing numbers and cost restrictions; the results showed that better decision-making, teamwork and collaboration are needed. Again, they concluded that a lack of cooperation among the differently skilled and different grades of frontline staff hinders nonpharmacological care interventions.

2.3.4.2 Person-Centred Care

Kim et al. [46] undertook a systematic literature review and meta-analysis to investigate the effectiveness of PCC for people with dementia. The authors reviewed 19 interventional studies. Kim et al. substantiated prior work in this area, suggesting nursing homes may substantially help with agitation in people with dementia using short term, individually tailored PCC approaches (Standardised mean difference [SMD]: 0.513; 95% CI: –0.994 to –0.032). However, they concluded that a reduction in depression or improvements in quality of life in people with dementia might only be shown with long-term interventions and studies (SMD: 0.191; 95% CI: 0.079 to 0.302). Furthermore, in their discussion, they highlighted the beneficial frontline staff outcomes (i.e. less burnout and stress) of PCC [46].

The frontline staff outcomes were further explored by Costello et al. [86], who reviewed the risk factors of burnout and psychological stress in nursing home frontline staff. To elicit these, they undertook a random effects meta-analysis with 17 quantitative research studies. They concluded no high levels of burnout or psychological stress in frontline staff caring for people with dementia from their analysis. However, they highlighted strong associations between poor work environments, that do not allow for discussion of care needs, poor teamwork and leadership support, burnout or stress. A better 'perceived caring climate in the unit' [86, p. 1213] was associated with lower job strain in one of their included studies, citing the same cross-sectional study by Edvardsson et al. [94] and equally highlighted by Kim [46].

2.3.5 Working with Family Members

Rees et al. [84] took more of a multimorbidity approach, with most of the included studies originating from a home care setting. They undertook a narrative synthesis of 12 studies on long-term conditions in people with dementia requiring self-management and management by a proxy. A person with dementia may find it challenging to communicate symptoms to family caregivers or medical staff. The likelihood of someone rejecting help to manage their long-term disease increases with behavioural and psychological symptoms. They theorised that, when self-management strategies such as memory aides stopped being helpful or memory deterioration reached a crucial point, people with dementia and their caregivers started to negotiate self-management support. The family caregivers viewed empowerment as a component of their caring responsibilities and looked for ways to help dementia patients maintain control. The empowerment of family caregivers was made possible by healthcare practitioners' ability to identify when cognition alterations have occurred.

Morris et al. [80] reviewed the effectiveness, acceptability and conceptual basis of interventions focused on communication training for formal and informal carers of people with dementia. Their synthesis found training interventions across 38 studies to improve communication and knowledge. Skills-based, practical simulation exercises were essential elements of effective interventions. The interaction between family members, frontline staff and person with dementia was crucial to provide PCC in advanced dementia [95]. Studies exploring programmes targeting these family members, frontline staff and people with dementia were reviewed by Backhaus et al. [89]. They undertook a systematic summary of intervention components in 14 studies. The review described the intervention components for programmes engaging family members of people with dementia living in nursing homes. An important finding was the programme foci. The reviewed programmes aimed to improve family–staff interactions, while family-resident or family-family engagement seemed less of an aim. Nursing home frontline staff was also the main target of the interventions. However, they could not conclude actual increases in the engagement of family members from the studies analysed.

Gonella et al. [90] also looked at family-staff interactions but with a focus on the end of life of people with dementia living in nursing homes. They analysed 11 qualitative and quantitative studies in a mixed methods systematic review. According to their findings, frontline staff should have regular conversations with family caregivers and offer them enough time and space for private conversations. They added that conversations on care should be held in person and accompanied by written material. In addition to regular family meetings about dementia care at the end of life, families may benefit from specialised psychoeducational programmes adapted to their needs [96].

2.3.5.1 Other Reviews

Two of the included reviews focused on other interventions. First, Abbot et al. [85] reviewed the effects of animal-like robots in nursing home care. Second, Tsai et al. [79] looked at the effectiveness of pain interventions in people with dementia.

Abbot et al. [85] looked at 19 projects with robotic animal-like objects' effects on older people living in nursing homes. They undertook a framework synthesis and random effects meta-analysis to understand and summarise the evidence. They were able to refine a logic model for the intervention in their framework synthesis. Also, they described the effects of loneliness and agitation but not other aspects of physical and mental health.

Tsai et al. [79] aimed to assess and evaluate the effectiveness of interventions for nurses to improve pain assessment and management in people with dementia. They undertook a systematic review and fixed effects meta-analysis of six studies. Projects solely implementing a routine pain assessment tool showed no effect on nurses' analgesic management (mean difference of 0.35 [95% CI –0.30, 1.00], $p = .292$, and $I^2 = 91\%$). Nevertheless , they highlighted the use of a pain tool while providing care for people with dementia, even though routine pain assessment tools seemed ineffective. According to Tsai et al., it is not a given that better pain management will follow from better pain evaluation. When devising an intervention targeting frontline staff, multifactorial, holistic pain theories may need to be considered, a conclusion the author also drew from the process evaluation of an older project [1].

2.3.6 Research on Person-Centred Processes in Nursing Homes

The first research question in this literature review was the following: 'What research describes interventions contributing to the person-centred processes for people with dementia living in nursing homes?' Although 10 of the 13 records covered all five PCC processes [46], [75], [80], [84], [79], [78], [87], [88], [90], none of the included reviews explicitly referenced McCormack and McCance's PCC framework [17] in their synthesis of the studies and referenced interventions and processes. Three reviews did not report on one or two PCC processes [77], [86], [85]. This is illustrated in Table 3. Below, comprehensive information and references related to each examined PCC is presented.

Table 3: Person-Centred Processes Identified in the Included Reviews.

First Author	Date	Working with Beliefs and Values	Engaging Authentically	Sharing Decision-Making	Being Sympathetically Present	Providing Holistic Care
Abbott, Noren, Whear *et al.*	2019	+	+	+	+	-
Backhaus, Hoeck, de Vries *et al.*	2020	+	+	+	+	++
Birkenhäger-Gillesse, Boudewijn, Achterberg *et al.*	2018	-	++	-	++	++
Costello, Walsh, Cooper *et al.*	2019	-	++	-	+	++
Gonella, Mitchell, Bavelaar *et al.*	2022	++	++	++	++	++
Kim & Park	2017	++	+	+	+	++
Kormelnick, Janus, Smalbrugge *et al.*	2021	++	++	++	++	++
Ma, Zhao, Wan *et al.*	2020	++	++	++	++	++
Morris, Horne, McEvoy *et al.*	2018	+	++	++	++	++
O'Donnell, Holland & Swarbrick	2022	++	++	+	+	++
Rees, Tuijt, Burton *et al.*	2019	+	++	++	++	++
Tsai, Browne & Inder	2021	++	+	++	++	++
Walsh, Dennehy, Sinnott *et al.*	2017	++	++	++	++	++

Keys: *+: one aspect covered, ++ multiple aspects covered, - not covered*

2.3.6.1 Working with Beliefs and Values

> '[…] one of the key elements […] was a meeting with residents' family members and friends, exploring residents' sources of comfort and pleasure to create an individual sensory biography of the resident.' [89, p. 11]

Backhaus et al. provided an example of this person-centred process. *'Working with Beliefs and Values'* was one of the caring processes that was the least frequently mentioned, along with *'Sharing Decision-Making'*. The rather tangible aspect of developing a clear picture of the person with dementia's life was mentioned frequently across the literature. Furthermore, holistic assessment and the integration of the collected information into care plans was important [46], [75]. Walsh et al. provided an example of *'integration into care plan'*:

> 'Listening to concerns and valuing everybody's opinion was critical, […] and participants felt that "by jointly looking at the problems and by learning from each other. we gained more clarity, much more peace, and also had a significant decrease in prescribed medication.' [75, p. 897.e8]

2.3.6.2 Engaging Authentically

This patient-centred process was described with reference to two main aspects: taking different stances to interactions and the reflection of interactions [17]. Evidence of beneficial self-reflection and team reflection was described in many facets. Kormelingk et al. highlighted the importance of frontline staff interactions and climate [87]. Possible associations of the opportunity to reflect interactions within the team with frontline staff outcomes were highlighted by Costello et al. [86]. O'Donnell et al. [78] provided citations from frontline staff, highlighting the value of interaction for learning. The different stances frontline staff took towards day-to-day interactions with people with dementia and exemplary reflections of such interactions is illustrated in the following:

> 'A care assistant succinctly states, "We are not supposed to know what it (psychotropic medicine) is or what it does, we're just people who give the medication" […] . In several studies, staff expressed how training aimed at improving communication skills with people with dementia, enhanced implementation of nonpharmacological strategies to support residents […]. "Before I had the training, I would just pick up and go, but now I know you have to first tell the person what you are going to do, not just go ahead and do it" (formal carer) […]. In addition, care home staff explain that the best training for managing behaviour that challenges is "hands on" work experience […]. "Being there, dealing with it, doing it, is the best training" (care assistant) […]' [78, p. 10]

2.3.6.3 Sharing Decision-Making

This PCC process was tied with *'Working with Beliefs and Values'* regarding the occurrence of reported aspects in the included reviews. According to its description, three attributes defined this process: the provision of tailored information, initiating and maintenance of the therapeutic relationship and the negotiation of care plans as equal partners.

Rees et al. [84] cited examples for the negotiation of care plans based on the relation family members have built with the person with dementia they care for. Gonella et al. [90] again highlighted the importance of relationship maintenance, as well as information provision, as a main finding in their review.

O'Donnell et al. [78] indicated that frontline staff are often aware of the pivotal role of relationships, again highlighting the interrelatedness and complexity of context and processes in the long-term care setting:

> 'In contrast, care home staff also reflected that psychotropic drugs may be used as a "quick fix", to minimise disruptions and allow carers to complete their duties in a timely manner, particularly in task-based-oriented care homes which prioritised completion of work tasks over relationships and social interaction with residents.' [78, p. 7]

2.3.6.4 Being Sympathetically Present

This care process was defined by four aspects: appropriate responding to cues, engaging in the maximisation of coping resources, the self-confidence in frontline staff to respond to identified needs and a conductive environment. Examples of coping support were given in all of the identified reviews.

The high awareness and sensibility to cues frontline staff show also becomes evident in all of the reviews, for example, when people with dementia were interacting with robotic animal-like objects:

> 'Residents were observed *[by frontline staff]* "talking to" and "talking about" the robopets, and staff perceived that "talking to" the robopet gave residents confidence to talk to others […].' [85, p. 16]

The need for a conductive environment—in this case culture and processes—was explicitly highlighted in Kormelinck et al.'s conclusions:

> 'Facilitating factors were a well-functioning and stable team, a less hierarchical structure and flexible organisational structures, being specialised in dementia care […], and having a small-scale care

> setting and rural environment […]. Barriers regarding high patient-to-caregiver ratios […] and multiple levels of management made access to resources challenging […]. Half of the articles found staff turnover/ absenteeism/fluctuations, shortages, and changing positions to be an impeding factor […].' [87, p. 882]

The need for frontline staff knowledge and self-confidence in skills to respond to needs was exemplified in multiple reviews. Morris et al. highlighted the usefulness of onsite skills-based training with subsequent discussion [80]. Tsai et al. highlighted the central role of human judgement complementing assessment tools when managing pain [79].

2.3.6.5 Providing holistic care

The provision of holistic care was also covered in most of the reviews examined; for example, Morris et al. stated the following:

> 'However, studies offered an insight into some of the benefits of training interventions; for example, seeing behaviour that challenges as communicating a need of the people living with dementia and working more creatively to reduce aggression or increase well-being and cooperation (such as, using music or singing).' [80, p. 877]

Similarly, Tsai et al. concluded the following:

> 'These qualitative studies found that many nurses perceived the pain assessment tools did not add value to their existing pain practice. A person's pain may fluctuate over time and therefore a pain score using a tool at a single point of time may not always reflect the person's pain problems and routine observations may not necessarily synchronize with the person's pain experience' [79, p. 1135]

Holistic care may also require inter- and transdisciplinary teamwork, as described by Walsh et al.:

> 'Furthermore, communication structures and interdisciplinary practices need to be optimized to improve the flow of vital information. It is important that peripheral members of this interdisciplinary team are not excluded from decision-making as they can often hold the key to successful behavioral management. There is also evidence to support the inclusion of pharmacists in these teams. Shared decision-making, a collaborative process that allows people with dementia, family members, and their healthcare team to make healthcare decisions together, should be encouraged. Shared decision-making takes into account the best clinical evidence available, as well as values and preferences of the person with dementia and the family.' [75, p. 897.e11]

2.3.7 Recommendations for Further Research in Nursing Homes

For the purpose of the second research question, the recommendations made in the reviews were grouped into three categories: research design considerations and methods, intervention characteristics and conceptual gaps. Two of the included reviews solely focused on recommendations for clinical practice [84], [88] and, therefore, were rejected.

2.3.7.1 Research Design Considerations and Methods

Only three reviews fell within the traditional call to conduct additional or more robust research in general [46], [80], [90]. However, Kim et al. and Morris et al. refined their argument by adding recommendations in the research design category [46], [80]. Morris et al. [80] and Backhaus et al. [89] recommended the development and reporting of a programme theory to show the intervention logic intended by the researchers. Backhaus also agreed with Kim et al. and others [77], [85] regarding how suggesting future studies should consider different carer, process and patient outcomes than those measured in the included studies. Kim et al. [46] and Costello et al. [86] recommended longitudinal, prospective designs going forward. The involvement of frontline staff or people with dementia into future research projects in a participatory sense was a topic identified in four of the included reviews [46], [75], [78], [89].

2.3.7.2 Intervention Characteristics

Because Kormelinck et al. [87] deductively analysed interventions according to the CIFR [93], their findings overlapped with some of the recommendations made by other reviews [78], [89], [90]. As evidenced by the abovementioned example, context was mentioned multiple times, with the need to pay special attention to, for example, local resources or culture [78], [87]. Furthermore, multicomponent interventions and innovations in intervention educational delivery were promoted by others [89], [90].

2.3.7.3 Conceptual Gaps in Dementia Care

Morris et al. and Tsai et al. highlighted the gaps in understanding of several concepts important to dementia care [79], [80], including decision-making in medication management, communication with people with dementia and holism in needs identification, communication and management. They specifically pointed out the benefit of qualitative research approaches to address these issues.

2.4 Discussion

All of the identified reviews were found to address multiple PCC processes without explicitly mentioning PCC processes as defined by McCormack and McCance. Holistic dementia care provision was addressed by all but one of the studies reviewed. Providing holistic care was mainly driven by the frontline staff's attention to cues by the person with dementia in day-to-day care and their engagement in teamwork. The process of working with beliefs and values was not reflected in two of the identified studies. Therefore, 'working with beliefs and values' was one of the least frequently mentioned processes tied with shared decision-making. Seven of the studies reflected both attributes of the former. These attributes were the development of a clear picture of the person with dementia's life and integration of these learnings into the care plan. Shared decision-making was identified in seven of the included studies with three aspects: information provision, relationship and negation of care plans. Sympathetic presence and authentic engagement PCC processes were evident in nine and eight analysed studies.

PCC and its predecessors were explicitly addressed in all the included studies. However, the authors often referred to Kitwood's PCC model [16]. A review of the use of Kitwood's PCC model was undertaken by Terkelsen et al. [97], who found evidence for the dimensions initially described by Kitwood represented in the literature. The development of Kitwood's model into McCormack and McCance's framework [17] was not discussed.

An incoherence of definitions and concurrence of multiple definitions for PCC was briefly mentioned in the background section of this chapter. The discussion in the introductory chapter of McCormack and McCance's provides a reference to the WHO's interpretation of PCC [70]. The WHO definition promotes a policy standpoint to support healthcare systems in shifting their focus from a disease-based to needs-based approach. At the service level, that is, the micro and meso level of care provision, the WHO's definition and elaboration lacks the qualities of the PCC model by McCormack and McCance. This disparity between the two definitions (i.e. the WHO's lack of guidance on a micro and meso level of health service provision) can be mainly explained by McCormack and McCance's model's positioning as a middle-range theory.

The conceptual uncertainty around PCC was investigated by Santana et al. [98]. Santana et al., however, defined PCC by process first [98]. In their view, PCC is driven by personalised and collaborative efforts between recipients and care providers. Through concept analysis, they developed an implementation framework closely tied to Donabedian's model for healthcare improvement [99]. Santana et al. elaborated on using person-centric measures and quality indicators.

Person-centred outcome measures support a shift towards a needs-based approach to healthcare delivery promoted by the WHO. Adequate outcome measures guide quality improvement in healthcare institutions and hold them accountable for public reporting. The quality indicators to underpin this public reporting were only introduced to Swiss nursing homes recently. The quality indicators, however, do not reflect many person-centred needs but mere minimal safety requirements [100], nor are they dementia specific or, in some cases, psychometrically sound [101].

To invoke PCC in nursing homes' frontline staff, Blake et al. [102] reviewed multiple interventions to change the care processes in favour of PCC. The primary outcomes for successful implementation in these studies were frontline staff behaviours. The interventions fell into eight categories: communication training, supporting staff with emotional reactions, dementia care mapping, interventions focused on retaining abilities, sensory-focused interventions, systemic interventions and others. Another definition of PCC was used by Blake et al. [102]. On one the one hand, their PCC definition was specific to people with dementia. On the other hand, it was merely defined by nine bullet points summarising Edvardsson's, Winblad's and Sandman's work [103]: acknowledging the individual and fostering personhood through authentic relationships and positive person work; viewing situations from the individual's viewpoint; sharing decision-making and offering choices; using life history to guide care; focusing on the people with dementia's skills and abilities; unconditional positive regard; prioritising well-being; skilled companionship; and personalised environments. Although these items may be linked to McCormack and McCance's work, they mainly lack the breadth to include the cultural and contextual dimensions of PCC. However, Blake et al. also showed how far-reaching Kitwood's and later Brooker's work were when it came to influencing the field [94], [104]. The need for more focus on culture rather than care interactions is taken up by McCormack and McCance [17]. However, they forewarned the required extensive implementation and practice development work needed to achieve this.

2.4.1 Strengths and Weaknesses of this Review

This umbrella review has provided a comprehensive overview of the current evidence in nursing homes for people with dementia. It has shown congruent and diverging themes and recommendations across the different reports. However, some weaknesses inherent to umbrella reviews and specific to the method used to produce the chapter should be considered.

With any literature review, the risk for publication bias was an issue [105]. The possibility of publication bias is even higher in umbrella reviews [105] because studies reporting positive or significant findings are more likely to be published and included in the reviews. Because the field seems comparatively small and outcomes heterogenous, the quality assessment revealed that most meta-analyses were conducted without funnel plots or sensitivity analysis-based selection models [77], [86], [85]. Furthermore, Figure 6 in Section 2.3.2 shows that the Anglo-Saxon countries majorly contributed to the primary research corpus within this review. Australia, the US and UK each added more than 30 primary research articles. Although the author tried to search as broadly as possible, in retrospect, the umbrella review may benefit from a multilingual research team and help from a librarian to develop and improve the search strategy.

Another shortcoming that should be highlighted is that the included reviews seemed to pay limited attention to the methodological quality of the included primary studies. During quality appraisal elaborated on in Section 2.3.3, it became evident that the authors of the records neither excluded studies based on quality, nor was quality appraisal consistently conducted by two or more independent parties.

For those primary studies with a qualitative approach, frequent lack of reporting of participant and researcher relations was an issue of credibility, particularly the concomitant issue of opaque power differentials in the context of vulnerable participants and interdependency between service and hierarchical structures.

Power differentials and complexity may also explain the issues with quantitative approaches featured in the included reports. Quantitative primary studies in nursing homes were frequently reported to omit or fall short on reporting of participant and assessor blinding, sampling strategies and attrition. Blinding participants, that is, frontline staff, people with dementia and family members to systemic or culture change interventions, may be challenging in inexperienced research settings like nursing homes. Blinding assessors may be achieved by introducing external personnel. However, this may be limited by available funding and for the same reasons (e.g., the staffs' research experience) cited above. Additional research designs may be indicated to address these issues of intervention concealment and performance bias.

Sampling strategies in the nursing home context are rather limited for longitudinal prospective designs. In most countries, nursing homes are private institutions neither obliged to nor inclined to divert funding to undertake research. Indeed, nursing homes could even be termed low-resource healthcare settings [106]. For example, university hospitals may profit from general consent procedures, allowing a large proportion of their patients to participate in research projects with a relatively low entry threshold. Nursing homes often have no such general consent processes, introducing complexity for obtaining written informed consent in vulnerable populations downstream. Research institutions may not have free rein to choose nursing homes randomly from any region but instead must build trustful partnerships with a few nursing homes to achieve the outcomes of their research projects.

2.4.2 Implications for Research

The incongruity of concepts and definitions used in science, especially multidisciplinary fields, such as healthcare research, is common. In the examples cited above, implementation scientists, public health researchers, psychologists and nurses bring different perspectives of PCC into the discussion. The differences in understanding may be framed as a drawback, leading to confusion and misunderstandings, complicating progress in research. However, conceptual incongruity is also a pointer toward the need for continued development of theoretical frameworks and may lead to new ideas. Future developments regarding PCC might be best addressed in open and collaborative transdisciplinary discussions where assumptions and definitions are deliberately explored. The exchange may be facilitated through transdisciplinary conferences or workshops that bring together experts from different fields to share their viewpoints and insights. The need for prospective, inclusive, patient-centred research has been repeatedly highlighted [46], [75], [86], [89] and may be addressed by utilising research designs [107], [108] other than RCTs. Possible experimental designs fitting this complex context could employ cluster randomisation or pragmatic effectiveness trial designs, where researchers integrate the intervention into routine clinical practice [108].

2.4.3 Implications for Clinical Practice

Unsurprisingly, the results favoured cultural and contextual change interventions and programmes to underpin the shift towards PCC. This would translate into nursing home interventions targeting leadership and service communities rather than skills and interactions between frontline staff, family members and people with dementia. In line with the PCC model, the intervention should be driven by the service recipients' needs. Concrete interventions, change and interactions targeting frontline staff may be introduced but should involve all the frontline staff and be implemented in ways that favour experiential and reflective learning.

One could hope for nursing homes to pursue something like a research agenda akin to university hospitals. Participatory action research approaches might be a promising method to engage more of the frontline staff, people with dementia and family members in quality improvement. Patient and public involvement and engagement (PPIE) evoke a time of culture change in research by providing more people with agency regarding how their care and caregiving should look and how current practice is reported in research.

2.5 Conclusion

In conclusion, this umbrella review has identified 13 reviews of interventions in nursing homes that covered multiple aspects of PCC processes. However, the literature has not adequately addressed the involvement of nursing home frontline staff in programmes and the adoption of PCC principles. Several unexplored dimensions, such as person-centred outcome measures and practice environments, have recently attracted research attention in other disease groups or settings [109], [110] but remain underexplored in the context of dementia care in Swiss nursing homes.

The findings from this review have underscored the need for further exploration and the development of a complex intervention facilitating communication between people with dementia, frontline staff and family members regarding symptoms, concerns and goals of care in Swiss nursing homes. The subsequent chapters will detail the adaptation and translation of the person-centred IPOS-Dem assessment instrument, its psychometric evaluation and the development of a protocol for a cluster randomised trial to test the effectiveness of the complex intervention, thereby bridging the identified gaps in the literature and contributing to the overall aim of the present thesis.

3 Materials & Method

This PhD work has been structured in accordance with the UK's Medical Research Council's guidance on the development and evaluation of complex interventions [111], [112], henceforth referred to as 'MRC framework'. This chapter aims to situate the specific projects included in this PhD and make a clear distinction between previous projects and the proposals and projects that will follow the completion of this PhD, and the overarching trial.

This chapter also addresses the following questions:

- Why is the MRC framework used, and what 'elements' are covered?
- What specific steps were taken in conducting the research, specifically the process and collection of data and rationale for the decisions made?

The previous chapter identified that research in the residential long-term care sector is hampered by issues regarding long-term follow-up, methodological rigour, a lack of clearly delineated person-centred outcomes and a paucity of interventions that fail to engage frontline staff delivering day-to-day care to people with dementia. Furthermore, the contextual factors described in the first chapter placed a high demand on nursing homes. The development of rigorous methods to identify and describe frontline staff caring and its effects on the quality of life of people with dementia is a priority for residential nursing homes and dementia research [7].

3.1 The MRC Guidance for Development and Testing of Complex Interventions

The MRC framework describes how complex interventions can be theorised and organised. An intervention might be considered complex because of the properties of the intervention itself, such as the number of components involved; the range of behaviours targeted; the expertise and skills required by those delivering and receiving the intervention; the number of groups, settings or levels targeted; or the permitted level of flexibility of the intervention or its components [111]. For this thesis, the overarching trial's intervention fulfils the criteria of complexity in the following ways according to the above guidance:

- On the recipient level, the people with dementia, as described in the previous chapter, are sometimes unable to verbally communicate their needs, often presenting at an advanced stage of dementia and with increasingly multimorbid disease, further increasing the number of possible healthcare needs frontline staff must monitor and reflect upon in day-to-day practice.
- At the institutional level, there is the heterogenous organisation of nursing home organisations in Switzerland, which is subject to regulations differing from community to community and from canton to canton. Teams within the institutions are organised, willing and able to conduct experimental research and person-centred care to varying degrees. However, the hierarchical culture and interface and responsibilities between frontline staff and external healthcare providers (physicians), differ, as do their communication patterns and models of care.

The first MRC framework, which was published in 2000, described four phases for intervention development: development, feasibility, evaluation and implementation [113]. In its newest iteration, the four phases and reoccurring core elements in the MRC framework have been described as iterative and overlapping [112]. This means phases are not necessarily moved through sequentially.

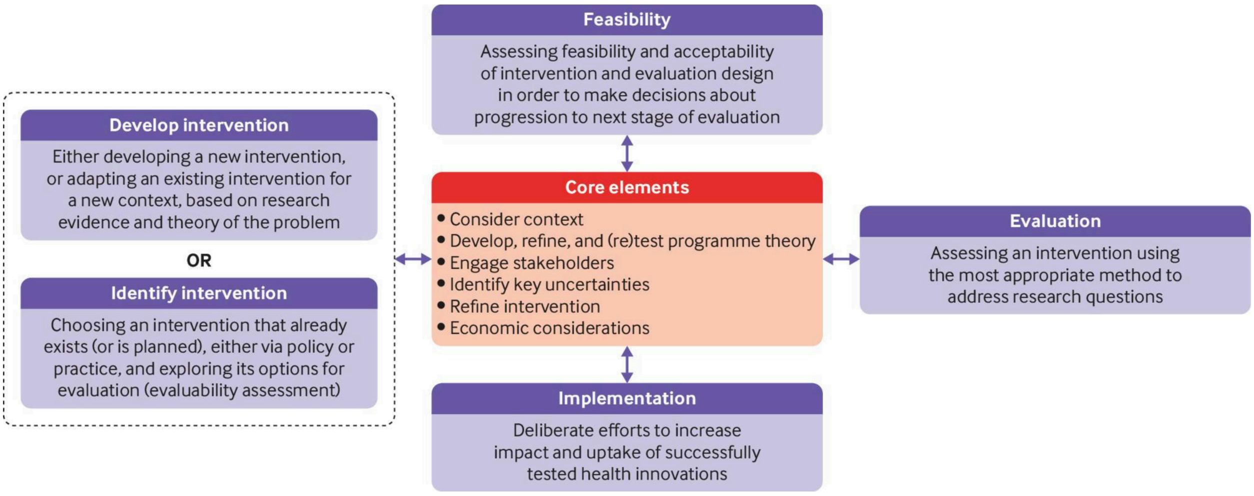

Figure 7: Framework for Developing and Evaluating Complex Interventions

Reprinted without changes from K. Skivington et al., 'A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance', BMJ, vol. 374, p. n2061, Sep. 2021, doi: 10.1136/bmj.n2061. Published with a CC-BY 4.0 license.

Skivington et al. described the latest update to the MRC framework as a pragmatic decision [111]. First, an update occurred because of the accumulation of evidence in process evaluation and implementation science. Second, the MRC framework is now clearly based upon a more pluralistic epistemology, inviting the scientific community to diverge from a pure efficacy or effectiveness perspective. Overall, the framework became more flexible and less prescriptive. This is also shown in Skivington et al.'s Figure 7 [111]. For the present thesis, focusing on the six intervention core elements enabled a more pragmatic interaction with the framework but still helped prioritise research questions and the structure of the methods.

3.1.1 Alternative Intervention Development Frameworks

For intervention design, other frameworks could be proposed. For example, in the present study, one could interpret systematic needs and concerns assessment and subsequent case studies as a behaviour change process in frontline staff and family members if viewed under a psychosocial paradigm. Intervention mapping [114] became popular through the need for clear guidance on intervention development in the MRC framework; this method structures the process using tools provided by Kok et al. [114]. Intervention mapping also seems well suited for behaviour modification in the context of unidimensional or limited behaviours [115]. After deliberation, Intervention mapping was not further considered as the meta-theoretic framework for the present study. It was ultimately abandoned because the needs of frontline staff, family members, people with dementia and the outcomes of the IPOS-Dem study intend to modify can be considered as having the following elements:

- are multidimensional [45], [116], [117];
- involve an interplay and consideration of multiple agents [118], [119];
- originate from complex disease processes with uncertain trajectories.

Additionally, introducing IPOS-Dem into routine practice could be seen as an intervention in and of itself. Ellis-Smith et al. [40] already theorised and described this IPOS-Dem introduction into practice mechanisms, as outlined in Chapter 1. Therefore, the instrument's introduction effects were assessed separately using the design and methods described in Chapter 6.

In conclusion, Skivington et al.'s work added to the knowledge base on context, pragmatism and implementation. The MRC framework was, therefore, used for this project because of its strength in previous IPOS-Dem studies [40] and adaptability to complex contexts and interventions.

3.2 Positioning this Thesis within the MRC framework

The overarching trial arose from a project on pain management in people with dementia living in nursing homes [1]. The link with preceding and planned projects is illustrated in Figure 8. The thesis and intervention development rely on evidence and models described by the Pos-pal consortium [44], [40], [42].

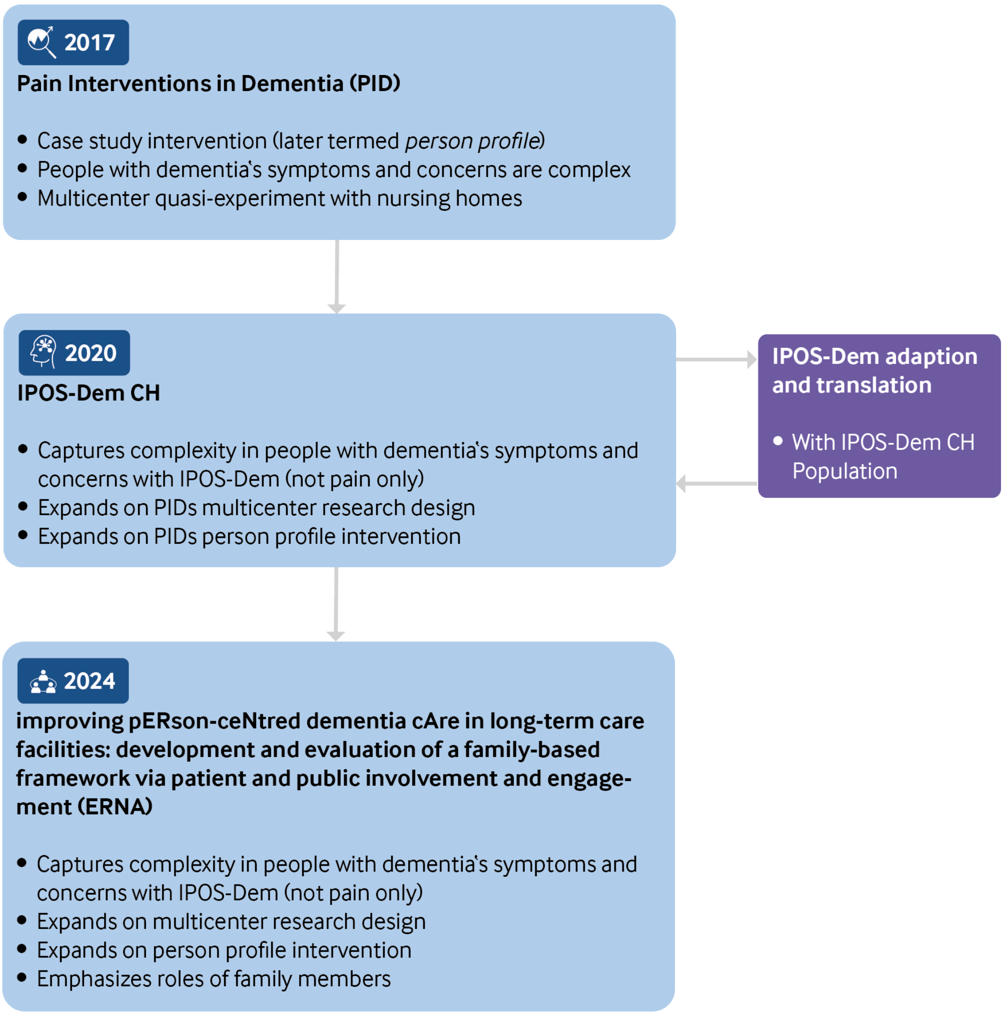

Figure 8: The Relation of the Thesis Project within Past, Current and Planned Projects

The MRC framework's foundational progression from development to implementation (starting left, moving clockwise across the boxes in Figure 7) serves to describe what has informed the present research project. Developing and implementing a complex intervention on a large scale while addressing all of the phases and core elements described in the MRC framework was beyond the scope of a doctoral thesis [120]. Therefore, the current thesis mainly addresses the development and feasibility phases of the MRC framework.

The work presented mainly furthers the 'develop or identify' phase corresponding to the MRC framework. Therefore, Chapter 4 and Chapter 5, which are situated in this phase, contain the bulk of the analysed data at the time of writing this thesis, specifically focusing on the translation and psychometric testing of IPOS-Dem, one of the core activities of the overarching trial intervention. These chapters focus on the IPOS-Dem's translation and psychometric testing [2], [57].

At first sight, nursing homes appeared to be a perfect environment for research: 24-hour onsite staff, controlled environments; that is, many processes are routinely performed, and outside influence or change regarding care processes is minimal. On closer inspection, many challenges can impact the conduct of controlled research in the long-term care setting: high staff turnover, the unfamiliarity of nursing homes executives and staff with the required rigour and processes of research conduct and missing or inadequate ethics guidance for recruiting people with advanced dementia living in nursing homes. A full-size trial coincides with the MRC framework's 'evaluation' phase. In Chapter 6, a stepped-wedge cluster randomised trial was proposed for the present study. This description and conduct, along an appropriate study design, served towards the methodological development and feasibility work for research conduct in the context of Swiss nursing homes. Chapter 6 proposes an appropriate study design and methodology furthering the evidence on the MRC framework's feasibility phase.

The present thesis informs the development of the IPOS-Dem project's intervention along the MRC framework's six core elements. Table 4 visualises the distinction between previous work, future projects and the MRC framework core elements covered in the current thesis.

Table 4: MRC Framework Core Elements - Which and Whose Work Informs Which Core Element?

MRC Framework Core Element	**Literature**	**Previous Work by the PhD Candidate**	**Identified within this Thesis**	**Future Projects Arising from this Thesis**
Context	Chapters 1 & 2	[1]	Chapters 1 & 2	-
Programme Theory	[40]	[1]	Chapter 3 (this chapter)	-
Stakeholders	[40]	-	Chapter 4 or [57]	ERNA[A]
Economic Considerations	-	-	Chapter 3	-

[A] *Improving Person-centred Dementia Care in Long-term Care Facilities: Development and Evaluation of a Family-based Framework via Patient and Public Involvement and Engagement (ERNA)"*

3.2.1 Context

The need and possible directions towards better caregiving for people with dementia living in nursing homes have been described in Chapter 1. In Switzerland, as shown in Chapter 2, there is a lack of evidence on the quality of life of people with dementia living in Swiss nursing homes. Furthermore little is known about staff's capacity to deliver care, caring and care quality. Quality reporting via quality indicators was introduced in Switzerland and became mandatory in 2018, but the indicators have been found to lack specificity for people with dementia. Nursing homes are known to have demanding workloads for frontline staff and high numbers of low-skilled staff operating in an environment where human resources are scarce. Koppitz et al. [121] showed that nearly half (45%) of the Swiss nursing homes demand better tariff systems for palliative dementia care (e.g., reimbursement for transdisciplinary collaboration, family-centred care, etc.). Furthermore Swiss nursing homes are seldomly equipped for prospective experimental trial research.

As demonstrated in Chapter 2, health-related quality of life in people with dementia living in nursing homes heavily depends on the collaboration of staff, family members and external healthcare professionals. Spichiger et al.'s [1], [122] previous study identified problematic hierarchies in nursing homes that hinder effective caregiving. However, the research also highlighted the importance of adopting bedside training and case-related learning for the nursing home staff to address these challenges.

The overarching trial started recruitment in Spring 2020, which coincided with public health measures to battle the COVID-19 pandemic. Switzerland enforced rules preventing frequent in-person contact on 16 March 2020, and these rules were only eased by the end of May and again imposed in December 2020. Swiss nursing homes, however, are subject to regulations by the cantonal public health administrations and their communities public health administration. Being mainly public-private or private institutions, Swiss nursing homes were allowed to impose their own additional restrictions. The restrictions were applied heterogeneously across the participating nursing homes from different cantons. The public health measures for COVID-19 required flexible planning of information and training sessions, individual agreements on procedures for activities regarding the intervention had to be made and will be a subject of the publication on the trial's main results.

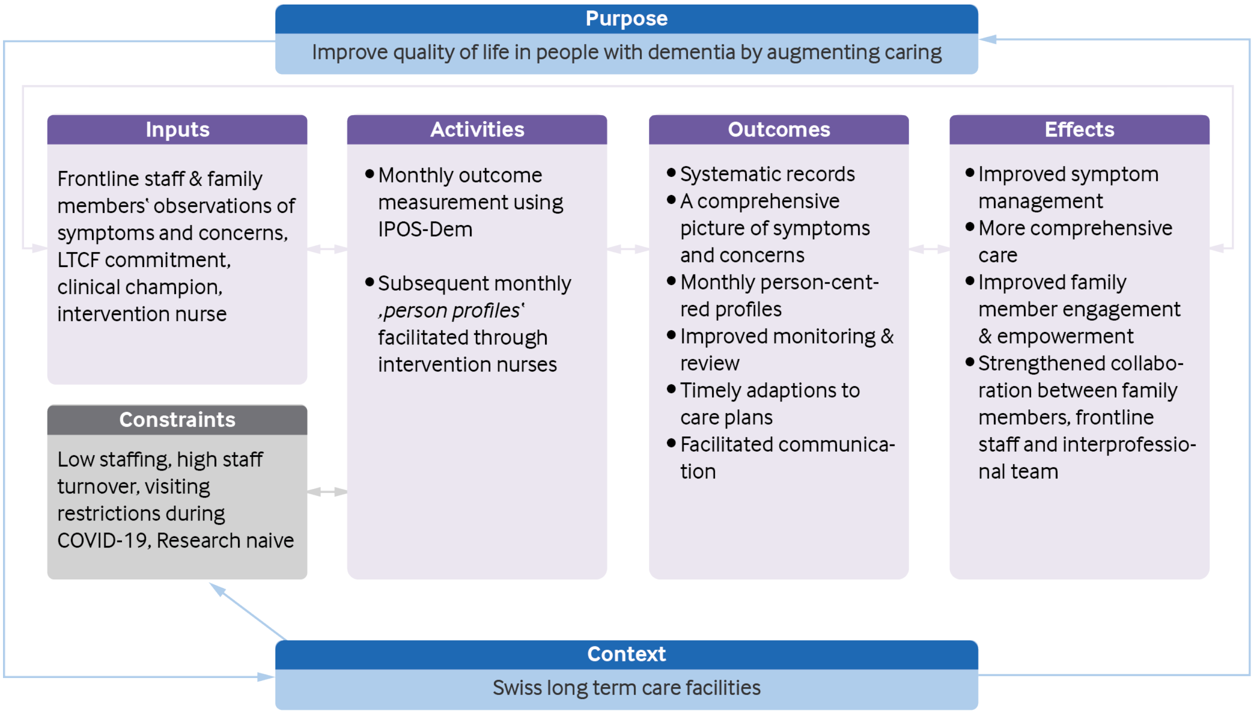

Figure 9: The Initial (Late 2021) Programme Theory

***Abbreviations**: Coronavirus disease 2019 (COVID-19), Integrated Palliative Care Outcome Scale for People with Dementia (IPOS-Dem), Long-term care facility (LTCF)*

3.2.2 Programme Theory—Development of the Overarching Trial's Intervention Logic Model

Figure 9 illustrates a logic model for the overarching trial, as devised at the beginning of the study. The model shows the relationships of elements theorised during intervention development. The ultimate purpose of the overarching trial was to improve the people with dementia's quality of life in line with the PCC framework [35]. The overall intervention intent and hypothesis are further elaborated in Chapter 6 and Appendix 8.IV. The contextual features of Swiss nursing homes are illustrated in the box 'Input' to the left. The 'Activities' box in Figure 9 shows the two core activities introduced during the intervention that interact with the inputs and constraints to shape change and pursue the overall purpose.

For the project, Ellis-Smith et al.'s IPOS-Dem theory [40] was expanded with the person profiles as an added activity, as implied by the second box in Figure 9. The six outputs and effects theorised were expected to be similar to the theory of change detailed in Figure 1 back in Section 1.3.1. The model that Ellis-Smith et al. developed for the IPOS-Dem application in nursing homes contains changes to the care and communication processes. In a later study, however, Ellis-Smith et al. highlighted that assessment and identification alone will not necessarily change routine clinical practice [43]. There is evidence that the time for reflection and care planning with the frontline staff must be allocated [123], [36], [124], [125].

3.2.2.1 Person Profiles

In the overarching trial's intervention condition, an intervention nurse external to the nursing home and a research team member held 'person profiles' (named 'case studies' in earlier iterations) with the frontline staff and family members. Person profiles refer to a series of monthly meetings with frontline staff and family members. The latest IPOS-Dem assessment for the person with dementia is discussed, and care plans are modified. The examination and subsequent discussion were theorised to lead to person-centred care goals for the person with dementia through a group discussion about the needs and concerns elicited in IPOS-Dem [126], [32], [127].

These person profiles are proposed to help reinforce the IPOS-Dem care process changes described by

Ellis-Smith et al. [40] through the following:(a) facilitated communication and collaboration among staff and family, (b) facilitated internal communication, (c) facilitated communication with external healthcare professionals and (d) systematic care planning and timely changes to care provision. This activity encouraged a collaborative examination of the IPOS-Dem observations from frontline staff and family members. In addition, repeated, frequent person profiles are theorised to allow for learning among frontline staff, more communication, goal-setting and timely person-centred care planning. A full intervention description for the study following the Template for Intervention Description and Replication (TIDieR)[128] is presented in Chapter 6 Section 6.4.5. That being said, Chapter 6 was completed and published before person-centric language was used to the describe components of the programme, so the person profiles are referred to as *'case-study intervention'*.

3.2.3 Stakeholders

The overarching trial intervention development was informed by the process evaluation results from the Pain Interventions in Dementia Project [1], [122]. A summary of the Pain Interventions in Dementia Project can be found in Appendix 8.V. The results from focus groups (n=2) where the Pain Interventions in Dementia study results [1] were reflected with nursing home frontline staff held in 2017 went into developing the IPOS-Dem intervention. Their feedback pertained mainly to the reflection of complexity in people with dementia's needs and symptoms. Furthermore, the intervention activity of collaborative onsite, case-by-case discussion and goal-setting was adapted for the IPOS-Dem project.

During the adaption and translation of the Integrated Palliative Outcome Scale for People with Dementia described in Chapter 4, stakeholders were engaged; these stakeholders included the following groups: people with dementia's family members, Swiss nursing home dementia care specialists and frontline staff. These stakeholders were invited to voice their concerns regarding the SW-CRT intervention and their conceptual understanding and ideas for using IPOS-Dem.

Additional stakeholders were involved informally during the recruitment phase for the trial, as outlined in Chapter 6. Recruitment (see Figure 11) involved 22 onsite or online discussions and introductions of the study goals, design and programme theory drafts. This recruitment phase at the institutional level allowed for informal interfacing with politicians and interest groups, the nursing home management boards and frontline staff and team leads. Their questions and feedback helped refine the overarching trial's programme theory, data collection and reporting procedures.

The involvement of the target population —people with dementia living in nursing homes— proved to not be possible. People with dementia living in nursing homes were invited to the information events by the nursing homes during recruitment. However, the cognitive impairment of eligible people with dementia was advanced. Furthermore, public health regulations during the COVID-19 pandemic prevented researcher meetings with people with dementia in most cantons. A proxy report for people with dementia by respective family members was made available, where possible. A notable factor in the inclusion of stakeholders was that the potential for funding of patient and public involvement in clinical studies in Switzerland was only introduced in 2021. Therefore, it was not possible to ensure financial resources for adequate compensation of participants, staff salaries and moderation and for this to be given in an adequate manner for people to voice their ideas, concerns and remarks on the current state of the intervention [129]. There is, however, a follow-up study, *Improving Person-centred Dementia Care in Long-term Care Facilities: Development and Evaluation of a Family-based Framework via Patient and Public Involvement and Engagement* ("ERNA"), directly involving people with dementia in multiple research stages proposed in the postdoctoral period.

3.2.4 Key Uncertainties

In 2020, there were two key uncertainties that have been partially addressed by the present thesis. Although IPOS-Dem was translated and adapted into multiple languages, field testing and psychometrical properties of IPOS-Dem have not been published. Ellis-Smith et al. [40] provided pilot data for 32 people with dementia living in nursing homes with their theory of change Figure 1. The complexity on multiple levels described in previous chapters might contribute to the slow progress of clinometric studies with IPOS-Dem. Prospective studies have been considered the best way forward to further nursing science [130] and were repeatedly emphasised by the reviews in the context of nursing home and for the population, as shown in Chapter 2. This led to the second challenge; the relative naivety of Swiss nursing homes when it came to undertaking trial studies. The need to conduct multicentre trials to reach adequate sample sizes for this population can pose enormous organisational challenges to the researchers. Furthermore, there seems to be a lack of flexibility in the current structures of the clinical trial units, inhibiting the capacity to adapt a clinical trial to the exigencies of the nursing home context.

3.2.5 Refining the Intervention

The overarching trial's 'person profile' intervention component is itself a refinement of the Pain Interventions in Dementia 'case study' intervention [1], [122]. The refinement of person profiles was informed by the stakeholders' feedback, process evaluation and literature, as outlined above. It is expected that this project's intervention, as outlined here and further described in Chapter 6, will undergo further extensive refinement based on the findings from the IPOS-Dem psychometric properties and ongoing and planned projects.

3.3 Connecting Research Aims and Methods

Person-centred care is essential for the well-being of those living with dementia because it promotes their autonomy, dignity and respect. To achieve this purpose, the main research aims were to culturally adapt and translate the IPOS-Dem instrument, psychometrically test it and design a research project to test the two intervention components' effectiveness and investigate nursing homes. The methods per aim are reported below.

3.3.1 Methods to Culturally Adapt and Translate IPOS-Dem

IPOS-Dem was translated linguistically and adapted culturally by following the Consensus-Based Standards for the Selection of Health Status Measurement Instruments (COSMIN) consortium's guidance [131], the stepped process of which was first described by Beaton et al. [132] and later elaborated upon by Acquadro et al. [133]. IPOS-Dem's cultural adaption and translation consisted of conceptual definition, forward and backward translation, expert review, cognitive debriefing and proofreading. The principles of easy-read language was applied to the German IPOS-Dem for translation and adaption to the Swiss-German nursing home context. Overall, 28 healthcare professionals outside the study team were involved during the different steps. Furthermore, five laypeople, easy-read translators and the original IPOS development team members were involved, as detailed in Chapter 4. The participants were recruited from the research team's professional network. Participating frontline staff in select phases were recruited from a collaborating nursing home in the canton of Thurgau, Switzerland. The translation and adaption process utilised multiple methods: focus groups, cognitive debriefing and literature reviews. The resulting translation and all documents detailing the process steps were proofread by IPOS-Dem's original developers before the instrument was published on https://www.pos-pal.org.

3.3.2 Methods Used to Test IPOS-Dem Psychometrically

The continued psychometric evaluation of IPOS-Dem was embedded into the overarching trial described in Chapter 6. Like the translation and cultural adaption, the design of this evaluation, which is further expanded upon in Chapter 5, was based on COSMIN criteria and terminology [134]. COSMIN groups psychometric characteristics into four major dimensions, as shown in Figure 10. The present thesis expands on the reliability, content and face validity measurement properties of IPOS-Dem, which Figure 10 highlights in green.

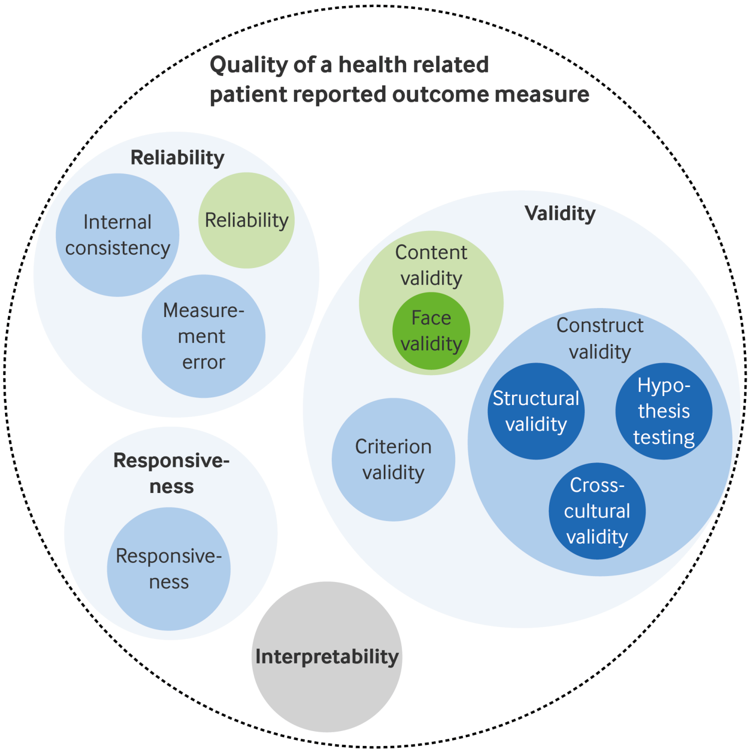

Figure 10: The COSMIN Taxonomy of Measurement Properties.

Adapted from L. B. Mokkink et al., 'The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes', Journal of Clinical Epidemiology, vol. 63, no. 7, pp. 737–745, Jul. 2010, doi: 10.1016/j.jclinepi.2010.02.006., Copyright (2010), with permission from Elsevier.

The literature review on person-centred outcome measures revealed a lack of research, especially for translated instruments regarding reliability, despite frequent use in research, which is detailed in Chapter 4. Therefore, as one of the first steps to test IPOS-Dem's psychometric properties and describe the individual items, a reliability study was undertaken, as presented in Chapter 5. At the overarching trial's baseline, IPOS-Dem was scored twice, each by an independent frontline staff member for the same person with dementia, and these results were entered into the analysis. Because of the overarching trial's nested design, a fully crossed design was not realised. Obtaining a sample size of 50 people with dementia in a single cluster, as recommended by the rule of thumb [135] for reliability studies, was not possible in the overarching trial's context. Therefore, the analytic method had to be adjusted to accommodate such a nested data structure and investigate bias introduced by different ratings. The analysis rested on an extension of classical reliability theory's intraclass correlation coefficients, which have been classified for different applications by Shrout and Fleiss [136]. This recommended intraclass correlation approach would not have been capable of capturing the nested, multisite nature of the data from the overarching trial. After preparing the data for analysis by calculating the experimental sum scores from the IPOS-Dem assessment, a reliability coefficient for this sum score between two ratings was estimated. The Generalisability Study (G-Study) [137], which is further detailed in Chapter 5, required two steps: (a) the estimation of variance components per factor by applying a generalised linear model and (b) the calculation of the reliability coefficient. However, this was extended to provide clinically valuable information because the G-Study was followed up with a dependability study (D-Study). The D-Study estimated how many repeated IPOS-Dem ratings sum scores would have to be averaged to obtain a reliable sum score for a person with dementia.

3.4 Ethical considerations

The potential benefit of the programme affects the entire nursing home in the long term, from improved symptom control for people with dementia to frontline staff's improved knowledge and skills regarding symptom management. Furthermore, it can assist with communication between nurses and residents, including their families, as well as (nursing home) physicians, to reduce symptom severity [40]. The realisation of the programme is critical because of the vastly increasing older population living with comorbidities such as dementia [70]. Also, a considerable amount of data from nursing homes in the German-speaking part of Switzerland were collected. The generated data on symptom severity in people with dementia can further be used for comparing the everyday clinical practice of care provided to people with dementia among nursing homes. Such comparisons can be used in a similar way to the Palliative Care Outcome Collaboration's exemplary application of their outcome measures in Australia to benchmark quality indicators for palliative care services [138].

3.4.1 Stepped-Wedge Design

This design has the advantage that all nursing homes receive the intervention, which is considered to be more ethical in trials like this when the intervention is believed to have a positive effect [139], thus improving the care. This advantage of the design is insofar applicable in the overarching trial, that residents with a high symptom burden and severity are picked-up by the IPOS-Dem measurement and that evidence-based interventions will be initiated as soon as possible. The stepped-wedge design will minimise possible confounding factors (e.g., the correct application of IPOS-Dem) because it takes into account such effects longitudinally [139]. Finally, the stepped-wedge design offers more time to start the clinical sites in line with the protocol, which balances the extended length of the study [139] in the overarching trial.

3.4.2 Participant Benefits

The implementation of the IPOS-Dem into clinical practice during the full trial duration has immediate benefits for the participating people with dementia, as well as the frontline staff [40]. As elaborated based on Figure 1 in Chapter 1, the IPOS-Dem offers a quick overview of the impact of symptoms and concerns on people with dementia. Therefore, immediate and targeted actions can be taken through the person profiles intervention by a geriatrics and palliative care specialist nurse [140]. Furthermore, frontline staff may feel empowered to assess the symptoms of people with dementia systematically and within a relatively short time because, previously, no such measurement instrument was available [13].

The present study involved a vulnerable patient population, which postulated that study personnel is proficient and senior in the field of geriatrics and palliative care research. However, the potential benefit to people with dementia, which should not be kept from them just because they are seriously ill or potentially unable to consistently communicate verbally by far outweighs this risk of overburdening frontline staff by the completion of the study measures. There is a vast number of studies supporting the conduct of research for everyone because many patients, view their participation as an act of altruism to make the life better for those who come after [141].

3.4.3 Legal Framework

The clinical trial was undertaken without testing drugs, transplant-products or organ transplants. Study category A implies that the intervention is considered to have minimal risk and minimal burden on study participants, in line with the Swiss Federal Act on Research involving Human Beings [142]. During the trial, frontline staff in nursing homes were trained in their symptom assessment based on the translated and adapted IPOS-Dem. The training included systematic observation in assessing the symptoms and

concerns of people with dementia.
The trial was approved by the Research Ethics Committee of the canton of Zurich, Switzerland (BASEC-ID: 2019–01847) as the lead ethics committee (see Appendix 8.X for the approval letter). The project was conducted in compliance with the protocol and the current version of the Declaration of Helsinki [143], the European Medicines Agency's guidelines for good clinical practice [144], the human research act and the relevant national, cantonal, communal and institutional legal and regulatory requirements. The overarching trial was registered with DRKS00022339. Clinical champions and frontline staff involved in handling study data have participated in a 'mini-GCP', as shown in Table 21 and further contextualised in Section 3.5.1. In line with the Research Ethics Committee's recommendation, the mini-GCP outlined the experimental nature of the project and explained the data protection rights of the participants.

3.4.4 Consent Procedures for all Individual Participants

All participants for the overarching trial have been provided with a participant information document and consent form describing the overarching trial and providing sufficient information for the participant to make an informed decision about their participation. All participants and/or their respective attorneys signed written informed consent for participation and publication, which has been adapted to the different target groups and can be accessed at DOI: 10.5281/zenodo.4008436. All raters have signed written informed consent for participation and publication.
Each participant was informed that participation in the study is voluntary and that they could withdraw from the study at any time and that withdrawal of consent would not affect their subsequent medical assistance and treatment (people with dementia, family member) or employment (frontline staff). The people with dementia and/or their respective attorneys have been informed that their medical records may be examined by authorised individuals other than their treating physician.

3.5 Recruitment

The recruitment of nursing homes was challenging for multiple reasons: the relative naivety of nursing homes' frontline staff in research processes, the lack of research support usually provided to other settings (i.e., university hospitals) by clinical trial units and the resource-intensive manifestation of longitudinal research projects.

The recruitment of people with dementia, frontline staff and nursing homes was conducted along the overarching tria's protocol between March 2020 and June 2021, co-occurring with public health measures enforced during the COVID-19 pandemic. The recruitment of nursing homes can be described in four phases, as illustrated in Figure 11.

After screening the cantonal nursing home registries, the nursing homes of a critical size (more than 20 places) were contacted with a personalised email, briefly introducing the project, project team and referring to prepared attached leaflets outlining the overarching trial and CVs of the researchers (see Recruitment material and templates for the IPOS-Dem trial, DOI: 10.5281/zenodo.7840060). Each institution that signalled interest was proposed a meeting date to discuss the overarching trial and critical procedures, such as the nomination of a clinical champion, the identification and informed consent for people with dementia and their family members or introductory workshops for frontline staff. Written agreement contracts between the responsible principal investigator and institution representatives were agreed upon shortly after verbal commitment. Both Chapter 6 and the publication [2] provide an explanation regarding sequences and randomisation.

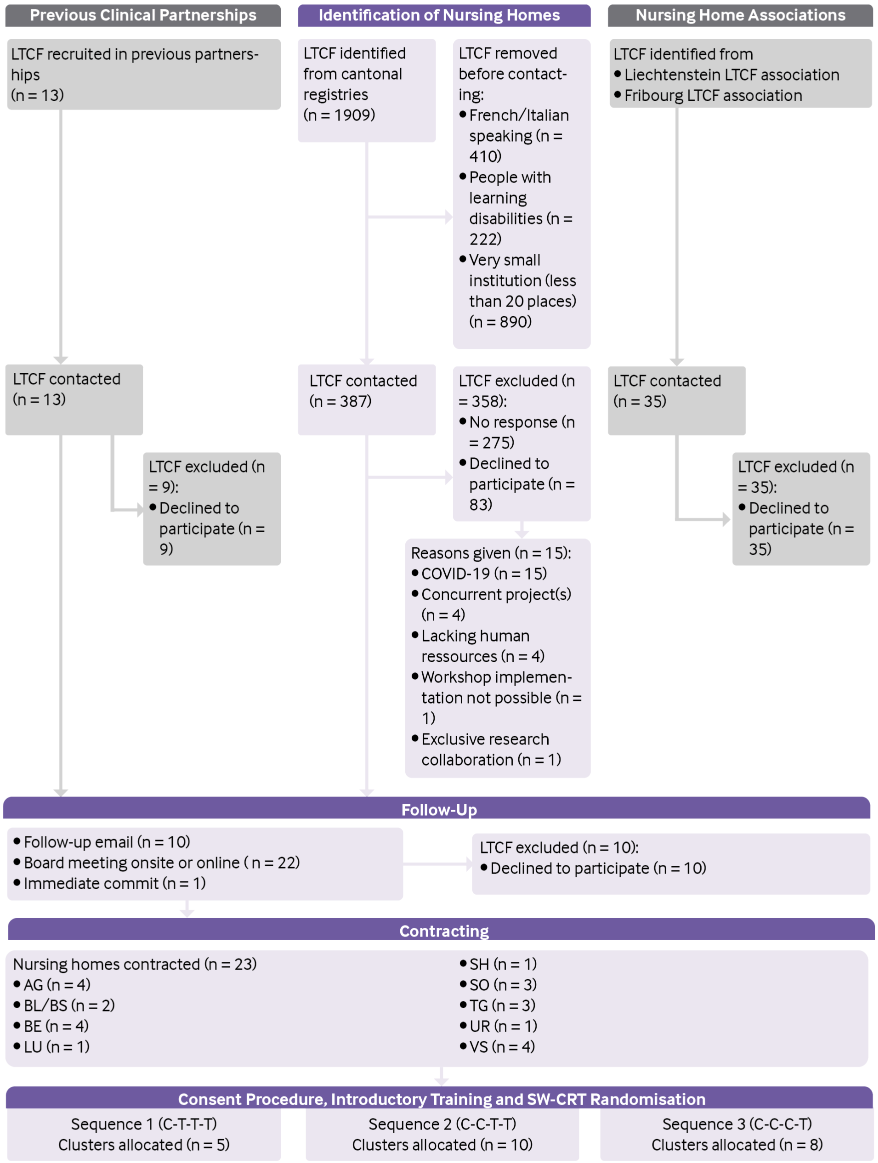

Figure 11: Recruitment of Nursing Homes for the SW-CRT, as Outlined in Chapter 6.

***Abbreviations**: Agrovia (AG), Bern (BE), Basel-land (BL), Basel-Stadt (BS), Coronavirus disease 2019 (COVID-19), Long-term care facility (LTCF), Lucerne (LU), Number (n), Schaffhausen (SH), Solothurn (SO), Thurgau (TG), Uri (UR), Wallis (VS)*

3.5.1 Key Personnel During the Overarching Trial's Conduct

Multiple actors were assigned to perform key activities or contribute to various components of the intervention, as shown in Table 5. The breakdown of each actor's role is further explicated in Table 21 in Appendix 8.VI based on Pressau et al.'s action, actor, context, target, time (AACTT) framework [145]. AACTT was used in combination with TIDieR [2], [128] to describe this complex intervention with multiple actors.

Table 5: Study Personnel as actor during different Intervention Components

Actor	Training Workshop	Symptoms and Concerns Assessment	Person Profiles
CNS trained in geriatric and palliative care [A]	Yes	No	No
Research staff [A]	No	Yes	No
Clinical champions [B]	No	Yes	Yes
Frontline staff [B]	No	Yes	No
People with dementia's family members	No	Yes	No
Intervention nurse [A]	No	No	Yes

[A] Employed by the research institution, [B] Employed by the respective nursing home
Summary of Appendix 8.VI, refer to the longer table in Table 21 for more in-depth information.
***Abbreviations**: Clinical nurse specialist (CNS)*

3.5.1.1 Clinical Champions

After contracts were agreed, the nursing homes' management boards were asked to assign a local clinical champion. The clinical champion was responsible for screening people with dementia living in their respective nursing home for eligibility. They worked in close conjunction with the research team over the full duration of the overarching trial. Besides initiating eligibility and consent procedures, the clinical champions were provided with information material to invite people with dementia, their family members or legal representatives to information events that where held onsite or online depending on the respective cantonal/institutional COVID-19 public health restrictions. The template information material available from DOI: 10.5281/zenodo.7840060 and DOI: 10.5281/zenodo.4008436 was modified to each nursing home's corporate image, and the cover letter was signed by the nursing home's management board. Clinical champions organised the aforementioned training workshops for the frontline staff (see Table 5 in Section 3.5.1 and Table 21 in Appendix 8.VI), which had to be planned about four months in advance because of the way operational planning is usually conducted in Swiss nursing homes. After a nursing home crossed over to the intervention condition in the overarching trial, the clinical champion took the lead in implementing the onsite activities discussed during person profiles and preparations of these discussions, that is, reserving a room, extending invitations to frontline staff and recording the changes to written care plans.

The choice to implement the two core components of the overarching trial's intervention in with clinical champions was, on the one hand, informed by the work of Antunes et al. [146], which is specific to the introduction of IPOS into specialised palliative care hospital units. On the other hand, the project built on the experiences from Bausewein et al. [147], who referred to Kitson et al.'s [148] definition of facilitators. Local opinion leaders would have been the primary selection for the clinical champion role. However, clinical champions were chosen, assigned or asked to be the clinical champion because of convenience. The clinical champion was primarily determined by their formal role in their respective nursing home or by the nursing home's leadership board. Highly qualified intervention nurses situated within the research team were necessary to moderate between informal opinion leaders, the remaining frontline staff and the designated clinical champions. The intervention nurse, research staff and clinical champion worked in close partnership to complete the overarching trial.

3.5.2 Intervention Nurse

The intervention nurse led and facilitated the person profile component in the overarching trial. It was an advanced practice nurse with expertise in chronic illness, palliative and dementia care. The intervention nurse also assessed intervention fidelity and adherence for the person profile intervention by keeping a record of memos of the person profile preparation, evaluations and comments regarding IPOS-Dem. The intervention nurses' memos remain to be analysed at the time of writing.

3.5.3 Research Team

Over the full period of the overarching trial, the clinical champions were the primary contact person for the research team regarding data collection, completion and transfer. An email for the clinical champion with the completed and remaining surveys in a regular weekly pattern was collated. This minimised the occurrence of missing data in the resulting dataset, and the tracking of attrition was instantaneous. The introductory training detailed in Chapter 6 was complemented by support meetings held every three months. These meetings were planned with cluster groups assigned to cross over six and nine months into the study (sequences 2 and 3 in Figure 11). In total, 26 support meetings were prepared and held between the clinical champions and research team. The aim of these meetings was to compensate for fluctuation in frontline staff during the control condition of the overarching trial. The clinical champion invited new frontline staff that could not participate in the initial training session to these meetings. Furthermore, the support meetings presented an opportunity for informal exchange on questions regarding study procedures and planning with the clinical champion. Nursing homes that had crossed over (or were randomised to sequence 1) and, therefore, were in monthly contact with the intervention nurse held the remaining 43 support meetings added on to the person profiles in the same three-month pattern. Questions from clinical champions and frontline staff during all support meetings were also documented in memos. The support meeting memos remain to be analysed at the time of writing the present thesis.

3.6 Methods Used to Investigate the Effect of a Complex Intervention in Swiss Nursing Homes

RCTs have long been seen as the only way to produce reliable evidence on causality in healthcare research. For vulnerable populations and on larger scales (i.e., population health), cluster randomised trial designs have become more popular. The main difference here is that randomisation is not conducted on the participant level but on the cluster level. Haines and Hemming [108] have extensively elaborated on these methods by arguing for stepped-wedge designs, where clusters can be moved along absolute calendar time and crossed over or moved from control to intervention conditions at relative time points while controlling for time effects in the analysis. The reporting guideline they published as an extension to the Consolidated Standards of Reporting Trials (CONSORT) [149], [150], as well as the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [151], was fundamental to develop and report the protocol for the overarching trial presented in Chapter 6 [2].

The sample sizes for the overarching trial were derived from simulations based on previous studies and the effect sizes expected from palliative care studies [152], [61]. The sample sizes required were shown to be heavily dependent on the intraclass correlations between outcomes among one individual nursing home, on the one hand, and along the repeated measures for each person with dementia (besides, of course, the expected effect size, number of clusters, cluster size and alpha level). Therefore, it was decided to use very conservative, low intra cluster correlations for the sample size calculations of .1 and .2. With careful planning for recruitment and previous experience with consent procedures, the overarching trial's protocol [2] outlines a comprehensive SW-CRT to test the evaluation of the two-component intervention outlined in Figure 9 with Swiss nursing homes.

3.6.1 Data Collection Procedures

Primary data collection was carried out on paper by the frontline staff, the clinical champions assigned frontline staff to people with dementia by convenience. Data were entered by the clinical champions into REDCap, an open-source, electronic, browser-based data entry tool [153], [154]. The instance of REDCap used for the present thesis was hosted at the HES-SO, School of Health Valais, Switzerland. Entries related to people with dementia were encoded with unique identifier (ID) tables and stored locally with the clinical champions only. The REDCap survey interface displays forms to the user allowing the immediate recognition of data in the wrong format, hence providing instant feedback to the person entering the data. The automated checks programmed into the survey interface analyse data for plausibility and completeness while it is being entered and when saved. A detailed protocol for analysis and the handling of attrition was developed and is presented in Chapter 6.

3.6.2 Estimated Cost for the Delivery of the Intervention

As recommended by the MRC Framework and Criteria for Reporting the Development and Evaluation of Complex Interventions in Healthcare: revised [155], the cost of the overarching trial intervention in terms of staff hours per patient was estimated. For nursing home recruitment, a cost calculation per person with dementia over the full four cluster-periods of the overarching trial was undertaken. This amounted to a total of 69 additional hours for the frontline staff involved over the full 17-month time frame of the overarching tiral runtime in each cluster. Table 6 below summarises staff costs and average monthly additional hours per patient. The estimated cost was an additional CHF 295 per month per patient compared with usual care. However, because current tariff systems do not display the costs for transdisciplinary meetings and the compound costs for Switzerland have neither been analysed nor published, no subtractions were undertaken. Furthermore, the nursing homes' use of the relevant tariff positions for some of the other activities that may overlap with 'usual care' was assumed to be heterogeneous. The cost per patient was calculated by assuming nursing homes paid the 2018 median hourly salary of CHF

42 for registered nurses and CHF 30 for healthcare assistants and interns [156]. In Switzerland, family members providing informal care would, on average, be able to apply for reimbursement of CHF 32 per hour [157]. The salary for the intervention nurse was calculated based on the Swiss National Science Foundation salary recommendation for study personnel with CHF 120 per hour.

Table 6: Cost Estimation per Patient and Month for the Overarching Trial's Intervention.

Activity	Staff	Work Hours (hh:mm)	Hourly Rate (CHF)	Source	Cost per Month (CHF)
Assessment(s)	RN	00:30	42.00	[156]	21.00
Person profile	RN	00:20	42.00	[156]	14.00
Assessment(s)	HCA	01:10	30.00	[156]	32.00
Person profile	HCA	00:40	30.00	[156]	18.00
Person profile	APN	01:00	120.00	[158]	20.00
Assessment(s)	Family member	00:10	32.00	[157]	5.50
Person profile	Family member	00:20	32.00	[157]	11.00
Symptom management	RN	00:40	42.00	[156]	28.00
Symptom management	HCA	00:40	30.00	[156]	18.00
Coordination	RN	00:10	42.00	[156]	7.00
Coordination	APN	00:10	120.00	[158]	20.00
Total per patient & month					***294.50***

***Abbreviations**: Advanced practice nurse (APN), health care assistants (HCA), hour (h), minute (m) registered nurses (RN)*

3.7 Methodological Conclusions

The overall aim of the present thesis was to help frontline staff in nursing homes talk about the changes they see in people with dementia. To do this, the overarching trial has employed different actions to help them documenting their contribution to care and contribute to the assessment and planning of care. This was achieved by adapting, translating and testing an available instrument in Chapter 4 and Chapter 5 as part of a complex clinical study further explained in Chapter 6. The methodological steps described here guide and structure the reporting and further work in the complex context, population and setting. The MRC framework breaks down the complex intervention development process into multiple phases while asking to describe the core elements, regardless of the current phase, which can be further iterated upon. Previous theory informed the overarching trial to develop methods and designs to conduct longitudinal studies in Swiss nursing homes, use IPOS-Dem as a clinical instrument and look into its psychometric properties. Furthermore, a ‘person profile’ intervention was adapted from previous studies to be applied in an experimental overarching trial. Multiple reporting guidelines are used for detailing the results and protocols in the following chapters. The MRC frameworks intervention identification and feasibility phases were used through the overarching trial’s development, conduct and will be reviewed in the discussion in Chapter 7.

F. Spichiger, A. Keller Senn, T. Volken, P. Larkin, and A. Koppitz, 'Integrated Palliative Outcome Scale for People with Dementia: easy language adaption and translation', Journal of Patient-Reported Outcomes, vol. 6, no. 1, p. 14, Feb. 2022, doi: 10.1186/s41687-022-00420-7.

4 IPOS-Dem: Easy Language Adaption and Translation

4.1 Abstract

4.1.1 Background

In this article, we report the cultural adaption and translation of the Integrated Palliative Care Outcome Scale for People with Dementia (IPOS-Dem) into a Swiss-German easy language version for proxy assessment of people with dementia living in Swiss nursing homes. The Swiss-German easy language version of the IPOS-Dem was developed and culturally adapted in a six-phase process from the German IPOS-Dem using recommended guidelines. With nursing home staff and laypeople, the conceptual definition and relevance of IPOS-Dem items were established during phase I. Phase II encompassed the completion of forward translations. Independent native speakers blind to the original scale translated and back-translated the German easy language version. The resulting IPOS-Dem version was then blindly back-translated in phase III. Experts reviewed all resulting translations in phase IV to produce a pre-final IPOS-Dem version. Finally, the phase V cognitive debriefing involved two focus groups assessing the pre-final IPOS-Dem version. Phase V included cognitive interviews with laypeople (n = 2), family members of those with dementia (n = 4) and staff from different care contexts (n = 12).

4.1.2 Results

The translation using easy language specialists yielded a clinically relevant, comprehensive and understandable translation. In addition, face and content validity for the easy language version were established in the cognitive interviews.

4.1.3 Conclusions

With an easy language IPOS-Dem, all frontline staff and family members can be empowered to communicate their observations after caring interactions. Enhanced clinical communication with easy language tools shows the potential for research and clinical applications. In addition, attentive use in scales of easy language communication may foster increased engagement with untrained laypeople in clinical and care research. Integrated Palliative Outcome Scale for People with Dementia: Easy Language Adaption and Translation

4.2 Introduction

People living with dementia in nursing homes and the community are at high risk of serious health-related suffering [4]. Since there are no curative treatment options for dementia, focussing on a palliative care approach is indicated [3]. Palliative care is a holistic approach to care. The needs and concerns of a person with any disease that does not respond to disease-modifying treatment are managed with priority [159]. Therefore, assessing needs and concerns is a prerequisite for providing high-quality care for people with dementia [159]. However, the timely and structured assessment of needs and concerns in Swiss nursing homes is rare [123], [160]. Furthermore, the assessment processes and instruments currently in use are biased towards behavioural, psychiatric symptoms instead of needs and concerns. Further, the regulations attached to the assessment do not formally permit most frontline workers to document their observations [32], [33].

The Integrated Palliative Care Outcome Scale for People with Dementia (IPOS-Dem) is a brief and multi-dimensional instrument for proxy needs and concerns screening by nursing staff [161]. It provides caregivers with an overview of the outcomes achieved and may determine whether a treatment is worthwhile, indicating which services and interventions are the most adequate. Care staff score 27 items in the IPOS-Dem with a Likert scale (0 to 4) [42]. Hodiamont et al. [162] translated the IPOS-Dem from English to German for use by German health professionals and family members.

Swiss dialects cannot be easily understood by German-speaking people [54]. People living in the Swiss-German region use a variety of Allemanic dialects in all day-to-day interactions [55]. The Allemenic dialects of Switzerland have a high presence; they seem resistant to being taken over by standard German. This sets them apart from Allemenic dialects spoken in Austria, Germany and northern Italy. Officially, Switzerland is a four-language state, where French, German, Italian and Romansh are used for written and spoken communication [54]. Swiss standard German, however, is usually spoken only on request and understood by the majority of people living in the Swiss-German region. It is much more accessible to other people speaking German, but subtle differences to standard German remain [55].

Up to 70% of frontline staff working in Swiss nursing homes have a migratory background [66]. Swiss nursing homes commonly employ a heterogenous mix of staff to care for people with dementia -this includes untrained personnel, volunteers, and interns with varying degrees of literacy and language skills. Papadakus [163] found that the linguistic accessibility of instruments and scales for patient assessment is lacking in the development of such instruments. Worldwide, an estimated 15 to 20% of the population has reading difficulties [164].

A standardised ruleset for 'leichte Sprache' (easy language or easy-read) has been agreed upon for German-language regions [165]. Plain language in care and medical settings has become popular in explanatory texts and self-management [166]. Linguistic assessment and critique, however, mainly focus on legal texts [167]. Easy language is a further development of plain language texts. Easy language enhances text accessibility and readability for people with and without reading difficulties compared to plain language. Easy language has recommendations for, e.g., word difficulty and precision, use of numbers in the text and sentence length [165]. International resources for easy language are available from https://www.inclusion-europe.eu/easy-to-read/ and for plain language at the European Publications Office [168]. Therefore, for our study involving nursing homes in the German-speaking part of Switzerland with heterogeneous frontline staff, we translated the original IPOS-Dem to easy language for the Swiss context.

4.3 Aims

In this study, the German IPOS-Dem version was translated and culturally adapted into easy German for the Swiss nursing home context and frontline staff. The secondary aim was to describe the discrepancies and differences that occurred during adaption compared to previous research.

4.4 Methods

Our linguistic and cultural adaption was guided by an internationally defined methodology [131] and a stepped process for translation [133], [132]. Our translation was undertaken between August 2020 and April 2021. Figure 12 illustrates the six-phase process for translation and adaption that we followed. The study was conducted in multiple centres in the eastern Swiss-German part of Switzerland. In the first translation, we involved certified translators for easy language from ProInfirmis. Scientific experts and laypeople consulted with us in later stages of the adaption in offsite, online meetings due to public health restrictions. We applied multiple methods during this process: forward and backward translation, expert focus groups and cognitive interviews with staff from different settings in which they work with people with dementia. Interview data were analysed via thematic analysis. Psychometric testing (stage VII proposed by Antunes et al. [169] will be detailed in separate publications.

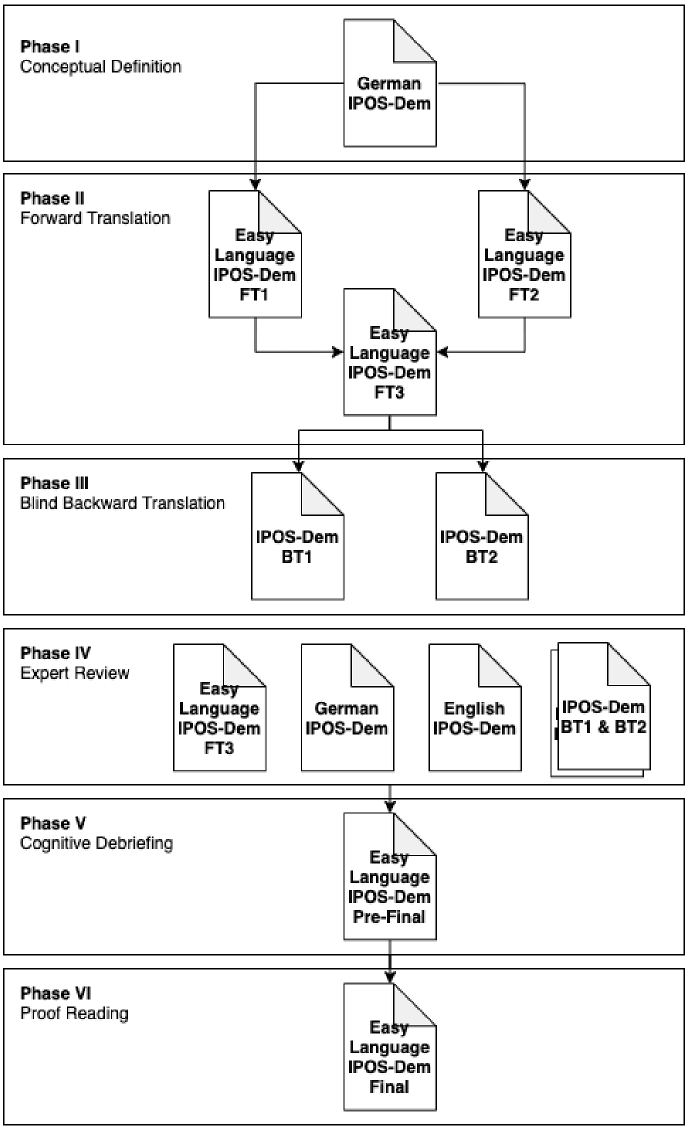

Figure 12: Phases and Documents Produced in the IPOS-Dem Translation and Adaptation to 'leichte Sprache'

Abbreviations: *BT1 and BT2: backward translations; FT1, FT2 and FT3: forward translations 1, 2 and 3, respectively; IPOS-Dem: Integrated Palliative Care Outcome Scale for People with Dementia*

4.4.1 Phase I: Conceptual Definition

We collated an overview of the literature related to current clinical practices in health-related quality of life measurement for people with dementia in Swiss nursing homes. We examined processes and systematic assessment behaviours in frontline staff. Furthermore, we interviewed our clinical partners on the use of routine assessment instruments, outcome measurements and health-related quality of life measures they know or use. With six participants, we conducted formal and informal discussions on the relevance of the IPOS-Dem items concerning their key concepts in August 2020. The formal discussions were recorded, and the anonymised transcripts were thematically analysed.

4.4.2 Phase II: Forward Translation

Three translators were involved in the forward translation process. Two certified translators for easy language with no clinical background wrote the first forward translation (FT1) from the German IPOS-Dem. Translator three had a nursing background with a specialisation in family nursing. Translator three wrote forward translation two (FT2) from the German IPOS-Dem. Finally, a research team member synthesised and consolidated the forward translations (FT1 and FT2) into forward translation three (FT3).

4.4.3 Phase III: Backward Translation

The translators involved in this phase were blinded to the original English IPOS-Dem and intermediary German IPOS-Dem. Both translators are native-English-speaking American nurse educators living and working in Switzerland who are also proficient in German. The translators were involved in the backward translation process of FT3. Each produced a German backward translation (BT1 and BT2). Five participants later reviewed and compared the German IPOS-Dem, BT1, BT2 and FT3.

4.4.4 Phase IV: Expert Review

An expert group (n = 9) held two online meetings in March 2021 to review and discuss the different versions: the original English IPOS-Dem, the German intermediary IPOS-Dem and FT3. Table 7 provides a short description of the expert group members. The meeting was facilitated by a research team member. Based on this review of the documents, the panel agreed upon and ratified the pre-final version.

4.4.5 Phase V: Cognitive Debriefing

The fifth phase assessed how participants understood and conceptualised the IPOS-Dem instructions, questions and scales. After the translation process detailed above, cognitive interviews with two focus groups were conducted in April 2021. Our interviews involved a convenience sample of 10 people from the primary user group, nursing home frontline staff. The focus groups were held face to face and remotely via video call. We outline the participant details in Table 7. As in previous cultural adaptions, we applied the ‘think out loud’ interview method, in which the participants verbalised their thought processes as they answered each survey question [170].

4.4.6 Phase VI: Proofreading

Detailed documentation of the process and results were submitted to the IPOS-Dem authors for review.

4.4.7 Setting and Participants

Study participants were nurses with clinical and academic backgrounds and certified specialists for easy language recruited from our professional network, as well as people without health care, linguistic or dementia care backgrounds, hereafter called ‘laypeople’. Participating clinical nurses in Phases II and V were recruited from a long-term care facility.

Table 7: Demographics of Study Participants across the First Five Phases of the IPOS-Dem Easy Language Translation and Adaption Process

Phase	Number of Participants	Participants’ Backgrounds
I: Conceptual definition	4	Health care professionals
	2	Laypeople
II: Forward translation	2	Easy language specialists
	1	Layperson
III: Backward translation	2	Health care professionals
III: Backward translation comparison	1	Layperson
	4	Healtch care professionals
IV: Expert review	6	Health care professionals
	2	Easy language specialists
V: Cognitive debriefing	4	Registered nurses
	8	Care assistants
	4	Family members
	2	Laypeople
VI: Proofreading	2	Original IPOS development team members

4.4.8 Study Procedures

Participants were asked for written consent with an information leaflet and were provided with a verbal explanation detailing the study and data-handling procedures. Following consent, participants completed the IPOS-Dem pre-final version and were invited to ‘think out loud’. All interviews were recorded using a digital audio recorder or the recording feature of the video conferencing software. During interviews, we asked the participants repeatedly how they understood the individual instructional paragraphs and questions and asked them to verbalise their thoughts and understandings of the IPOS-Dem. If ambiguous or unclear passages were highlighted, we asked participants to suggest a rewording. The recordings of the Swiss-German interviews were transcribed verbatim by the last author.

4.4.9 Data Analyses

The last author analysed the resulting transcripts per item and coded them using ATLAS.ti version 9.1 for MacOS. Then, the first and last authors compared the conclusions of the different groups. Finally, essential parts and remarks were cleaned and collated in tables for each stage.

4.4.10 Ethical Considerations

The study procedures and compliance with applicable research regulations [144], [143] were confirmed by the Zurich cantonal ethics board (BASEC-ID: BASEC2019-01847).

4.5 Results

Besides the findings presented per phase in the paragraphs below, each phase produced and asked for different iterations of the IPOS-Dem. Table 8 illustrates inputs and outputs of each phase we used and referred to below.

Table 8: Input and Output of Intermediary Documents for Each Phase

Phase	Description	Input(s)	Output(s)
I	Conceptual Definition	German IPOS-Dem	
II	Forward Translation	German IPOS-Dem	FT1/FT2, FT3
III	Backward Translation	FT3	IPOS-Dem BT1/BT2
IV	Expert Review	German IPOS-Dem English IPOS-Dem FT3 BT1 BT2	Draft easy-read IPOS-Dem
V	Cognitive Debriefing	Draft easy-read IPOS-Dem	Pre-final easy-read IPOS-Dem
VI	Proofreading	Pre-final easy-read IPOS-Dem	Final easy-read IPOS-Dem

Abbreviations: *BT1 and BT2: backward translations; FT1, FT2 and FT3: forward translations 1, 2 and 3, respectively; IPOS-Dem: Integrated Palliative Care Outcome Scale for People with Dementia*

4.5.1 Phase I: Conceptual Definition

A few nursing homes applied the Edmonton symptom assessment scale, an instrument validated for symptom assessment and screening in palliative care cancer patients, to people with dementia [171]. However, none of the outcome measurement processes or instruments identified in use were intentionally designed with the target population of people with dementia in mind. Instruments built into the resident assessment instrument for nursing homes (RAI-NH) and the resident classification and billing system for care services provided (BESA) are more widely used. Nevertheless, the processes attached to these are sub-optimal for the rigorous surveillance of changing and complex symptoms and concerns required in people with dementia. RAI-NH and BESA are only assessed every six months and only by registered nurses qualified to do so [172]. The specialist discussion concluded that an adapted, easy-to-use, and brief multi-dimensional outcome scale for clinical practice is not available.

Discussions with nursing home staff, specialists, laypeople and family members using the German IPOS-Dem concluded that IPOS-Dem concepts are appropriate and well recognised for Swiss nursing homes and dementia care in general. Nevertheless, it was remarked that the German IPOS-Dem was presented in too elaborate a way for the majority of frontline staff to understand [173].

4.5.2 Phase II: Forward Translation of the IPOS-Dem to ‘Leichte Sprache’

In the following paragraphs, we present the changes made with English translations in parentheses. The forward translations FT1 and FT2 were similar. The significant differences decided on for FT3 were the introductory texts and the first three questions. Long words and words not in everyday use were omitted in favour of shorter and more common synonyms. ‘The person affected’ was changed to ‘person with dementia’ following the Dementia Engagement and Empowerment Project (DEEP) guidance [174]. Sentence structures were adapted according to the easy language rules [175]. The introductory text was expanded to make the questionnaire self-explanatory. It introduced the recall period chosen and led to the general purpose of the questionnaire.

For consistency with the lead-in, a change to the scale was suggested. We translated ‘mäßig’ (‘moderately’) to ‘mittel’ (‘medium’), ‘stark’ (‘substantial’) to ‘Schlimm’ (‘severe’), ‘sehr stark’ (‘very substantial’) to ‘Sehr schlimm’ (‘very severe’) and ‘Nicht beurteilbar’ (‘not assessable’) to ‘Weiss nicht’ (‘don’t know’).

In the symptom list and later questions, ‘z.B.’ (‘e.g.’) was always omitted. For dyspnoea, we added an explanatory sentence in parenthesis. Compound words like ‘Mundtrockenheit’ (‘dry mouth’) were split into their stems, in this case ‘Trockener Mund’. The three translators independently agreed to omit the example ‘z.B. bewusstlos’ (‘e.g., unconscious’) entirely, instead presenting the ‘Weiss nicht’ (‘don’t know’) option for the second set of questions. The question asking for practical problems was revised to enable the use of the same scale used with the preceding questions. It omitted the very uncommonly used term ‘angegangen’ (‘approached’) from all four descriptors.

4.5.3 Phase III: Backward Translation to German

For Phase III, we reported the agreement during the review. In FT3, 37 changes to the original IPOS-Dem were suggested. After reviewing BT1 and BT2 and the original IPOS-Dem, our group achieved good agreement (four out of five members agreed to the change) or better than good agreement for 30 changes. None of the changes were definitively rejected. We discussed items with significant discrepancies and minor changes between BT1 and BT2 and the original IPOS-Dem in the expert group meeting.

4.5.4 Phase IV: Expert Group Review

Our group reached at least a fair agreement (five out of eight agreed) or better for all changes in FT3 regarding concepts, semantics and experiential and content equivalence. Controversial items for which our group reached a fair agreement are provided in the supplementary files . Based on the discussion, a pre-final version was compiled for cognitive interviews.

4.5.5 Phase V: Cognitive Debriefing with Staff and Specialists

Both focus groups interpreted the questions very well. There were no specific questions or recommendations for rewriting in this stage. The comments regarding comprehension are presented in Table 9. Both groups independently agreed again that the German version of the IPOS-Dem was unclear for the Swiss-German context. They proposed the easy language version to be most acceptable for nurses, frontline staff and family members. Completion time was usually less than 10 minutes. The group concluded that caring quality, quality of care and needs could be assessed well using the easy language version.

Table 9: Comments on Modified Pre-Final IPOS-Dem Sections from Cognitive Interviews

Pre-Final IPOS-Dem	Findings
You are caring for a person with dementia, We would like you to tell us: How was the person with dementia doing during the last 7 days? What worried the person with dementia's family or friends? Which problems did you or someone else encounter during nursing and social care? Important: All questions always concern the last 7 days Please write clearly	ProInfirmis recommendations are well written and clear '7days' instead of the words 'last week' is the better alternative.
Date today (day/month/year)	'Date today' is clearer than just 'date'
No appetite (don't want to eat)	Clear; A lot of people with dementia have a poor appetite. The English term is not accurate in the Swiss context.
Problems with teeth	The change in the pre-final version is clearer
Is tired or sleepy during the day	Sleepiness is more apparent than drowsiness; explanatory example is not needed.
Impaired mobility (trouble walking, cannot get up, falls)	Impaired mobility is apparent, especially in the context of kinaesthetics.
Difficulty communicating (speaking or any kind of body language)	Addition in the brackets is straightforward and also necessary.
Can't sleep (during the night)	Addition in the brackets is precise and also necessary.
Agitation	Discussion about the explanation in the brackets. However, it is not necessary for the Swiss context because of STI.
Has she/he been feeling anxious or agitated?	Changes in the German version are apparent due to the usage of the STI.
Do you think she/he felt sad or unhappy?	Sad and unhappy are both necessary
Has she/he been able to talk to others or get in touch in some way (team, family, residents)?	Addition with 'positively' is not necessary
If there was a problem, were you able to do something to resolve it? (help with hearing aids, organise foot care or smooth food)	Practical problems are to be considered in the context of everyday life

Abbreviations: *IPOS-Dem: Integrated Palliative Care Outcome Scale for People with Dementia, STI: Serial Trial Intervention*

4.5.6 Phase VI: Proofreading

The final Swiss-German easy language IPOS-Dem version was endorsed and published by the original developers after proofreading the process report. The Swiss-German IPOS-Dem easy language version can be downloaded and used for free at pos-pal.org. The development team for the German IPOS-Dem and English IPOS-Dem wait for psychometric evaluations with the Swiss-German easy language IPOS-Dem version before considering easy language adaptions for their respective versions.

4.6 Discussion

We demonstrated the content and face validity of a Swiss-German easy language version of the IPOS-Dem. In cognitive interviews with specialists and frontline staff, an easy language version was discussed. Frontline staff found the pre-final IPOS-Dem in easy language to be brief and relevant. However, even after Pos-Pal approved the final version of the easy language IPOS-Dem, a psychometric validation of the scale is still warranted.

We encountered challenges translating the IPOS-Dem similar to those described by Sterie and Bernard [176]. Regarding gender-inclusive and non-discriminating language, we improved the questionnaire by continually referring to ‘Mensch mit Demenz’ (‘person with dementia’) throughout the text. Frontline staff in nursing homes refer to people with dementia in many ways: ‘resident’, ‘guest’, ‘client’. In dialect day-to-day communication, clinicians and laypeople also tend to use ‘the demented [person]’, which is considered ableist [177]. Furthermore, all terms like this, when translated into German, always lead to the necessity of gender-inclusive language, resulting in similarly complex sentence constructions, like ‘Bewohner:innen’ or even ‘Bewohnerinnen und Bewohner’ for ‘Residents’. A uniform and handy reference derived from ‘resident’ also seemed contradictory to the original intersectoral approach with IPOS-Dem. Therefore, in the expert rounds, we agreed to use the wording suggested by DEEP [174].

There were other options, most prominently ‘Betroffene Person’ (‘person affected’). We acknowledged the benefit of inclusion, possibly allowing assessment also for older people without a formal diagnosis. However, the German translation resulted in ‘Betroffene Person’, which should be avoided for two reasons when applying the easy language ruleset [175]. First, short words in everyday use are encouraged (we conferred with ProInfirmis that mentioning dementia is acceptable without an explanation since users will know the term because of the setting). Second, ‘affected’ in German implies a negative impact on the person, whereas easy language promotes positive writing.

Popular opinion towards easy language appears ambiguous and was described by Maaß as ‘having an acceptability issue’ [167]. Easy language was developed for inclusion, mainly for people with learning disabilities. Some critics have argued [167] that the open and distinctive presentation of easy language texts may stigmatise the primary target group and further reduce the acceptance of easy language texts. Providing a patient-centred outcome measure in easy language is an example of exposing easy language application to individuals other than people with learning disabilities. Since scales always have a distinctive look, easy language’s possibly disruptive looks and features are somewhat concealed from users.

‘Easy language’ enabled us to circumvent the syntactic inconsistencies in items beginning with ‘Do you think…’ right from the beginning. Rephrasing the item regarding practical issues was a strong recommendation by our experts and translators. It now uses the same frequency scale as previous items. In easy language, we do not use the involved and spacious scale ‘problems addressed/no problems’. Because practical problems are to be considered in the context of everyday life, we rephrased it to ‘Wenn es Probleme gab, konnten Sie etwas dagegen tun?’ (‘If there was a problem, were you able to do something to resolve it?’). Surprisingly to the research team, the translation and concept of ‘im Frieden mit sich selbst [sein]’ (‘being at peace’) was taken up very well in all phases and never showed discrepancies in the discussion rounds.

4.7 Conclusions and Implications

4.7.1 Clinical Practice

Projected developments in the professional nurse workforce point to local and global shortages in registered nurse human resources [178]. These shortages have repercussions for hospitals but also mandate novel models of care in nursing homes. Frontline staff spend many hours of their shifts directly interacting with people with dementia. While a substantial part of the frontline staff in Swiss nursing homes receives little to no formal training in nursing [8], they provide valuable observations and substantially contribute to caring outcomes. To empower them, routine instruments for their use need to be easily accessible and clinically relevant. Using the information conveyed through IPOS-Dem, an interprofessional team may gain insight to manage further the complex needs of people with dementia living in nursing homes [40].

4.7.2 Research Implications

Easy language may have further applications in patient and public involvement. Its unique qualities enable the development of inclusive and accessible patient-centred outcome measures or self-management pamphlets. The attentive use of easy language communication may also foster increased engagement with untrained laypeople or people with migratory backgrounds in clinical and care research.

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Terminology Clarification
In this 2023 publication, the term "IPOS-Dem Project" was employed. It should be noted that in all other sections of this thesis, the term has been replaced with "overarching trial". This acronym internally designating the research project, was found to lead to confusion with the instrument used.

5 Inter-rating reliability of the Swiss Easy-Read IPOS-Dem

5.1 Abstract

5.1.1 Background

The Integrated Palliative Care Outcome Scale for People with Dementia is a promising instrument for nursing home quality improvement and research in dementia care. It enables frontline staff in nursing homes to understand and rate the needs and concerns of people with dementia. We recently adapted the measure to include easy language for users from various educational backgrounds.

5.1.2 Objectives

In this study, we examine the inter-rating reliability of the Integrated Palliative Care Outcome Scale for People with Dementia for frontline staff in nursing homes.

5.1.3 Methods

In this secondary analysis of an experimental study, 317 frontline staff members in 23 Swiss nursing homes assessed 240 people with dementia from a convenience sample. Reliability for individual items was computed using Fleiss Kappa. Because of the nested nature of the primary data, a generalisability and dependability study was performed for an experimental IPOS-Dem sum score.

5.1.4 Results

The individual Integrated Palliative Care Outcome Scale for People with Dementia items showed kappa values between .38 (95% CI .3–.48) and .15 (95% CI .08–.22). For the experimental IPOS-Dem sum score, a dependability index of .57 was found. The different ratings and time between ratings explain less than 2% of the variance in the sum score. The different nursing homes make up 12% and the people with dementia make up 43% of the sum score variance. The dependability study indicates that an experimental IPOS-Dem sum score could be acceptable for research by averaging two ratings.

5.1.5 Conclusion

Limited research has been conducted on the measurement error and reliability of patient-centred outcome measures for people with dementia who are living in nursing homes. The Swiss Easy-Read IPOS-Dem is a promising instrument but requires further improvement to be reliable for research or decision making. Future studies may look at its measurement properties for different rater populations or at different stages of dementia. Furthermore, there is a need to establish the construct validity and internal consistency of the easy-read IPOS-Dem.

5.2 Background

Dementia is a name given to a group of progressive cognitive diseases [3]. People with dementia may develop impaired functioning, memory, cognition and performance of activities of daily living [3]. According to Sleeman et al. [4], people with moderate to severe dementia face the prospect of health-related suffering. Evidence indicates that people with dementia have inadequate access to the palliative care required for their complex symptoms [179], [180], [4], [181]. The complexity of caring for people with dementia arises from their multidimensional symptoms that influence their health; these symptoms also limit accurate prognostic assertions, palliation and treatment [4], [182]–[184]. In addition, the quality of life and care of people with dementia are also frequently impacted by compromised verbal communication [181], [10], [152], [185]. A structured, systematic symptoms assessment process that fosters communication among people with dementia, their family members and frontline staff may help identify symptoms, enable family members to gain insights into caring for people with dementia and improve therapy regimes [138], [89], [13], [40].

In Switzerland, people with dementia live in nursing homes for an average of two years and often have multiple comorbidities [30], along with the main diagnosis of moderate to advanced dementia. Swiss nursing homes' usual care follows routinely used assessment instruments [33], namely the Resident Assessment Instrument (RAI-NH), 'Bewohner/-innen-Einstufungs-und-Abrechnungssystem' (BESA). Evaluations using these standardised instruments routinely occur only every six months. Frontline staff in Swiss nursing homes may not have the optimal skills to meet all the care needs of people with Dementia nor are there enough qualified staff [186]. Moreover, limited resources are available for frontline staffs support in Swiss nursing homes, resulting in a lack of systematic use of expertise, assessment instruments and evidence in everyday dementia care [8].

The Integrated Palliative Care Outcome Scale for People with Dementia (IPOS-Dem) is a tool used to inform assessments. The IPOS-Dem is multidimensional; using a person-centred approach, it asks about the most important symptoms and concerns of people with dementia. Using this instrument, frontline staff and family members can identify and address symptoms and concerns [40]. Being attentive to symptoms and concerns is considered a core process in dementia care [41]. The IPOS-Dem may also improve screening, communication, care quality and outcomes in routine care [40]. The IPOS-Dem and its family of tools are informed by empirical qualitative and quantitative work among various populations with palliative care needs [147], [42], and all versions can be downloaded at https://pos-pal.org/.

Thus far, no reliability data have been published for the IPOS-Dem [40], [44], [162]. Ellis-Smith et al. reported on feasibility, mechanisms of action and content validity after analysing focus group and semistructured interview data using directed content analysis [40], [44].

The original IPOS for general palliative care populations, from which the IPOS-Dem is derived, showed inter-rater reliability for 11 of 17 items, ranging from $\kappa_w = .4$ to $\kappa_w = .82$. Several items—including 'Having had enough information', 'Having had practical matters addressed', 'Sharing feelings with family or friends', 'Drowsiness', 'Inner peace' and 'Dry or sore mouth'—repeatedly stood out in analyses, with the κ_w ranging between .02 and .29 [42].

The rater population—frontline staff working with people with dementia—is primarily made up of nurses with secondary vocational training degrees or without formal training but with several years of employment and clinical exposure [186], [187]. In Swiss nursing homes, less than one-fifth of the staff working with people with dementia are registered nurses; therefore, we included interns, healthcare assistants and nurses with secondary vocational training.

We developed a Swiss easy-read version of the IPOS-Dem [57] to use in the IPOS-Dem project, which has a stepped-wedge controlled randomised trial (SW-CRT) design [2]. Compared with its predecessor, the easy-read IPOS-Dem is more understandable and adapted to the skill-grade mix and competence of frontline staff in nursing homes [57]. The translation and adaption to IPOS-Dem is described in detail in another study [57]. Here, we present the inter-rating reliability, generalisability and decision study for the easy-read IPOS-Dem, as assessed by frontline staff. Aspects of the validity of the IPOS-Dem will be reported separately to follow Kottner et al.’s [188] Guidelines for Reporting Reliability and Agreement Studies (GRRAS).

5.3 Methods

This is a secondary analysis of a multicentre experimental study with a total of 15 time-shifted assessment periods. For the analysis presented in the present study, data from the baseline measurement period were used. The sample size was determined by power calculations for the overarching SW-CRT, in which the IPOS-Dem was applied. The psychometric analysis of IPOS-Dem was preplanned during the SW-CRT preparation. For this SW-CRT, we aimed to enrol 220 people with dementia living in 22 nursing homes [2] between September 2020 and October 2021. Regarding the raters, we aimed to enrol 20 frontline staff members per nursing home, resulting in a rater population of 440 people. The sample of people with dementia was determined by the nursing homes and based on the agreement of people with dementia to participate (i.e., a convenience sample). The raters were also assigned according to convenience; therefore, no comparison among different levels of training or experience was undertaken. The detailed recruitment process is described in the SW-CRT protocol cited above.

5.3.1 Ethical Approval and Consent to Participate

The study was approved by the Research Ethics Committee of the canton of Zurich, Switzerland (BASEC-ID: 2019-01847) and was conducted in line with the principles of the Helsinki Declaration [143]. The overarching trial was registered with DRKS00022339. All participants and/or their respective attorneys signed written informed consent for participation and (as outlined in the PLOS consent form) publication. All raters have signed written informed consent for participation and (as outlined in the PLOS consent form) publication.

5.3.2 Population

5.3.2.1 People with Dementia

People with dementia were included if they (a) were not hospitalised at baseline and, therefore, were physically present in the nursing home at the commencement of the study, (b1) had a diagnosis of vascular dementia or Alzheimer's disease or (b2) had minimum data sets (MDS) data indicating symptoms of dementia.

5.3.2.2 Frontline Staff

Frontline staff members were invited to participate if they (a) were at least 18 years old, (b) had a tenure of at least 3 months in the nursing home, (c) worked at least 20% of the full-time equivalent, provided continuing care to people with dementia (d) and were able to communicate in German.

5.3.3 Data Collection

Each participating nursing home was assigned a clinical champion, that is, a full-time on-site employee who oversaw recruiting, data collection and the general study coordination with the study team, as outlined in the overarching SW-CRT protocol [2]. At baseline, the clinical champions entered the demographic and clinical details of the people with dementia, as derived from their nursing homes' MDS [189], [190] , into our research electronic data capture (REDCap) data management system [153]. A survey developed for the frontline staff was completed by them directly following a training session. The participating staff had 120 minutes of on-site introductory training, and they attempted to complete an assessment for a chosen case using the IPOS-Dem.

Frontline staff were explicitly informed during the training—through an informed consent discussion and written material—that inter-rating agreement was being assessed at baseline. For the reliability study, staff independently assessed people with dementia during the baseline period of 30 days. There were no data captured on which of the staff members submitted the IPOS-Dem to the clinical champion. The clinical champion, however, assured that two independent staff members assessed IPOS-Dem independently during baseline. Staff independently rated and completed the instruments for people with dementia between August 2020 and January 2022. Staff were never blinded to clinical information about the people with dementia and completed the paper version of the IPOS-Dem. The data were subsequently entered into REDCap [153], browser-based software that could give continuous feedback to the clinical champion entering the data (e.g., erroneous or missing data). Automated tests run by REDCap also checked the data for plausibility and completeness.

5.3.3.1 Study Measures

The Swiss easy-read version of the IPOS-Dem consists of 27 items related to physical, psychological, spiritual and practical concerns [57]. While mostly taking a self-proxy perspective [191], it asks three types of questions. After an introduction, there are three open questions about main issues during the last week the person with dementia had from the person with dementia's, the frontline staff's and the family member perspective. Following the textboxes, the user is asked to rate a 19-item list of symptoms and concerns regarding how much the symptoms and concerns impacted the person with dementia during the last week, in their opinion. These items are scored on a 5-point scale ranging from 0 (not at all) to 4 (very severe), with each point having its own descriptor. The symptom list continues with eight more questions, switching to a proxy–proxy perspective by asking how frequently a situation occurred. These items are scored on a 5-point scale ranging from 0 (not at all) to 4 (always), with each point again having its own descriptor. IPOS-Dem closes with three scoreable 'wild card' symptom fields. The IPOS-Dem was completed independently by frontline staff at the baseline of a cluster-randomised trial. The clinical champions oversaw frontline staff members' independent completion of two assessments per person with dementia at baseline. In previous studies [40], it took frontline staff on average between 4 and 12 minutes to complete IPOS-Dem, depending on their experience with the instrument.

People with dementia's sociodemographic information was captured by the clinical champion at baseline, as derived from the nursing home minimum datasets and charts at the time point. The minimum datasets in Swiss nursing homes we referred to are a translation of the RAI-NH [189] or BESA [190]. The extracted chart and minimum dataset data were gender, marital status, nursing home, dementia type (if diagnosed) and dementia severity (if diagnosed).

5.3.4 Analysis

For each rating, an experimental IPOS-Dem sum score was calculated by adding the individual item responses of the 27 standard items. The scores are added with list-wise deletions of missing and 'do not know' responses. To inform the analyses of inter-rating reliability, we calculated information on the duration between the two IPOS-Dem assessments at baseline and developed an experimental sum score. The sum score was computed per assessment, with the list-wise exclusion of missing or 'do not know' ratings. The answer option 'do not know' was handled as missing. If not stated otherwise, missing data were excluded pairwise from the item-wise analyses. Sociodemographic and clinical data were analysed for the frontline staff, as well as the people with dementia using frequencies, proportions, ranges and distributions, both per nursing home and in total, with the tidyverse package 1.3.2 for R 4.1.2 [192], [193]. The IPOS-Dem item scores were described in a similar manner.

5.3.4.1 Item-Wise Analysis of Inter-Rating Reliability

Fleiss' kappa is an extension of Cohen's kappa and can be used for more than two raters [194]; it considers the proportion of agreement beyond chance that would be expected if all ratings had been randomly scored. Fleiss' kappa ranges from 0 to 1, with values closer to 1 indicating higher inter-rater reliability. The coefficient (κ) is computed by the proportions of expected (P_e) and observed (P) agreements between ratings: $\kappa = \frac{\mathrm{P}-P_e}{1-P_e}$. To complement the reporting, the percentage of agreement per item was also calculated and is presented in tables.

5.3.4.2 Generalisability Study

Generalisability theory allows for the estimation of reliability for various combinations of raters in complex study designs [195]. Our design was based on 460 observations, with four additional factors: 230 people with dementia; 24 different durations between two assessments; 23 clusters and two ratings. This was a nested design, where some factors were nested within levels from other factors. Therefore, the ratings were nested within durations between the two assessments and nursing homes. Furthermore, people with dementia are nested within ratings and nursing homes. The reliability of the experimental IPOS-Dem sum scores is expressed by generalisability coefficients. Like an intraclass correlation coefficient, the generalisability coefficients indicate the reliability of a scale. By estimating variance components, the generalisability coefficients can be calculated. The variance components are estimated using a restricted maximum likelihood approach.

The variance components were estimated with the experimental IPOS-Dem sum score as the outcome variable and each of the factors (person with dementia, rating, cluster and time between assessments) as a random effect. Reliability was then quantified, with the universe score being the expected IPOS-Dem sum score of a person with dementia over the facets of generalisation for rating but fixed for clusters and time between measurements. The index of dependability (Φ) of a single measurement is the ratio of a person with dementias' score variance to the observed score variance.: $\Phi = \frac{\sigma_P^2+\sigma_C^2\llbracket+\sigma\rrbracket_T^2}{\sigma_P^2+\sigma_C^2\llbracket+\sigma\rrbracket_T^2+\sigma_\varepsilon^2}$. In this model, the index is computed with a formula for consistency rather than agreement. A consistency model was chosen because IPOS-Dem is considered complex and multidimensional; this was also done to adjust for chance agreement. Model fitting and variance component estimation were performed with the lmer package [196] in R [192] 4.1.2.

5.3.4.3 Additional Analysis and Criteria for Interpretation

The dependability index Φ represents inter-rating reliability for one assessment sum score for a randomly chosen time and cluster. To compute the reliability of the mean measure of k measurements, we undertook a decision study. This means that the error variance components are divided by k to quantify the reliability of an average sum score over k repetitions. This decision study can help determine how many repetitions (i.e., ratings) would be required to reach an acceptable dependability Φ. For our analysis, this was performed for k = 1, 2, 3, to six repetitions.

For the interpretation of the results, different interpretation criteria were used. The item floor and ceiling effects were interpreted according to the criteria proposed by McHorney and Tarlov [197]. Their defined threshold for such an effect to occur was 15%, that is, the proportion of the sample rated with the lowest (floor) or highest (ceiling) possible score possible. The κ was interpreted according to Fleiss' classification. Fleiss' classification for the interpretation sets only two cut-off values; kappa values below .40 are deemed 'poor', kappa values between .40 and .75 should be considered 'fair to good', and all kappa values above .75 'are deemed excellent' [198]. The G- and D-Study index values can range from 0 to 1 and are interpreted according to Nunnally's proposed criteria [199]. Nunally [199] described coefficients at .7 as 'modest' and sufficient for early stages of research for instrument development.

5.4 Results

5.4.1 Observations

We analysed data from 257 people who were recruited from 23 nursing homes. On average, frontline staff completed the two IPOS-Dem measures for the inter-rating reliability analysis at baseline of the SW-CRT within 6.1 days (standard deviation [SD] = 7.4). The majority completed both observations within the first week, while some took up to 30 days to complete the repeated assessments. The heterogeneity in the time between the two assessments per nursing home is illustrated in Appendix 8.VIII.

5.4.2 Sample Characteristics

Table 10 shows the sociodemographic and clinical details of the people with dementia. Because the data were derived from a multicentre trial, we refer the reader to Appendix 8.VIII for an illustration of the heterogeneity between the nursing homes.

Table 10: Sociodemographic and Clinical Details of People with Dementia.

Variable	**N (%)**	**Mean (SD)**	**Min–Max (Median)**
People with Dementia	257 (100%)		
Gender			
Female	180 (70%)		
Male	77 (30%)		
Age		86 (7.29)	56–102 (86)
Marital Status			
Single	21 (8%)		
Married	70 (27%)		
Divorced	30 (12%)		
Widowed	136 (53%)		
Area of Residence			
Intermediate	176 (68%)		
Rural	43 (17%)		
Urban	38 (15%)		
Dementia			
Alzheimer’s	83 (32%)		
Vascular	22 (9%)		
Other	106 (41%)		
Not formally diagnosed	46 (18%)		
Severity			
Mild	6 (2%)		
Moderate	81 (32%)		
Advanced	86 (34%)		
Not applicable	84 (32%)		

As expected, 79% of the frontline staff were involved in various nursing roles, as shown in Table 11. Interns, therapists, chaplains and others made up 15% of the raters. The mean tenure was 6.5 years. (Please see Appendix 8.VIII, which illustrates the heterogeneity between the nursing homes.)

Table 11: Sociodemographic Details of Frontline Staff (i.e., Raters).

Variable	**N (%)**	**Mean (SD)**	**Min–Max (Median)**
Staff	311 (100%)		
Age	304 (98%)	43 (13.6)	18–70 (45)
Gender			
Female	277 (89%)		
Male	34 (11%)		
Tenure (years)		6.6 (6.6)	0–32 (5)
Occupation			
Registered nurse	108 (35%)		
Nursing associate professionals	58 (19%)		
Health care assistants	96 (31%)		
Registered nurse (intern)	9 (3%)		
Nursing associate professionals (intern)	19 (6%)		
Intern	1 (< 1%)		
Other[a]	17 (5%)		
Missing	3 (< 1%)		
Education			
Tertiary	121 (39%)		
Upper secondary	137 (44%)		
Lower secondary	23 (7%)		
Other	28 (9%)		
Missing	2 (< 1%)		

[a] *'Other' included: housekeeping staff, chaplains, volunteers and social workers*

5.4.3 Item Characteristics

The item characteristics for the baseline data are presented in Table 12. At baseline, we were able to match between 139 and 239 ratings per item per person with dementia. The items 'Nausea', 'Shortness of breath' and 'Vomiting' showed substantial floor effects, with more than 80% of the answers concentrating on a rating of 0. For the items 'Family anxious or worried', 'Inner peace' and 'Lost interest', frontline staff chose 'Don't know' in more than 29% of the assessments. Additional item characteristics are provided in Supplementary Material B.

5.4.4 Inter-Rating Reliability

In terms of Fleiss' kappa, the values varied between .39 and .15, as shown in Table 13. The proportions of exact agreement varied between 39% and 89.5%.

Table 12: Easy-Read IPOS-Dem Item Characteristics.

Item	**Mean Score**	**Score (SD)**	**None (%)**	**Some (%)**	**Moderate (%)**	**Severe (%)**	**Very Severe (%)**	**Don't Know (%)**	**N Matched Cases**
Pain[a]	1.3	1.1	26.7	35.1	25.1	10	3.1	10.6	220
Shortness of breath[a]	0.2	0.6	83.5	10.8	4.5	0.8	0.4	5.7	232
Weakness[a]	1.5	1.1	20.9	33.3	29.8	11.2	4.9	4.9	234
Nause[a]	0.2	0.6	83.9	10.7	3.8	1	0.6	11.4	218
Vomiting[a]	0.1	0.4	93.8	3.9	1.2	0.8	0.2	7.3	228
Poor appetite[a]	0.8	1	53.7	24.7	14.7	4.5	2.4	6.5	230
Constipation[a]	0.7	0.9	56.9	25.6	13.5	3	1.1	14.6	210
Sore or dry mouth[a]	0.4	0.9	75.9	12.4	8.3	1.5	2	18.7	200
Drowsiness[a]	1.5	1.1	21	31.4	28.8	12	6.7	6.5	230
Poor mobility[a]	1.2	1.4	43.6	22.2	12.5	11.3	10.3	4.5	235
Sleeping problems[a]	0.8	1	51.9	26.2	12.8	7.5	1.7	11.4	218
Diarrhoe[a]	0.3	0.7	78.4	14.3	5	1.5	0.8	11.8	217
Dental problems[a]	0.6	1	70.2	14.5	8.7	3.2	3.4	14.2	211
Swallowing problems[a]	0.5	1	74.5	13.1	6.3	2.9	3.3	6.5	230
Skin breakdown[a]	1	1.1	44.8	27.1	16.6	8.9	2.6	4.1	236
Difficulty communicating[a]	1.6	1.4	31.7	19	22.2	14.1	13.1	4.1	236
Hallucinations and/or delusions[a]	0.8	1.1	61	16.5	11.2	7.9	3.3	19.9	197
Agitation[a]	1.7	1.3	22.6	21.8	27.7	16	11.8	2.8	239
Wandering[a]	1.3	1.4	45.3	15.1	17.1	12.2	10.2	6.5	230
Anxious or worried[a]	1.8	1.1	15.9	20.3	37.8	21.5	4.4	3.7	237
Family anxious or worried[a]	1.6	1.3	28.8	22.6	24.8	11.8	12	43.5	139
Felt depressed[a]	1.5	1	18	29	36.4	14.8	1.9	13	214
Lost interest[a]	1.1	1.2	42.7	22.3	19.5	12.3	3.2	31.3	169
Inner peace[a]	1.5	0.9	9.7	48.2	25.8	13.4	3	29.3	174
Able to interact[a]	1.5	1.3	29.5	24.9	19.9	18.9	6.8	3.3	238
Irritable or aggressive[a]	1.3	1	27.6	26	33.2	12.1	1.2	3.7	237
Practical matters[a]	1.4	1.1	24.5	34.3	24.9	10.6	5.7	14.6	210

Item characteristics for baseline data (more in Supplementary Material B). Items are ordered as they occur in the easy-read IPOS-Dem.

[a] *Items with floor effect (more than 15% of answers in lowest category).*

Table 13: Item-Wise Reliability Coefficients and Proportions of Agreement.

Item	**Kappa**	**CI Lower Bound**	**CI Upper Bound**	**Don't Know**	**Agreement**	**Adjacent**	**Two Scores Apart**	**Three Scores Apart**	**Four Scores Apart**
Pain[a]	0.33	0.25	0.41	10.6	50.7	38.5	9.5	1.4	0
Shortness of breath[a]	0.35	0.25	0.45	5.7	80.6	15.1	3.4	0.4	0.4
Weakness[a]	0.15	0.08	0.22	4.9	37.2	50.9	9.8	1.7	0.4
Nausea[a]	0.39	0.28	0.49	11.4	80.9	14.5	3.2	0.9	0.5
Vomiting[a]	0.21	0.11	0.31	7.3	89.5	6.1	2.2	1.8	0.4
Poor appetite[a]	0.25	0.17	0.33	6.5	52.8	33.3	10.4	2.6	0.9
Constipation[a]	0.28	0.19	0.37	14.6	56.2	29.5	10.5	3.8	0
Sore or dry mouth[a]	0.3	0.21	0.4	18.7	72.8	14.9	8.9	2	1.5
Drowsiness[a]	0.22	0.15	0.29	6.5	40.7	45.9	10.8	2.2	0.4
Poor mobility[a]	0.29	0.22	0.37	4.5	49.4	32.3	13.2	4.3	0.9
Sleeping Problems[a]	0.28	0.2	0.37	11.4	54.3	35.6	9.1	0.5	0.5
Diarrhoea[a]	0.34	0.24	0.44	11.8	74.3	20.2	2.8	2.3	0.5
Dental Problems[a]	0.39	0.3	0.48	14.2	71.8	19.7	5.6	2.3	0.5
Swallowing problems[a]	0.31	0.23	0.4	6.5	71.3	18.3	7	0.9	2.6
Skin breakdown[a]	0.28	0.2	0.35	4.1	50	32.2	12.7	4.2	0.8
Difficulty communicating[a]	0.31	0.24	0.37	4.1	46.2	30.1	17.8	5.1	0.8
Hallucinations and/or delusions[a]	0.34	0.25	0.42	19.9	61.6	18.7	13.8	3.9	2
Agitation[a]	0.26	0.19	0.32	2.8	41.8	37.2	17.6	2.9	0.4
Wandering[a]	0.33	0.26	0.41	6.5	52.4	24.2	16.5	5.6	1.3
Anxious or worried[a]	0.21	0.14	0.28	3.7	40.9	46	11.4	1.3	0.4
Family anxious or worried[a]	0.24	0.16	0.33	43.5	41.3	29.7	20	5.8	3.2
Felt Depressed[a]	0.24	0.16	0.31	13	44	42.1	11.1	2.3	0.5
Lost interest[a]	0.2	0.11	0.29	31.3	44.1	30.5	16.9	7.9	0.6
Inner peace[a]	0.17	0.08	0.26	29.3	45.1	46.7	7.1	0.5	0.5
Able to interact[a]	0.27	0.2	0.34	3.3	44.1	37	13.9	4.6	0.4
Irritable or aggressive[a]	0.26	0.18	0.34	3.7	46	42.6	10.1	1.3	0
Practical matters[a]	0.18	0.1	0.25	14.6	39	41.3	14.1	4.7	0.9

Fleiss' kappa (κ) from two matched independent frontline staff assessments, including 95% confidence intervals (CIs) and proportions of agreement per IPOS-Dem. Items are ordered as they occur in the easy-read IPOS-Dem.

[a] *Items with floor effect (more than 15% of answers in lowest category).*

5.4.5 Generalisability and Decision Study for an Experimental Sum Score

We computed matched IPOS-Dem sum scores for 230 people with dementia; further statistics are shown in Table 14 below. The maximum possible sum score was 108, which was not reached in our sample.

Table 14: Characteristics of the IPOS-Dem Sum Scores for Both Ratings.

Statistics	**1st Assessment Sum Score**	**2nd Assessment Sum Score**
Number of matched cases	230	230
Mean (SD)	25.3 (13.0)	28 (13.7)
Median (IQR)	25 (17.75)	27 (17.75)
Range (min – max)	0–73	0–78

We fitted a linear mixed model to the sum score with person, rating, cluster and occasion as random intercepts. The resulting variance components are given in Table 15.

Table 15: Variance Components with Respective Proportions

Component	**Absolute Variance Component**	**% Variance Component**
Person σ_P^2	79.28	42.71
Time between ratings σ_T^2	3.25	1.75
Rating σ_R^2	3.36	1.81
Cluster σ_C^2	22.99	12.39
Residuals σ^2	76.73	41.34

With this approach we computed $\Phi = 0.58$ for a single rating on a random day in a random cluster. In addition, we computed Φ for a mean of k ratings (k = 1, 2, 3, …, 6) to compute an acceptable lower bound of reliability for the sum score. The dependability coefficents for k ratings are shown in Table 16.

Table 16: Dependability Coefficients for Multiple Ratings

Number of Ratings (k)	**Coefficients**
1	0.579
2	0.733
3	0.805
4	0.846
5	0.873
6	0.892

Our dependability study indicates that an acceptable sum score above the .7 could be obtained by averaging the sum scores from two ratings.

5.5 Discussion

The present study aimed to assess the reliability of the newly developed, easy-read IPOS-Dem when used by frontline staff in nursing homes. We computed the generalisability coefficient from two ratings of an experimental sum score and the individual Fleiss' kappa for each item. The κ of the items was between .38 (95% CI .3–.48) and .15 (95% CI .08–.22), indicating 'poor' agreement ($\kappa < .4$) when interpreted with Fleiss [198] criteria.
An experimental IPOS-Dem sum score was used to enable the computation of a reliability coefficient under the generalisability framework. The findings of these analyses show a G-coefficient of .58. Our decision study shows that, by averaging two ratings, acceptable reliability for research could be obtained. The generalisability study also showed that the differences between participating nursing homes could explain 12% of the variance in the sum IPOS-Dem scores. Only small fractions of the variance were explained by ratings or time between assessments alone. The high proportion of IPOS-Dem sum score variance (41%) explained by residual variance may indicate interactions and measurement errors that must be investigated in future studies. Furthermore, without further investigation into the validity of the IPOS-Dem, the construction of a sum score remains experimental.

5.5.1 Limitations and Strengths

We were able to obtain data from a considerable sample of people with dementia and involve frontline staff with different backgrounds, experiences and education in the primary study. This is the first study to evaluate the psychometric properties of the IPOS-Dem in a larger sample. The present study has several limitations that we want to highlight. First, we were not able to ensure blinding of the raters regarding prior findings, clinical information and the accepted reference standard measurements like the RAI MDS. Second, there is no consensus in the literature on the stability of the IPOS-Dem ratings, as well as the symptoms and concerns of people with dementia in general. Because routine measurement is undertaken every six months, the relatively research-inexperienced setting and the design of the overarching SW-CRT, we considered one month suitable. We could have determined the sample size based on acceptable CIs (i.e. ± 0.1/ ±0.2) for ICCs reported in previous IPOS studies presented above [135], [200]. With 256 people with dementia, however, we exceeded the typical recommended number of participants in reliability studies often based on rule of thumb (n = 50) [135]; the 95% CIs around the Fleiss kappa are provided in Table 13.
The assignment of assessors to people with dementia was delegated to clinical champions, and the assessors' skills and grades were not linked to their respective ratings. The sample of people with dementia was rather heterogeneous, with a fifth lacking a formal diagnosis and different stages of reported severity. The lack of a severity assignment in a third of the sample deterred us from analysing the subsamples of the population and may also have contributed to the observed reliability. To control for the lack of assessment, the use of dementia staging instruments like FAST [201] at the baseline of research projects is highly recommended instead of relying on routine data. These shortcomings of the reported design may contribute to a major part of the unexplained variability in the sum scores.

5.5.2 Comparison with Other Instruments for People with Dementia

QUALIDEM [202] was developed for observation-based quality of life assessment in people with dementia living in nursing homes. Ettema et al. [202] developed a scale for rating by nursing assistants, placing their scale within a similar scope as the IPOS-Dem. In their study, 68 raters assessed 238 people with very severe dementia. Ettema et al. subsequently calculated an overall reliability coefficient between .55 and .79. With later improvements in the German translation of QUALIDEM, reliability coefficients for individual items were improved. This was achieved by increasing the number of response options from four to seven and by the development of a detailed guide booklet [203], [204]. Dichter et al.'s

German QUALIDEM study involved 36 people with advanced dementia who were rated by four caregivers with the revised QUALIDEM. In Dichter's QUALIDEM paper, only 6 out of 18 items showed floor or ceiling effects, although the authors opted to define floor effects by mean scores, with kappa values between .31 and .62. The items with the lowest reliability coefficients in the study were from the affect and social subscales. Similarly, some of the items that had low reliability in our study (i.e., 'Felt depressed' or 'Anxious or Worried').

Dichter et al. concluded that the QUALIDEM subscales generally showed sufficient reliability (between .64 and .91). However, in their related work, Dichter et al. [205] highlighted the lack of reliability investigations for instrument translations specific to the dementia population. The current Swiss guideline for dementia care in nursing homes [9] does not include any recommendations for instruments that can be used with all frontline staff members (e.g., Health care assistants, nursing associate professionals and interns).

Other popular instruments used for research on people with dementia are the Quality of Dying Instruments End-of-Life in Dementia Comfort Assessment in Dying (EOLD-CAD) and the Quality of Dying in Long-Term Care (QOD-LTC) [206]–[208]. However, the EOLD-CAD's reliability coefficient was moderate (0.59) and fair for the QOD-LTC (0.28) [206].

A review of instruments tested in long-term care settings by Ellis-Smith et al. [13] showed that different symptom-specific measures had reliability coefficients ranging between .76 and .73 for pain, .47 and .66 for measures of oral health and .20 for the single identified depression scale. In accordance with Dichter et al. and Kupeli et al. [205], [209], Ellis-Smith et al. highlighted that the evaluation of psychometric properties for many instruments is lacking. The findings regarding measurement properties identified above is in line with Soest-Poortvliet et al. [210], who looked at instruments evaluating end-of-life care and dying in long-term care residents. Their review of different instruments showed reliability coefficients between .25 and .59. These and our findings imply the difficulty [211] and complexity [205], [212] of evaluating patient outcomes in people with dementia.

5.5.3 Implications

5.5.3.1 Clinical Practice

With the evidence reported in the present, the Swiss Easy-Read IPOS-Dem cannot be recommended for routine use in clinical practice or decision making. Further research into its psychometric properties needs to be conducted. To improve the reliability of the IPOS-Dem, additional actions targeting rating and observation procedures could be proposed. For example, a handbook could complement raters' training; this has already proven to be successful in developing other measures for this population [213], [214]. However, the underlying philosophy of user-friendly symptoms and concerns assessment permeates the IPOS family of measures [42]. An advantage of using the easy-language IPOS-Dem is its accessibility to frontline staff and family members in clinical practice without extensive training or a reading exercise in a handbook. This strength of the IPOS-Dem was theorised as mitigating setting-specific barriers to the effective implementation of palliative and person-centred care, such as high staff turnover, low incentives for professional staff development and the supersaturation of methods and instruments for geriatric care.

5.5.3.2 Research

With the evidence reported here, the Swiss Easy-Read IPOS-Dem experimental sum score might be used in research when averaged over two ratings. Because of these limitations, we caution against generalising our findings to other populations, settings and configurations of rater populations. Furthermore, the structural validity and validity of the sum score must be investigated first. Future studies investigating the reliability of the easy-read IPOS-Dem may avoid specific sources of variation in the ratings. There are a few options by means of restrictions in the design of such psychometric studies. A classical fully crossed design to determine test–retest and interrater reliability could be realised. First, researchers could restrict the rater population regarding qualifications and clinical exposure in a future study. Second, rigid assessment scheduling could be imposed on the day, the time between assessments and other factors. To date, there has been no guidance on the frequency at which routine assessments of symptoms and concerns in people with dementia should be conducted; therefore, we had no guiding frequency for imposing limitations on the scheduling of assessments or rater–subject assignments. Further improvements and changes regarding implementation and development will be derived from the experience of our colleagues at the United Kingdom Outcomes Assessment and Complexity Collaborative [215] and findings from the Australian Palliative Aged Care Outcomes Collaborative [138].

5.6 Conclusion

Comprehensive studies on the reliability of multidimensional instruments for people with dementia living in nursing homes have been infrequent. Especially in translated measures, reviews have not reported many publications on this measurement property. Generally, the reliability coefficients of most instruments to rate individual symptoms, quality of care or health-related quality of life in people with dementia hover below acceptable thresholds for clinical decision making and research. Some of the easy-read IPOS-Dem items have shown comparably poor coefficients. The experimental IPOS-Dem sum score may be reliable if averaged over two ratings. However, its validity needs to be investigated first. The present study has provided comprehensive information on the statistical parameters of measurement properties in the Swiss easy-read IPOS-Dem for its intended rater population. Our research shows that further development is needed to improve the easy-read IPOS-Dem to the point that the results can be considered reliable for research on caring quality and clinical decision making.

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Terminology Clarification
In this 2021 publication, the term "case studies" was employed. It should be noted that in all other sections of this thesis, the term has been replaced with "person profiles". This modification in terminology was made to align with a more person-centric approach. It is believed that "person profiles" more appropriately and respectfully characterizes the individuals discussed.

6 Improving caring quality for people with dementia in nursing homes using IPOS-Dem: A stepped-wedge cluster randomized controlled trial protocol

6.1 Abstract

6.1.1 Aims

We aim to evaluate the effectiveness of the Integrated Palliative care Outcome Scale for people with dementia-based case studies to improve the caring quality for people with dementia in nursing homes by frontline staff and family members.

6.1.2 Background

Swiss nursing homes mostly care for people with dementia. This population is at high risk of receiving little to no palliation for their complex needs. The majority of Swiss frontline healthcare staff do not systematically report on the needs of their residents. Additionally, family members do not routinely participate in assessment processes.

6.1.3 Design

We will conduct a stepped wedge cluster randomised trial of repeated assessment using the Integrated Palliative care Outcome Scale for people with dementia (IPOS-Dem) and subsequent case studies. Clusters will consist of Swiss nursing homes randomly assigned to one of three sequential intervention time points.

6.1.4 Methods

The study population will consist of people with dementia living in nursing homes with and without specialised dementia care facilities. Over 16 months, staff working at the frontline and family members

will assess the needs and concerns of people with dementia using IPOS-Dem. Depending on sequence allocation, facilitated case studies will start after three, six or nine months. The primary outcome will be caring quality measured by QUALIDEM. The secondary outcome will be symptoms and concerns, as indicated by the IPOS-Dem sum-score. The Zurich Ethics Committee approved the study in 2019 (BASEC2019-01847).

6.1.5 Impact

The results of this study will contribute to improving the effectiveness of person-centred care for people with dementia. Collaboration between healthcare staff and family members will be systematically developed and built upon thorough assessment using the IPOS-Dem and related case studies. The use of IPOS-Dem will offer all frontline staff a systematic approach to have an independent voice within the nursing process, regardless of their qualification or grade.

6.2 Introduction

Dementia is an umbrella term for several neurological conditions that progress to impaired functioning and cognition and the inability to perform daily life activities [3]. According to Sleeman et al. [4], people with moderate to severe stages of dementia (PWD) face the prospect of health-related suffering. There is evidence that PWD have inadequate access to palliative care for their complex needs [180], [4]. The complexity of caring for PWD arises from their multi-dimensional needs, which in turn influence the individuals' health and limit accurate prognostic assertions, palliation and treatment [183], [3]. The quality of life and caring of PWD and their families are compounded by untreated and undertreated symptoms, unmet needs and undisclosed wishes and choices [10], [152], [185].

In 2009 Ecoplan [30] estimated that about 130′000 PWD were living in Switzerland. More than 65% of PWD were aged 80 or older. The number of PWD in Switzerland is projected to increase to 280′000 by 2050 [30]. Similarly, Livingston [3] reported 50 million PWD worldwide, with a three-fold increase projected by 2050. As their disease progresses, most PWD eventually move into nursing homes [3]. In Switzerland, as in most European countries, 65% of nursing home residents have dementia [27], [216]. Registered Nurses (RN) in Swiss nursing homes usually provide nursing care collaborating with nursing associate professionals, health care assistants and other personnel [8]. In the German-speaking part of Switzerland, RN make up 30% of the grade mix in nursing homes, 41% of their colleagues are nursing associate professionals, and 30% are trainees, interns and assistant staff [8]. Nursing homes in Switzerland have a broad organisational staff skill mix. An RN in Switzerland usually monitors the nursing process and medical management and delegates some direct care activities. Sometimes, RN in Swiss nursing homes are involved with quality and innovation [8]. Frontline staff in nursing homes establish caring relationships based on systematic observation of needs [49]. For this study, and like that articulated by Watson [217], caring is defined as a moral imperative and ethical foundation of nursing. When engaging in caring, frontline staff in nursing homes are not merely performing instrumental tasks but performing conscious and intentional forms of "being" [218], [217].

6.3 Background

Frontline staff in nursing homes have a challenging role; when caring for PWD, they frequently evaluate needs, medical symptoms and possibly undisclosed choices and wishes. They must monitor PWD for their needs and concerns, despite PWD having impaired cognitive abilities that influence their ability to report medical symptoms and corresponding needs [37]. Caring in nursing homes is a collaborative task. Still, miscommunication between a staff member and a PWD or other frontline staff or family members may impede the complete detection and subsequent management of issues [40], [36]. In Swiss nursing homes, processes for routine assessments are in place, e.g. Resident Assessment Instrument, "Bewohner/-in- nen-Einstufungs- und -Abrechnungssystem" and "Planification Informatisée des Soins Infirmiers Requis" (RAI, BESA and PLAISIR). However, the processes and policies attached to these routine assessments appear to prevent timely and relevant monitoring of PWD [126], [32]. Two-thirds of the frontline staff in nursing homes are not formally permitted to document their observations in routine assessments, leading to a deficit in their capacity to elicit critical concerns for PWD [34], [33].

The instruments and processes in use also neglect family members' perspectives and their consequential disclosure of current and prior decisions of PWD [33]. Processes and proposed interventions to foster family involvement in nursing homes are heterogeneous [89], although the unique perspectives of family members to augment the framing of quality of life, developments, and caring quality of PWD are well-documented [40], [219]. A structured, systematic symptom and needs assessment that fosters communication between family caregivers and frontline staff may help recognise unmet needs and enable family caregivers to gain insight into PWD [89], [13], [40]. The use of the Integrated Palliative care Outcome Scale for Dementia (IPOS-Dem) helps carers to recognise symptoms and concerns of PWD [161]. The brief and easy-to-use IPOS-Dem is built on a comprehensive family of proxy and patient-reported outcome measures for palliative care [161]. The IPOS-Dem informs an overview of the quality of life and caring quality for PWD with its holistic and multi-dimensional perspective [40]. Quality of life for PWD is considered by disease severity and individual and environmental factors [202]. Furthermore, Banerjee et al. [220] conceptualised quality of life for PWD as multi-dimensional well-being in various domains. Therefore, the quality of life for PWD seems to be sensitive to psychological and behavioural symptoms, cognitive and functional decline and the caring quality a PWD experiences [49], [220] . Ellis-Smith [40] reported that the use of the IPOS-Dem improved aspects of caring quality for PWD. Quality of care, caring quality and quality of life seem closely interrelated, especially for PWD [49]. Caring quality for PWD can be captured in the QUALIDEM.

Establishing a shared value set and management strategies based on the needs, concerns, and collaborative observations of PWD is crucial to improving caring quality for PWD. Implementation of regular, systematic assessment of PWD in nursing homes is a prerequisite [221], [38].

6.4 The Study

6.4.1 Aims

We aim to evaluate the effectiveness of case studies based on a structured needs assessment using the IPOS-Dem to improve caring quality and quality of life for PWD in Swiss-German nursing homes by frontline staff and family members.

6.4.2 Design

We propose a stepped-wedge cluster randomised trial (SW-CRT) design [222], [223] to examine the objectives. An SW-CRT starts without exposing the clusters, nursing homes in our case, to the intervention to allow for baseline data collection. During study conduct, the clusters or cluster groups are exposed to the intervention in a step-wise fashion, occurring after regular intervals until all clusters are exposed to the intervention. We will employ mixed-effects models, i.e., random effects, to adjust for cluster-specific factors and repeated measures design. This trial will evaluate whether structured symptom assessment and subsequent case studies augment caring quality for PWD. The intervention will be assessed by (a) caring quality with the QUALIDEM and (b) changes in identified needs, as assessed by the IPOS-Dem.

The SW-CRT has three advantages for our study. First, the design allows long-term effects, i.e. trends, to be assessed during the study [224]. One expected trend is that the caring quality, as measured by the QUALIDEM, will improve over time. The implementation of purposive data collection using the IPOS-Dem, representing the control condition, could also be interpreted as a trend by itself, with a learning curve for frontline staff. The stepped-wedge design will enable an objective assessment of both trends during the trial. Secondly, we aim to offer nursing home management boards added value for their residents through using an SW-CRT because exposure to the case study intervention for six months is guaranteed. Thirdly, our case study intervention is dependent on the observations of frontline staff and family members using IPOS-Dem, which promotes inclusivity and participation. Introducing the intervention en bloc was considered challenging regarding logistics regarding the prerequisite above and the complexity of the case study intervention. Therefore, we will employ measurements at fixed periods across the trial duration in participating nursing homes and consider the time effects in the models for analysis [108]. In other words, the presumed effect of the implementation of the IPOS-Dem and QUALIDEM will be levelled out by the time the intervention commences.

Data collection will occur over 15 months, with frontline staff and family caregivers collecting data each month from the same participants (i.e., a closed cohort). We will randomly allocate participating nursing homes to three groups. The three groups will cross over at different time points from the control condition to the intervention condition; they will cross over with steps three, six and nine months after the trial start. In an SW-CRT design, the nursing homes can enrol in the study at different absolute time points as long as the planned sequence of measurement, conditions, and steps are followed through as planned. An SW-CRT, therefore, greatly improves the feasibility for the study team.

6.4.3 Study Settings

Nursing homes in the German-speaking part of Switzerland, with and without a dementia unit, will be invited to participate in the study. Participating nursing homes will be randomly assigned to one of three sequences using a random number generator from the base 3.6.2 R-package [192]

6.4.4 Participants

Frontline nursing home staff and family members of PWD will be involved in this study. All inclusion criteria are detailed in Table 17. Potential nursing homes were identified by data-mining lists from cantonal websites that contained accredited nursing homes and by referrals by cantonal Alzheimer associations.
After obtaining consent from the nursing home management board, the participating nursing homes will assign a local clinical champion [146], [147]. The clinical champion will screen subjects for eligibility using the criteria listed below and invite frontline staff, family members, attorneys (legal representatives) and PWD to separate introductory presentations and facilitate consent procedures.

Table 17: Inclusion Criteria

Participant Category	Inclusion Criteria
People with dementia living in the nursing home	Not hospitalized during the recruitment phase and therefore physically present in the nursing home at the commencement of the study *AND* Diagnosis of vascular dementia or Alzheimer's disease *OR* People with symptoms indicating dementia which is documented in the nursing home records (BESA and RAI-NH)
Family member of person with dementia	A family member/legal guardian of people with dementia as described above
Nursing home frontline staff	At least 18 years of age Employed at least 3 months in the respective organisation Must work at least 1 day per working week Able to communicate in German and follow the procedures of the study Provide continuing care to people with dementia
Nursing home	Provide continuing care to at least eight people with dementia

6.4.5 Intervention: IPOS-Dem Case Studies

This description follows the template for intervention description and replication (TIDieR) [128]. Tailoring, modifications and adherence will be reported according to the last three TIDieR items in conjunction with the main results. During the intervention, IPOS-Dem observations from frontline staff and family members will be discussed during case studies. Each case study will include a 15-to-thirty-minute group discussion about the symptoms and concerns rated with the IPOS-Dem instrument. Systematic case studies in nursing homes led by an intervention nurse will be encouraged [126], [32], [127]. The intervention aims to reinforce the IPOS-Dem care process changes identified by Ellis-Smith [40]: (a) facilitated communication and collaboration among staff and family, (b) facilitated internal communication, (c) facilitated communication with external health care professionals and (d) care planning and changes to care provision. Case studies will follow the completed IPOS-Dem instrument structure. The IPOS-Dem instrument structure enables a systematic approach to discuss and reflect on the concrete issues of caring for PWD, despite the nursing homes' differing local conditions. The local clinical champion will implement onsite activities (i.e., extending invitations to family members, preparing case studies and recording changes to care plans). An intervention nurse will lead moderation and deliberation during the case studies. The intervention nurse will be an advanced practice nurse with a PhD and expertise in chronic, palliative and dementia care. Frontline staff, the local clinical champion and family members will receive training (described below) to be sufficiently prepared for the case studies. On-duty frontline staff and available family members will be present during these group case studies at the respective nursing home. The intervention nurse will lead the case studies monthly across rotating shift patterns for twelve, nine or six months, depending on randomisation. The presence of staff and family members, the environment and notes and resources (e.g., separate room, flip-chart) will be adjusted according to the local conditions and regulations in the participating nursing homes. Family members are invited to attend in groups if they wish to. But they attend only the case study for their relative living in the nursing home. The intervention fidelity and adherence will be assessed using memos recorded by the intervention nurse.

6.4.6 Training

Frontline staff and family members who have provided informed consent to participate in this study will be required to attend a mandatory introductory event one to four weeks before the baseline assessment. Separate two-hour introductions will be held for frontline staff and family members. They will receive training in the study intervention and be introduced to the instruments for measuring outcomes: the IPOS-Dem and QUALIDEM. The introductions will be conducted by members of the study team experienced in teaching and supporting staff [225], [215]. A video recording of the introduction will be made available to those who cannot attend the introduction event in person. Follow-up events will be scheduled every three months for frontline staff and family members to ask questions and clarify uncertainties about completing the instruments.

6.4.7 Outcomes

We will assess the study outcomes in the sequence relative to the nursing home, as illustrated in Table 18. The scales and measures to be implemented are the German versions of the QUALIDEM [226], [202], [227] and the Swiss-German adaptation of the IPOS-Dem. Both the QUALIDEM and IPOS-Dem will be assessed on a cluster and an individual nursing home level.

Table 18: Sequence of Outcome Assessment

Outcome	Measured at the Beginning of Period
Socio-demographics	T0
BESA/RAI MDS	T0
QUALIDEM	T0, T2, T5, T8, T11, T14
IPOS-Dem	T0, T1, T2, […], T13, and T14

6.4.7.1 Primary outcome: Caring quality measured with the QUALIDEM

The 18-item QUALIDEM will be completed by nurses for each PWD in a three-month cycle, as shown in Table 18. The QUALIDEM was developed to rate the quality of life, including caring quality for PWD living in residential settings by professional caregivers [202]. For people with severe dementia, a short version with 18 items and a six-subscale profile was validated [214]. The QUALIDEM subscales demonstrated Cronbach’s alpha to be between 0.83 and 0.61 for the short version [226] we will use. Ettema et al. [227] reported the original Dutch QUALIDEM inter-rater reliability as modest, ranging from an intra-class correlation (ICC) of 0.55 to 0.83 for the short version.

The individual subscale scores will be re-calculated into a percentage score, as is usual for studies using the QUALIDEM [212], [228]–[230]. We will obtain an overall score by calculating the mean of the summed percentage scores.

We will calculate and illustrate longitudinal, total and individual subscale percentages for PWD to indicate the caring quality and quality of life trajectory.

6.4.7.2 Secondary outcome: Symptoms and concerns measured with the IPOS-Dem

We will report on the secondary outcome (symptoms and concerns) by calculating the total score comprised of the 27 given IPOS-Dem items assessed for the PWD by frontline staff and family members. IPOS-Dem data will be collected at the beginning of every period, that is, monthly, as shown in Table 18 above, by frontline staff and family members.

The IPOS-Dem is a questionnaire designed to be completed by carers. It contains 27 items about common and additional needs and concerns of PWD. Each item is scored on a five-point scale ranging from 0 (no concern) to 4 (overwhelming) [161]. The IPOS-Dem was developed for the nursing home setting, where its introduction to routine care was established as feasible and acceptable [40], [44]. The reliability and validity of the Swiss-German adaptation of the IPOS-Dem will be assessed during the first three months of this project. We intend to detail the psychometric validation elsewhere. Furthermore, subgroup comparisons between single-item and subscale percentages or respective scores between the QUALIDEM and IPOS-Dem will be tested.

6.4.8 Recruitment, Consent and Data Collection

The project leaders will arrange meetings with the nursing home management boards to introduce the study. The suitability and availability of the nursing home for inclusion in the study will be discussed. If a nursing home management board agrees to participate in the study, a trial agreement will be signed by the head of the nursing home and the University of Applied Sciences and Arts Western Switzerland (HES-SO), School of Health Fribourg.

We will provide all study participants, as outlined in Table 17, with appropriate information sheets and respective consent forms that describe the study and with sufficient information for the participants (and, if applicable, their attorneys) to make an informed decision about their participation. We will give the participants (and, if applicable, their attorneys) as much time as they need to make an informed decision. The rationale for this study, which is to critically improve caring quality and quality of life for PWD in nursing homes in the future, will be emphasised to participants and communicated so that everyone can understand [231]. A research staff team member will also be present in the nursing homes regularly to offer flexibility in how PWD are informed about and consent to inclusion in the study [231]. Participants and study sites will be able to withdraw from the study procedures at any time. The informed consent will include information to confirm that the submitted anonymised data will be used until the decision to withdraw consent.

For eligible participants, the following baseline data will be captured:

- Demographics of PWD (age, gender, marital status, care dependency [232], dementia type and severity).
- Demographics of family members (age, gender, marital status and relation to the person with dementia).
- Demographics of frontline staff (age, gender, professional role, highest completed education, type of palliative care training and the number of years of working experience).
- The latest documentation within RAI or BESA.

The clinical champion assigned in each nursing home [146], [147] will primarily oversee the measurements of the IPOS-Dem and QUALIDEM. The IPOS-Dem measurement will take place monthly (T0–T14). A study team member will be responsible for ensuring that all the scheduled measurements are conducted by reminding and supporting the clinical champions and the clinical contact person at each site. The clinical champion will ensure that the QUALIDEM is measured and completed at the time points specified in Table 18.

6.4.9 Sample Size Calculation

The sample size was calculated using simulations for a cohort stepped-wedge design. The primary outcome would be repeatedly obtained from the same participants within each cluster (nursing home), as in previous similar studies [233]. Based on previous QUALIDEM results, we assumed a baseline mean of 71.3 and a standard deviation of 16.7 [230]. The number of nursing homes was set to 20 with three cluster groups. The attributable difference in the QUALIDEM was expected to be around 5%, as derived from clinical expertise. We set the number of steps to three for practical reasons (study rollout). After baseline measurement, nursing homes will switch from the control condition to the intervention condition at given periods until all nursing homes are applying the intervention regime. To determine the appropriate sample size, we varied the average cluster size in our simulation over a range of 4 to 16 subjects per cluster. We assessed the sensitivity of the sample size calculations by varying the cluster-specific and subject-specific ICC. More specifically, we used ICC values for $\mathrm{Rho}[1] = \{0.1, 0.2\}$ and

$\mathrm{Rho}[2] = \{0.2, 0.3\}$, respectively. In our simulation, we used a standard closed cohort mixed-effects model. The latter comprised a random effect for the clusters (α) and a random effect for the repeated measurements on the same cohort of individuals (ζ). Moreover, the model included a fixed effect to account for time trends (β) and a fixed effect representing the treatment effect (θ).

$$y = \mu_{\mathrm{ij}} + e_{\mathrm{ijk}} \tag{1}$$

$$\mu_{\mathrm{ij}} = \mu + \alpha_i + \zeta_{\mathrm{ik}} + \beta_j + X_{\mathrm{ij}}\theta \tag{2}$$

$$\zeta_{\mathrm{ik}} \sim N\left(0, \sigma_{\zeta}^2\right) \tag{3}$$

$$\alpha_i \sim N(0, \sigma_{\alpha}^2) \tag{4}$$

$$e_{\mathrm{ijk}} \sim N(0, \sigma_e^2) \tag{5}$$

To estimate our models, we used the linear mixed-effect method (lmer) from the R-package lme4 [196] Furthermore, we set the acceptance probability for a Type I Error to p = 0.05 and the acceptance probability for a Type II Error to p = 0.20 (power = 0.80).

The required sample sizes to achieve the desired power of 0.80, given the above parameters and assumptions, are shown in the two scenarios plotted in Figure 13.

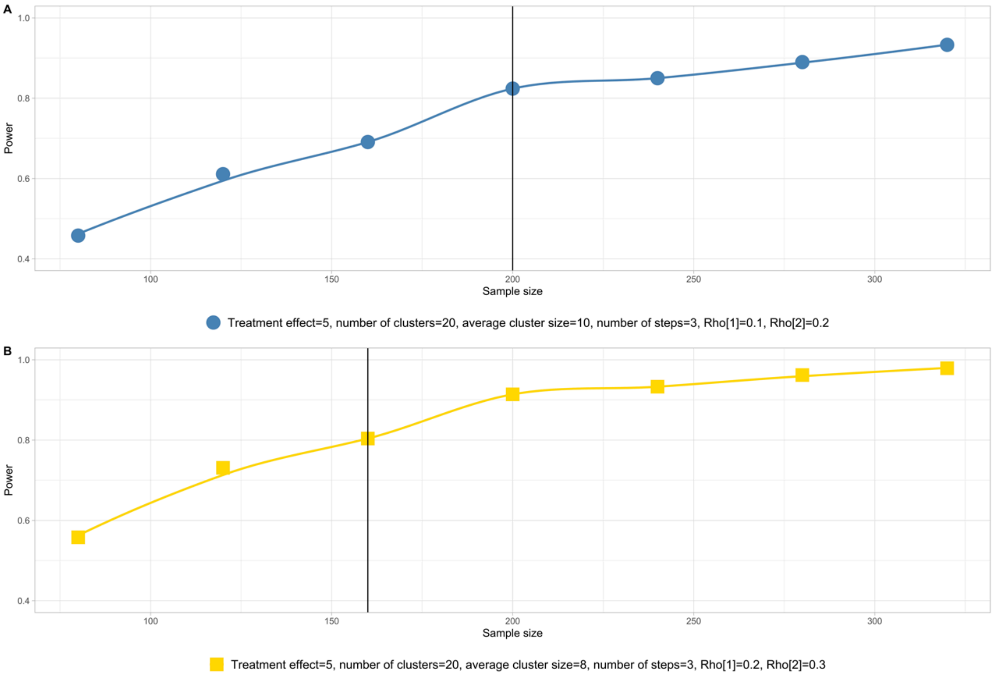


Figure 13: Power and Sample Size over a Varying Range of the Mean Number of Subjects per Cluster

Overall, a higher ICC yielded a lower total number of subjects needed to achieve the desired power Figure 13 (panel B compared to A). We found the solution with 200 participants, 20 nursing homes and three steps Figure 13 (panel A) to be optimal because three steps put much less burden on participants and study staff than a greater number of steps. On the other hand, the proposed ICCs are more conservative. Furthermore, it seems highly feasible to administer the intervention to participants in the randomised clusters within three steps. To account for attrition, we further adjusted the required sample size. Husebø et al. [152] and Chenoweth et al. [61] reported 20–25% attrition. We increased the number of clusters from 20 to 22 to address the risk of underpowering our study. To summarise, our study will enrol and follow 220 participants in 22 clusters over six discrete measurements (one at baseline and five during the control and intervention conditions), which will yield a total of 1,320 observations. We do not intend to conduct interim analyses of the outcomes.

6.4.10 Validity and Reliability

The allocation of a nursing home to a group will be concealed from the researchers and nursing home management during the recruitment phase. Depending on local schedules for staff rotation and planning, the cross-over date (from control to intervention) will be communicated to the intervention nurse and nursing home to allow for scheduling case studies during the intervention. Blinding participants to the intervention will not be possible due to the intervention nurse visits and scheduling of the case studies. Introductory sessions for all nurses and family members in all nursing homes will be conducted by the same members of the study team and the intervention nurse to avoid any teaching bias. A clinical champion will be allocated to ensure data quality in terms of completeness of data and completion pattern [147].

The QUALIDEM and IPOS-Dem questionnaire responses will be anonymised and entered into an electronic case reporting form (eCRF) using REDCap electronic data capture tools hosted at HES-SO, Valais Switzerland [153], [154]. The original papers will remain in the nursing home.

The eCRF will consist of forms and data entry fields that allow capturing of single events and visits. Data will be entered by the trained family members, clinicians and study personnel. eCRF data entry fields will be created that only allow data to be entered in a specific format (e.g., date fields, number fields). Automated checks implanted in the eCRF will check the data for plausibility and completeness while it is being saved. REDCap is a browser-based software that will give continuous feedback to the person entering the data (e.g., erroneous or missing data). All data will be subject to monitoring by an independent reviewer.

6.4.11 Statistical Analyses

The data will be analysed on an ‘intention to treat’ basis and analysed per protocol to verify the intention to treat results, as in previous similar studies [233]. Missing data will be examined using the R-package naniar 0.5 [234] and multiple imputations will be used if required.

Linear mixed-effects will be used to assess intervention effects on our primary outcome measured using the QUALIDEM over the study period. The broader category of generalised linear mixed-effects models (GLMMs) will also be used to analyse secondary outcomes. GLMMs are extremely flexible since they support various distributions of the outcome variable, such as Gaussian, Bernoulli, binomial, gamma, negative binomial, ordinal and Poisson, as well as several link functions (e.g., identity, log, logit, probit and log-log) [235], [236]. Moreover, these models will handle non-normal data and adjust the effects of clustering. Individuals will be nested in each cluster, and individuals will be measured at baseline and at five additional timepoints [108], [237].

Consequently, we will use GLMMs to investigate secondary outcomes, such as the symptoms and concerns of PWD. All models will be adjusted for potential confounding factors, such as age, gender, marital status, care dependence, dementia type and severity at baseline. All statistical analyses will be performed using R statistical software [192]. An alpha level of 0.05 will be accepted as significant. The results of the mixed-effects modelling will be presented in outcome-specific effect sizes, including the corresponding 95% confidence intervals.

6.4.12 Ethical Considerations

This trial was registered at the German clinical trials register (DRKS00022339). The full registration can be accessed online at https://www.drks.de. The Zuerich cantonal ethics board, as the lead board, reviewed the protocol, consent forms, educational material and eCRF (BASEC-ID: 2019-01847). The trial’s scientific content and compliance with applicable research regulations [144], [143] was confirmed. The ethics board in Zuerich will coordinate with other cantonal boards in this multicentre study. The sponsor, the ethics committee or an independent trial monitor may visit the clinical and research sites for quality assurance. All involved parties are required to keep all participant data strictly confidential. In the event of an audit by a local or cantonal ethics committee, all source data, eCRFs and raw data will be made available to the auditors by the study team.

All raw data will be handled with the utmost discretion and will remain accessible to authorised personnel who require the data to fulfil their duties within the scope of the study only. On all documents and eCRFs, participants will only be identified by unique participant numbers. Source data will be kept at the clinical sites and will remain within the nursing homes. During a monitoring visit, eCRFs on an encrypted memory stick will be handed to the corresponding clinical site where the monitoring is to be conducted.

6.5 Discussion

Currently, frontline staff in Swiss nursing homes need help for timely screening and reporting of needs and concerns observed in PWD [123]. When caring for PWD, they may observe complex and interrelated symptoms. Frontline staff needs to interpret, address and manage observed needs and concerns with an interprofessional team. Therefore, frontline staff needs time and support to reflect and plan interactions, care or symptom management with other people, preferably also oriented to the person with dementia [238]. Furthermore, family members can provide valuable input and context for frontline staff to caring for the PWD and vice versa [219], [44], [89].

In reviewing the literature, no research describing PWD living in Swiss nursing homes symptoms and concerns and its management, be it palliative or curative, is reported [31]. The Swiss federal office for public health (FOPH) and Swiss Alzheimer society [31] promote models for family member involvement for nursing homes, although frequency and form of exchange and participation are not determined and heavily based on family information provision members. FOPH made no specific recommendation for assessment and screening instruments for frontline staff other than the routine instruments. The relevant German guideline [10] refers to the nurse observation scale for geriatric patients (NOSGER) [11], a scale for nurses to observe and rate behaviour that challenges, social behaviour, mood and functional impairment. However, neither NOSGER nor any of the routine assessment instruments reflect the person-centred approach integral to palliative care, person-centred care and caring quality in PWD [61], [239], [240]. With IPOS-Dem, a promising model for multi-dimensional needs and concern assessment Figure 1, improved communication, and result caring quality, quality of care, and quality of life in PWD has been described and identified [40].

Therefore, we propose to evaluate a novel case studies intervention based on accessible systematic observation of needs and concerns by family members and frontline staff. The case studies intervention is conducted by an expert nurse external to the nursing home, trained to encourage open discussion and bottom-up management needs and concerns in PWD participating in the study. We expect to encounter heterogeneity in Swiss nursing homes regarding the needs and concerns of PWD and organisation, leadership, staffing, and grade mix. Therefore, to account for the complexity of the intervention, we planned the study with an SW-CRT design. SW-CRTs have been shown to work well in the exploratory phase of developing complex interventions [113].

On the one hand, our decision to conduct an SW-CRT reconciles the practical ethical and logistical concerns another trial may have posed for the PWD, us and the nursing home managers involved and the research team. On the other hand, there are drawbacks to employing this design: An SW-CRT usually requires a larger sample size than corresponding designs, also with the staggered starting times, the study duration is increased [108], [223]. However, since blinding frontline staff and family members (i.e. the outcome assessors) is not possible in our study, we proceed with utmost care to reduce the risk of bias [108], [222]. The increased sample size and, therefore, nursing homes contribute data on both intervention and control condition. The resulting datasets will be made accessible to interpret and apply to international long-term care contexts.

6.6 Conclusion

This SW-CRT will evaluate the effect of frontline healthcare staff and family members performing repeated structured assessment and subsequent case studies on the caring quality, symptoms and needs of PWD. Implementing the IPOS-Dem may further encourage routine usage of outcome measures and foster more excellent staff-family communication. The use of the IPOS-Dem will empower frontline staff in nursing homes and family members to report their insights about PWD. Furthermore, case studies led by specialist nurses and based on IPOS-Dem-informed professional and family input may improve quality of life and ameliorate the needs and concerns of PWD.

7 General Discussion - Introduction

This chapter discusses the overall findings from the thesis by looking at the initial assumption to the conclusions made based on the findings in the studies presented. The integrated discussion below links the discussion points from Chapters 4 to 6 and argues for the findings contributions to the body of research in nursing science and dementia care in nursing homes. To help frontline staff in nursing homes talk about changes they see in people with dementia, the present thesis followed three main aims. The first is to culturally adapt and translate IPOS-Dem for use in the Swiss nursing home context. The second is to psychometrically test the adapted IPOS-Dem instrument. The third is to develop a study to evaluate the effectiveness of person profiles based on the IPOS-Dem assessed by frontline staff and family members to improve person-centred care for people with dementia in nursing homes.

The beginning of Chapter 7 summarises each of the article's main findings, and the thesis' main purpose is restated. This is followed by a discussion on the central topics pertinent to the present thesis. First, the topic of person-centred care (PCC) is briefly reviewed and linked to IPOS-Dem, the clinical measure developed and tested during the current thesis. Another topic discussed is the measurement properties and positioning of this project within the MRC framework feasibility phase. Finally, Chapter 7 will review the strengths and limitations of the dissertation. Chapter 7 concludes with a brief discussion on the relevance of the present study and its outcomes for contemporary Swiss and international nursing science research and practice.

7.1 Rationale for this Chapter

Because this is a thesis based on published articles, there is a need to highlight the overall integration of the different articles and chapters. Integration can be described as the close connection and successful orchestration of different parts or elements [241]. In Chapter 7, the findings presented throughout the thesis are abstracted, analysed and interpreted. Chapters 1 to 3 have introduced a body of literature and theory on the topic of dementia care, PCC and research in nursing homes, along with seminal works, with which the results will be compared and discussed. To develop the implications and restate the significance of this project, the relevant Swiss Research Agenda for Nursing Science 2019-2029 [242] priority areas served as a framework to develop Chapter 7. From there, Chapter 7 provides rationales and further direction for future research, clinical practice and policy.

7.2 Dissertation Summary

7.2.1 Thesis Purpose

There were three objectives for the present thesis. First, IPOS-Dem had to be translated and culturally adapted for usage in Swiss nursing homes. Second, conducting the psychometric evaluation of the modified IPOS-Dem measure was required. Third, research to test how well frontline staff and family members can use person profiles based on IPOS-Dem to provide more PCC for nursing home residents with dementia was proposed. It was hypothesised that a) IPOS-Dem needs extensive adaption for use with all frontline staff and family members in Swiss-German nursing homes and that b) IPOS-Dem will show at least fair reliability coefficients for its items between ratings.

7.2.2 IPOS-Dem: Easy-Read Translation and Adaption

The first article, reprinted as Chapter 4, reported the cultural adaption and translation of IPOS-Dem into a Swiss-German easy-read version for proxy assessment of people with dementia living in Swiss nursing homes. The Swiss-German easy-read IPOS-Dem was developed and culturally adapted in a six-phase process, as illustrated in Section 4.4′s Figure 12, with nursing home frontline staff and laypeople (i.e., people without healthcare, linguistic or dementia care backgrounds), hence establishing the conceptual definition and relevance of IPOS-Dem items. Independent native speakers blind to the original scale translated and back-translated the Swiss-German easy-read version, and experts reviewed all resulting translations to produce a prefinal IPOS-Dem version. Cognitive debriefing involved two focus groups assessing the prefinal IPOS-Dem version. Face and content validity for the easy language version have been confirmed in the cognitive interviews. The results showed that using easy language specialists yielded a clinically relevant, comprehensive and understandable translation.

7.2.3 IPOS-Dem: Reliability

The study reprinted in Chapter 5 examined the inter-rating reliability of the Swiss easy-read IPOS-Dem described above for frontline staff in nursing homes. This study calculated the inter-rating reliability by generalising the formula for inter-rater reliability. Because of the hierarchical nature of the data resulting from the multicenter study design producing the primary dataset, this generalisation of common reliability formulas was indicated. The results showed that the individual items showed kappa values between .38 (95% confidence interval [95% CI] .3–.48) and .15 (95% CI .08–.22). For the experimental IPOS-Dem sum score, a dependability index of .57 was found. The different ratings and time between ratings explain less than 2% of the variance in the sum score.

The dependability study indicated that an experimental IPOS-Dem sum score could be acceptable for dementia care research in nursing homes by averaging two ratings. From our investigation, clinical use may not be recommended and should be carefully supervised. Further development and validation of the IPOS-Dem and similar instruments for research and clinical practice in nursing homes is indicated and extensively discussed further in Chapter 7.

7.2.4 Stepped-Wedge Cluster Randomised Trial

The stepped-wedge cluster randomised trial (SW-CRT) protocol presented in Chapter 6 details how the overarching trial evaluated the effectiveness of the IPOS-Dem–based discussions, termed person profiles (at that point still termed ‘case studies’) to improve the caring quality for people with dementia in nursing homes. The study population consisted of people with dementia living in nursing homes with and without specialised dementia care units. Over a period of 15 months, staff and family members from 22 centres assessed the needs and concerns of people with dementia using IPOS-Dem. The primary outcome was caring quality measured by QUALIDEM, and the secondary outcome was symptoms and concerns, as indicated by the IPOS-Dem sum score. The results will contribute to the evidence on effectiveness of PCC for people with dementia. Collaboration between healthcare staff and family members built upon through assessment using IPOS-Dem and related person profiles was systematically developed. At the time of writing the present thesis, data collection for this trial has closed. Analysis regarding the primary and secondary endpoints is underway and expected to conclude in late 2023.

7.3 Integrated Discussion

7.3.1 Revisiting Person-Centred Care

In light of the epidemiologic reality and projections related to older people and the dementia epidemic specifically, the WHO [243] called for the greater implementation of PCC, particularly in nursing homes. PCC has been shown to improve outcomes, in line with the PCC model developed by McCormack and McCance and introduced in Section 1.3.2′s Figure 2, but it has also been shown to provide more distal outcomes such as decreased job strain for frontline staff [244]. Nursing homes and nursing continue to advance research pragmatically, despite confronting adverse political conditions such as underfunding and societal challenges like low prestige and workforce retention issues [245]. The quest for better care standards persists, even amid the conceptual ambiguities that arise from the diverging perspectives between Kitwood's person-centred dementia care model and subsequent reinterpretations, such as those by McCance and McCormack [246], [247]. These complexities, which extend beyond dementia care to encompass broader nursing and contextual factors specific to nursing homes, were discussed in Chapter 2.

A pragmatic consensus definition of PCC for primary caregivers was put forward by Edvardsson [248], stating that PCC puts people's subjective experience of illness first, postulating that subjective care is the primary goal before responding to any disease or illness. This interpretation may be an evolution from the Need-Driven Dementia-Compromised Behaviour model proposed by Kolanowsky [249], [250]. The Need-Driven Dementia-Compromised Behaviour model challenges clinicians to interpret BPSD as unfulfilled needs. This thesis project was able to revisit the conceptualisation of PCC and how routine assessment of symptoms and concerns may be considered in and of themselves and how the assessment can be person centred.

7.3.2 The Operationalisation of Person-Centred Care in this Thesis

The overarching trial operationalised PCC in two core activities: the routine assessment of needs and subsequent person profiles (please refer to Chapter 3, Table 21 on the trial's programme theory, to see the intervention in context.) Mohr et al. [247] proposed the classification of PCC interventions, and this project's multicomponent intervention falls into the *training and support* category for professional caregivers and care organisations. In their taxonomy of PCC interventions, Mohr et al. [247] described organising care as the discussion and advice regarding the day-to-day care plans and care delivery at large on behalf of the person. An in-depth description of the person profile intervention component has been included in the SW-CRT protocol (i.e., Chapter 6, Section 6.4.5) and is elaborated more in Table 21.

7.3.3 Assessment in Person-Centred Practice

The process of evaluating and planning nursing care is driven not solely by isolated and standardised clinical tests and proficiency, but also by the multiple opportunities in day-to-day practice during the caring interactions of frontline staff with people with dementia and their family members [251]. Thus, person-centred assessment must be receptive to the experiences and relationships emerging in each opportunity. 'Assessment' suggests a goal-driven, task-focused action. Within caring and, by extension, PCC, however, assessment starts with appreciating the experience of being in the present with another individual, the comprehension of their experiences and getting to know their uniqueness. To develop individual goal-oriented care plans, it is essential to detect issues that detract from the quality of life the individuals defined [251]. Furthermore, the experience and findings informing care plans for people with dementia that can no longer communicate verbally or recall their symptom experience(s) should be verified with them and as many people close to them as possible [251]. As indicated in the opening chapters and supported Moloney et al. [251], care and treatment plans for people living with dementia should always be developed collaboratively.

7.3.3.1 Limitations in the Measurement of Person-Centred Practice

The evidence presented in chapters 2, 5 and 6 has pointed to the fact that only a few measures for use in nursing homes are person centred [248], [252], [101]. The manuscripts included in the present thesis mainly introduced, discussed and criticised the limited recommended measures from current guidance and the mandatory routine measures in nursing homes. In Chapter 6, reference to the German dementia care guidance for nursing homes with their recommended measure for dementia care [10] has been made. In chapters 5 and 6, the discussion was based on the routine measures used in Swiss nursing homes.

The contemporary guidelines for dementia care [10] refer to the Nurses' Observation Scale for Geriatric Patients as the measure of choice in nursing home routine practice [11]. The Nurses' Observation Scale for Geriatric Patients mainly focuses on observing changes in function, challenging behaviour and mood [253]. However, Chenoweth [61] pointed out that such a focus on function, agitation and neuropsychiatric symptoms in people with dementia may contradict the principles of PCC. Given that PCC is the desired model of care to be implemented in nursing homes, it raises questions about the appropriateness of routinely using the Nurses' Observation Scale for Geriatric Patients.

Quality improvement and care planning in German-speaking Swiss nursing homes is mainly driven by the Resident Assessment Instrument (RAI-NH) and its national counterpart:, the Bewohner:innen-Einstufungs-und-Abrechnungssystem (BESA) [190]. As noted in Chapter 5, these are the main drivers for quality improvement and assessment in nursing homes in German-speaking Switzerland. Lepore et al.'s [252] recent country comparative study found these routine measures are insufficient when it comes to reflecting the needs of people with dementia. The quality indicators derived from these routine assessment measures are not considered person centred [101] but have been successfully used to yield insights into the general care provided to people living in Swiss nursing homes, to a certain degree [254]. In Chapters 5 and 6, an argument was made that routine assessment every six months may be not enough to capture gradual change in the symptoms and concerns of people with dementia and their caregivers. The lack of evidence on the intensity and frequency of nurses' assessment found in Chapter 2 is further reiterated in Chapter 5. The nature of person-centred assessment as described above [251] may indicate diverging disciplinary priorities for PCC assessment, especially between medicine and nursing. Therefore, it is necessary to adapt and test a brief and easy-to-use symptom and concerns measure in nursing homes.

Another point regarding assessment raised across all chapters was that frontline staff working closely with people with dementia need to reflect on and be able to share their tacit knowledge about the people with dementia in a timely and efficient manner. Kim and Park [46] noted the importance of 'internal staff' to improve people with dementia's quality of life. Congruent with the PCC model, it is in the day-to-day interactions, where the processes and prerequisites frontline staff experience and bring with them into their work with people with dementia, that foster quality of life. However, Kim and Park [46] did not substantiate their claim with data from their meta-analysis. In their article [46], Kim and Park argued, based on Spector and Orrell's [255] findings, that continued relationships between frontline staff and people with dementia allow for improved social interaction and, consequently, better quality of life. Additionally, O'Donnell et al. [78] concluded that reciprocity between the different frontline staff grades and skill levels in nursing homes was the most conducive to PCC. On the one hand, O'Donnell et al. based this need for reciprocity on their reading of Dupuis, Wiersma and Loiselles' treatise on pathologising behaviour [256]. On the other hand, O'Donnell et al. cited the findings from Kolanowski et al. [257], who discussed the tacit knowledge frontline staff, especially HCAs, gather and how it is overlooked in care planning.

Therefore, it is clear that there is an intersection of reciprocity and the utilisation of tacit knowledge in the nursing homes' care models. This intersection, while noted in the literature, may have not been adequately used and integrated into interventions to foster PCC for people with dementia. In the present thesis, this oversight was addressed by using the easy-read IPOS-Dem first introduced in Chapter 4. This approach may reveal the significant potential of harnessing the unique viewpoints of all frontline staff, particularly healthcare assistants working in nursing homes.

The chosen approach brings a fresh perspective to the pathologising behaviour framework established by Dupuis, Wiersma and Loiselles [256]. As posited in programme theory introduced in chapter 3, figure 9 regarding the intervention tested with the SW-CRT from Chapter 6, the healthcare assistants' tacit knowledge is valued and integrated into care planning during the person profiles, which, in turn, may lead to a more reciprocal relationship with patients. Person profiles conducted in this manner may not only validate the frontline staff's crucial role, but may also enhance the overall quality of caring. The overarching trial intervention's programme theory detailed in Figure 9 back in Chapter 3 underscores the importance of *reciprocity* and *tacit knowledge* in developing a more effective, empathetic and comprehensive care plan. Based on the SW-CRT's future findings, a more robust integration of these under-recognised aspects into nursing homes' standard practices and research may be set up, challenging and enhancing the status quo.

In dementia care research, the literature mainly focused on proxy descriptors of PCC [258], like the prevalence of behaviour that challenges, agitation or neuroleptic medication. As a concept in its own right, PCC was not measured *per se*. The IPOS-Dem SW-CRT also omitted evaluation of PCC, as shown in Chapter 6 Section 6.4.7. The decision not to measure PCC can be explained by the measurement burden imposed on frontline staff, on the one hand, and by the unfit purposes of identified candidate measures, on the other hand. Edvardsson and Innes's 2010 review [248] identified 12 measures that intend to evaluate PCC, with only one being dementia specific. Most of the measures were intended primarily for research and to be used by researchers, not to support practice development or care planning. Edvardsson and Innes identified one measure in their review aiming to develop clinical practice: dementia care mapping (DCM) [248]. DCM is an observational tool to be used by trained clinicians. Coding frames are provided to help clinicians view the situations and interactions from the person with dementia's point of view. A point of criticism is that DCM requires a minimum of a two-day course, and the data collection is rather time-consuming [248]. In summary, when the present thesis and overarching project was planned, there was a need for feasible, easy-to-use, clinical, holistic measure that could help capture a proxy of PCC, or, according to McCormack and McCance's model, the central outcomes of PCC (see Figure 2). The easy-read IPOS-Dem adapted to the Swiss-German nursing home context translated [57] and tested [58] is a viable response to that gap in clinical practice and research.

Therefore, based on the needs identified in the planning stage of the present thesis with previous research results, it is evident that the Swiss-German, easy-read IPOS-Dem can fill a significant gap in both clinical practice and research in nursing homes. This adaptation, as outlined in Chapter 4, not only responded to the existing demand for a holistic measure that captures a proxy of caring quality, but also aligns with McCormack and McCance's model of central PCC outcomes (see Figure 2, Chapter 1).

By offering a feasible, easy-to-use clinical tool, frontline staff may better evaluate the caring quality and further encourage the adoption of PCC practices across nursing homes [57], [40]. This is particularly critical in the Swiss-German context, where such measures have previously been lacking. The broader implications of the routine use of such a measure combined with person profiling may extend beyond its immediate practical applications; it may also provide a robust platform for further research and innovations within nursing homes, driving advancements in PCC within nursing homes, ultimately improving or at least sustaining the quality of life for people with dementia. In essence, the current thesis and proposed complex intervention bridges theory and practice, underscoring the pivotal role of appropriate measurement tools in improving caring quality.

7.3.4 The Origins of IPOS-Dem and its Importance

IPOS-Dem fulfils the role of a PCC proxy measure to a certain degree. However, it can be argued that IPOS-Dem may be measuring the inverse of quality of life—the impact of symptoms and concerns on people with dementia. This relationship between quality of life in people with dementia and IPOS-Dem has been hypothesised and will be tested in further work [259]. The value of routinely measuring symptoms and concerns as a proxy outcome to PCC has been proposed [260], [251].

IPOS-Dem allows frontline staff and family members to routinely document their tacit knowledge from interactions they have with people with dementia [261] but emphasises holism—a core feature shared between person-centred and palliative care, which is accomplished by integrating social, psychological and spiritual needs with physical needs. IPOS-Dem owes its emphasis on holism to its origins in palliative care [44], [262], [263]. Hughes et al. [264] argued that there might be additional properties to an outcome measure for research in nursing homes besides the COSMIN measurement properties (introduced back in Chapter 3, Figure 10). Hughes et al. again highlighted the issues of time and resources available in nursing homes and their argument in favour of specific adjustments to the layout and format of any measure, accompanying guidance and instructions to be used in nursing homes. Furthermore, they noted the importance of the availability and accessibility of these measures. According to these additional criteria to COSMIN measurement properties, Hughes et al. concluded that none of the currently available measures can be recommended for routine use in nursing homes by frontline staff [264]. Therefore, when synthesising the functionality of the IPOS-Dem with Hughes et al.'s criteria for an ideal outcome measure, it was found that the IPOS-Dem emerged as a promising candidate for routine use in nursing homes [44], [40]. IPOS-Dem embodies the core features of PCC by acknowledging and documenting the tacit knowledge gathered by frontline staff and family members, hence ensuring that a holistic care approach can be achieved—integrating the social, psychological, spiritual and physical needs of people with dementia [40], [57]. Furthermore, IPOS-Dem's origins in palliative care (1) underscore its adaptability to the unique conditions and constraints present within nursing homes, such as limited time and resources. Its user-friendly layout, instructions and format speak to Hughes et al.'s call for more accessible and usable measures within these settings [264]. However, it must be acknowledged that its availability and accessibility still need to be optimised to fully fulfil the criteria suggested by Hughes et al. and COSMIN measurement properties [265], [264]. In essence, although there is no one-size-fits-all measure currently recommended for routine use in nursing homes by frontline staff, IPOS-Dem, as adapted and tested in the present thesis, provides a viable, contextually sensitive solution that may bridge this gap, thus enhancing the caring quality for patients with dementia as a core component of the proposed complex intervention.

Table 19: COSMIN Overview for the Swiss Easy-Read IPOS-Dem Measurement Properties

Publication	**Internal Consistency**	**Reliability**	**Measurement Error**	**Content Validity**	**Structural Validity**	**Hypothesis Testing**	**Cross-Cultural Validity**	**Criterion Validity**	**Responsiveness**
[57] *Chapter 4*	-	-	-	Fair	-	-	-	-	-
[58] *Chapter 5*	-	Poor	-	-	-	-	-	-	-

COSMIN measurement properties are reviewed per item and “the worst score counts”

7.3.5 Measurement Properties

The findings from Chapter 4 have indicated fair content and good face validity for the easy-read IPOS-Dem. However, Chapter 5 has indicated that item-wise reliability was poor ($\kappa < .4$) for all the items. Table 19 shows an overview for the easy-read IPOS-Dem measurement properties identified. Each of these measurement properties are discussed further in the following sections.

7.3.5.1 Content Validity

Section 4.4.1 in Chapter 4 has detailed the informal evaluation of IPOS-Dem set against the Swiss-German nursing home context, whose frontline staff is mainly familiar with the RAI and BESA routine measures cited above and the Edmonton Symptom Assessment System revised (ESAS-r) [266]. ESAS-r was popularised through incentivising palliative care in nursing homes through the Swiss palliative care strategy [267]. The published version of Chapter 4 [57] includes a supplementary table (reprinted in Supplementary Material B) illustrating the agreement between the expert group members. Conceptually and experientially, that is, regarding the translated experiences or items occurrence in Swiss nursing homes [169], there was good or complete agreement. The experts reached fair agreement only regarding semantics (6 out of 31 changes) or content equivalence (7 out of 31 changes), which may be mainly because of the reductionist vocabulary of the easy-read German version.

For example, there was complete agreement that ‘Schlechter Appetit’ (‘Poor appetite’) and ‘Kein appetit’ (‘No appetite’) was conceptually the same for this population, although it differs semantically. The participants raised the point that, in the context of discussing a problem’s impact (on the person with dementia) as assessed by a proxy, this nuance, that is, switching from the observation of the person not being interested in any food at all/most times (more similar to no appetite) to a judgement of ‘poor’ improves the accessibility for the raters.

These nuances of proxy versus self-assessment can be viewed in the context of the Integrated Palliative Care Outcome Measures’ origins in (mainly) oncologic palliative care [262], where self-assessment by the person with symptoms and concerns using IPOS are the most common use cases [42]. The phrasing in IPOS-Dem that was criticised by the expert group during the adaption and translation process (‘schlechter Appetit’) was intended to make the user (i.e., people who self-assess using IPOS) contrast their current perception of symptom impact against their previous recollection of symptom impact, in this case being their usual eating pattern. This contextualisation presents an abstraction that may not be indicated in people with dementia and in the proxy assessment of this population. Therefore, the phrasing for this item was changed from ‘poor appetite’ to ‘no appetite (doesn’t want to eat)’ in the adaption and translation of IPOS-Dem.

Cognitive debriefing was used to evaluate the comprehension of the Swiss-German easy-read IPOS-Dem translation further, elicit specific questions and collect statements for rewriting. The findings here, for example, led to the final confirmation that weight information, which is captured in the original English version of IPOS-Dem, would be misplaced on a Swiss-German easy-read IPOS-Dem because it is sufficiently covered by the routine measures and quality indicators mandatory in Swiss nursing homes [254].

7.3.5.2 Reliability

Chapter 5 has mainly discussed the issue related to a lack of reliability in the measures designed to capture symptoms, concerns or quality of life in people with dementia. Poortvliet et al. [207] worked with sample sizes between n = 23 (family members) and n = 103 (staff), while the cited review [13] included median sample sizes of 68 (minimum = 8, maximum = 29,120). Therefore, the analysis as reported in Chapter 5 was based on a substantial sample (n = 240). It was argued that the sample could be stratified further along different staff qualifications or the severity of dementia, which may be important threads to follow up on. Especially in Poortvliet et al.'s [207] work, the proxy assessment in advanced stages of dementia was less reliable. However, in their study, they compared different rater populations (family–nurses, nurses–physicians), not the ratings between frontline staff themselves, as reported in Chapter 5. Family member ratings were made available from the data collected during the main project, which may contribute to strengthening the evidence base on the reliability of IPOS-Dem.

Regarding the feasibility and acceptability of the overarching trial, it was decided not to track the assessors (i.e., assign encoding identifiers (IDs)) to the frontline staff. In the overarching trial, there was a need to reduce the impact on IPOS-Dem's ease of use and potential for errors by not having frontline staff remember their own IDs, in addition to the ID of the person with dementia. The inability to discern which frontline staff member filled out which assessment during the overarching trial led to major deviations from the planned analysis regarding the measures' reliability. Common methods, such as Shrout and Fleiss' [136] intraclass correlation coefficient for random raters and agreement (ICC2,1), would require random but identified raters from the dataset. Furthermore, the ICC models were not built to reflect the hierarchical nature of the data resulting from the SW-CRT design. This complexity in the data structure was captured with G-theory, as outlined in Chapter 5.

The G- and D-theory coefficients in Chapter 5 were calculated using nonvalidated IPOS-Dem sum scores. The need for checking the validity of this sum score is discussed within the limitations section of the chapter. However, the need to use sum scores highlights the importance of following the hierarchy of measurement properties: 1) content validity; 2) structural validity, internal consistency, cross-cultural validity; and 3) reliability, criterion validity, hypotheses testing, construct validity and responsiveness [268]. Therefore, prioritising work on IPOS-Dem's structural validity, internal consistency and cross-cultural validity was paramount. Determining the dimensionality of the easy-read IPOS-Dem should be prioritised and may be approached by exploratory factor analysis before further work (e.g., inter-rater reliability family–staff, criterion validity) is undertaken. With the subscales for IPOS-Dem defined, the analysis of the secondary trial endpoints (see Chapter 6, Section 6.4.7), as well as further psychometric validation, will be undertaken going forward using the data captured during the stepped-wedge cluster randomised trial outlined in Chapter 6.

7.4 Trial Conduct – The Use of the MRC Framework

Chapter 3 positioned the overarching trial in the MRC framework's feasibility and development phases. There remains a lack of consensus in defining what constitutes a feasibility study. Moreover, the question of whether the process of developing and testing an outcome measure, such as IPOS-Dem in the present thesis, fits within these discussed parameters of a feasibility study continues to be a point of debate. Given that 'feasibility' serves as the principal methodological phase and that the overarching trial has been a precursor to a larger study, the text or even title of Chapter 6 should underscore that it revolves around a feasibility trial, as stipulated by the CONSORT criteria [269], but it does not. However, the study was not planned as a feasibility study and occupies a space in between an efficacy and feasibility study. According to Thabane et al. [270], there are four major classifications of rationales for pilot and feasibility studies: process, resources, management and scientific, as presented below.

7.4.1 Process Feasibility

Chapter 6 has shown that the calculation of retention and recruitment rates for the overarching trial planning could be derived from previous work [152], [1]. Although the sample size was adjusted for attrition by 20% based on previous findings in this population [152], the sample size and protocol were not amended to reflect the impact of the COVID-19 pandemic, which may have driven the attrition rate significantly higher. Because of the rather conservative estimates of intracluster correlations chosen during power calculation (i.e., the correlation of QUALIDEM scores in the individuals and in each of the nursing homes) of $\rho_1 = 0.1$ and $\rho_2 = .02$, a treatment effect of $\theta = \pm 5$ might still be detected over time and in cluster groups, despite the high attrition using the methods described in Chapter 6.

7.4.2 Resource Feasibility

Time and budget issues as well as time for data collection supervision processes were equally informed by our previous research [1]. As developed in Chapter 3, a time estimate per person with dementia recruited to the overarching trial was presented and discussed, most often with the nursing homes' leadership board. The estimate presented in Table 5, Section 3.6.2 would have been modified based on feedback, but modification during the recruitment phase turned out to not be necessary.

7.4.3 Management Feasibility

During the overarching trial an internal pilot study with two clusters was conducted to determine the optimal processes for coordination between different actors. The initial processes were minimally adjusted to accommodate data collection delays during the second wave of COVID-19 and issues with the data entry forms on the online data management and survey platform used in the overarching trial (REDCap).

7.4.4 Scientific Feasibility

The assessment of treatment safety, dose-response, effect and effect variance is the main driver of the categorisation under the MRC framework's feasibility phase. As the secondary outcome and primary component of the present thesis programme theory (see Chapter 3, Figure 9), the IPOS-Dem measure was not available as a translated measure adapted to local needs. Therefore, it had to be further adapted and psychometrically tested, as elaborated in Chapter 4 and Chapter 5. Furthermore, the hypothesised mechanisms of change developed and reported by Ellis-Smith et al. [40] have been further investigated and could be tested in a clinical setting. The proposed outcomes may be explored using the quantitative and qualitative data from family and frontline staff collected during the SW-CRT, as described in Chapter 6, which will be analysed going forward.

7.4.5 Feasibility Studies

Feasibility studies and pilot studies are mainly conceptualised for laboratory research settings and pharmacologic research [271], [272], [270]. The present thesis presents a project of particular interest to nursing science, which will be discussed further in this chapter. Nursing science started to frame nursing as a complex intervention in and of itself [130]. Researching nursing as a complex intervention requires longitudinal trial data instead of cross-sectional, nonexperimental data [130] so as to move the discipline's research agenda forward. Pilot and feasibility studies may hold merit to determine if feasibility goals or criteria have been set [270]. However, the protocol presented in Chapter 6 was based on sound previous research within the research team and strong external partnerships. In addition, the calculation of sample sizes was grounded in evidence. Therefore, a full stepped-wedge cluster randomised trial was proposed. The presented description and conduct along an appropriate study design serves towards the methodological development and feasibility work for research conduct in the context of Swiss nursing homes and nursing science.

7.5 Relevance for Nursing science

According to the US National Research Council, nursing science delves into three main themes concerning human function [273]: (1) the rules governing well-being and function in both sickness and health; (2) human behaviour patterns when facing critical situations with the environment; and (3) methods to enhance health outcomes. Essentially, it merges biobehavioural human responses within health sciences, acting as a bridge in clinical research aimed at bettering healthcare and overall health. It emphasises alleviating disease effects, managing illness symptoms, aiding people in need of care and families in adjusting to ailments, promoting wholesome lifestyles across diverse groups and refining the healthcare environment to positively influence outcomes for patients, families and communities.
By integrating the IPOS-Dem measure and its subsequent person profile into the nursing landscape, the present thesis has significantly deepened our scientific understanding of PCC for people with dementia. The trial testing of the person profile emphasises the measures' efficacy in facilitating the development of customised care plans, which are inherently anchored to both the individual needs of the person with dementia and available local resources. More crucially, the IPOS-Dem measure provides a concrete mechanism for the systematic and scientific evaluation of person-centredness in care. This shifts the paradigm from a general conceptual understanding of PCC to a more empirical, measurable approach. As a result, the present research not only aligns with, but also advances the objectives of nursing science by offering tangible means to measure, evaluate and enhance PCC for those with dementia. The present thesis, however, focuses specifically on the dementia nursing aspect within Swiss nursing homes. The findings are structured and discussed in alignment with the relevant priority areas identified by the Swiss Research Agenda for Nursing 2019-2029 (SRAN) [242].

7.6 Nursing Research in Switzerland

Although nursing homes are an integral part of healthcare across multiple disciplines, the current research places particular emphasis on the role of nursing within the Swiss nursing home context. Indeed, in recent years, substantial research efforts spanning various academic fields have sought to understand the current state, challenges and potential directions for Swiss nursing homes. This cross-disciplinary interest underscores the importance and wide-ranging implications of doing research in the long-term care sector.
Two SRAN-identified priority areas are particularly relevant to the present thesis [274], [242]: *'Nursing Care Interventions'* and *'Quality of Care and Patient Safety'*. Within the following paragraphs, the aim is not to limit the importance of nursing home research conducted in the present thesis to nursing alone, but rather, the goal is to highlight the valuable insights and advancements that can emerge when nursing practices in these facilities are carefully studied and optimised.

7.6.1 Nursing Care Interventions

SRAN proposes that the *'nursing care interventions'* priority research area looks at nursing care interventions serving various demographics. To equip nurses with the knowledge necessary for differentiated clinical decision-making, they highlighted the need for research focusing on creating and implementing PCC [274]. This makes the overarching trial proposed in the current thesis highly relevant for nursing science in Switzerland.

7.6.1.1 Patient-Related Outcome Measures and Patient-Reported Experience Measures.

SRAN proposed a focus on developing patient-related outcome measures (PROMs) and patient-reported experience measures (PREMs). IPOS-Dem and the larger family of measures certainly can be attributed to PROMs, although they are—for the time being—mainly proxy rated [161], [57], [58]. IPOS-Dem may help nursing home frontline staff take the person with dementia's perspective and discuss care plan adaptions, potentially improving interteam communication, as outlined in Chapter 1 and Chapter 3. These benefits of using PROMs like IPOS-Dem seem especially important in Swiss nursing homes. Brunkert et al. [275], for example, highlighted the horizontal discrimination among Swiss nursing home frontline staff, similar to what has been described in Chapter 3 and elsewhere [123], [1], hence leading to communication breakdown and inefficient pain or general symptom management. Brunkert et al. furthermore identified turnover and staffing as major barriers to PCC adoption in nursing homes, rather than a lack of knowledge [275]. Brunkert et al. [275] concluded by advocating for the active inclusion of nurse healthcare assistants in all processes, emphasising the importance of routine multifaceted reflection on symptoms, similar to what was proposed in the active components of the intervention outlined for the present thesis in Chapter 3 and Chapter 6.

The dataset obtained in the overarching trial proposed in Chapter 6 can be used to evaluate epidemiologic data similar to the trans-European Palliative Care for Older People (PACE) study [206], [276], [179], of which Pautex et al. contributed the Swiss data [277]. Pautex et al. found the quality of palliative and end-of-life care in Swiss nursing homes as being lacking. According to their findings, the nursing homes seemed very well equipped to provide fundamental nursing care but underperformed regarding symptom management and advanced care planning (ACP), a care and communication process to reflect on the values and goals of care with the care recipient to support future surrogate decision-makers in preparing for their decision(s) [278]. Pautex et al.'s [277] findings contrasted the deep integration of palliative care principles and guidance that the nursing homes claimed to have when questioned by the Swiss Federal Office of Public Health [121]. Pautex et al. explained this by the staff's knowledge of palliative care and hypothesised that the training programmes developed in PACE were inappropriate for all grade and skill levels among frontline staff. The Swiss cluster of PACE nursing homes consisted of eight nursing homes in Switzerland's French- and Italian-speaking regions [279]. It may be worthwhile to compare their results regarding symptom burden with the dataset generated during the overarching trial. PACE used the End-of-Life in Dementia Scales-Comfort Assessment while Dying [280], and 6 of its 14 items measure similar concepts as IPOS-Dem. Zimmerman et al. [208] compared the two measures (or versions of the measures) and showed significant correlations ($r = -0.57, p \leq .01$)./

7.6.1.2 Promotion of Patient-Centred Care and Reduction of Suffering and Burden.

The second and third subareas put forward by SRAN regarding nursing care interventions are the promotion of PCC and reduction of suffering and burden. The SRAN authors especially highlighted that nursing homes require an improvement regarding the adoption of PCC practices and improvement of patient outcomes. The current state of PCC in Swiss nursing homes, as derived from the work of Blaser and Berset [281], indicates that PCC is a known concept for frontline staff in nursing homes. However, PCC is mainly promoted in specialised units within the nursing homes rather than nursing homes in general. This may be explained through the seniority of the specialised dementia care field, which evolved with the PCC concept described by Kitwood, as detailed in Chapter 2. The imbalance between specialised and general nursing home units is in line with the works by Zùñiga et al. [282], [283] because they underscore the desire for more PCC among nurses in expanded roles. Zùñiga et al. have an implementation focus that promotes specially trained specialists in nursing homes. However, the effectiveness of the study's primary outcome was a reduction of unplanned hospital admissions [282] of older people living in nursing home. According to McCormack and McCance, this is less of a PCC outcome than that of a patient safety or care process outcome. Despite the conceptual misalignment with PCC, reduced hospitalisations have been widely accepted as a valuable and nursing-sensitive [284] outcome. With the quality of life, symptoms and concerns as the primary and secondary outcomes in the overarching trial, the overarching trial may show efficacy in line with the PCC model.

Reflection and clinical supervision was the main focus of the person profiles in the project outlined in the present thesis. The rise of ACP has been identified as a major driver of unplanned hospitalisation measurement. The feasibility of ACP in Swiss nursing homes was researched by Bosisio et al. [285], who ultimately decided not to move beyond the pilot trial stage based on challenges regarding research design, healthcare communication and structural challenges in nursing homes; they concluded that larger-scale trials on ACP with people with dementia are not feasible in western Switzerland. Their research emphasised the need to simplify procedures for implementing changes in nursing homes. The authors also explained how caregivers prioritise daily care planning over ACP for people with dementia [285].

In line with the Swiss research agenda for nursing [274], the present thesis developed a patient-related outcome measure, that is, a priority area for enabling patient-centred care in nursing homes. The proposed intervention core components outlined in Chapter 3 and Chapter 6 complement the findings from other Swiss research in nursing homes. The results of the forthcoming overarching trial, which is outlined as a protocol in this thesis' Chapter 6, will provide valuable insight into the evolving problems and concerns of people with dementia at the end of life. Once completed, the published dataset will enable a comparison with data from other language regions of Switzerland.

7.6.2 Quality of Care and Patient Safety

The measurement and enhancement of healthcare performance, here from the perspective of individual frontline staff to broader systems, are deeply tied to the quality of care provided, including the safety of patients. The continued development of nursing-sensitive outcomes—outcomes influenced by nursing care processes and structures—is crucial [274]. Ensuring patient safety necessitates continuously monitoring clinical practices and evaluating intervention packages that consider human and system factors [274].

As outlined in Chapter 3, the complex intervention that was developed to be tested in the overarching trial focused on using routine assessment results to reflect the care planning, to update care plans and to implement new interventions in a timely fashion. This may be a way to cyclically and systematically evaluate care provision in nursing homes, in addition to the nursing home quality improvement mechanisms in place. With IPOS-Dem, Ellis-Smith et al. [44] developed a scale specifically designed for these populations of care recipients and raters. The proposed programme theory [40], as outlined in Chapter 1 Figure 1, was foundational for the programme theory outlined in Chapter 3, Figure 9 and to be tested in the overarching trial outlined in Chapter 6. Jain et al.'s [286] comparative study identified the similarities and differences between UK and Swiss nursing homes. Notable differences include the staffing and funding models, with Swiss nursing homes being more often publicly or semipublicly funded. Furthermore, one must consider the federalist nature of healthcare policy in Switzerland, with nursing homes governed (and quality controlled) on the municipal level. As highlighted above, regionalised quality reporting has been somewhat mitigated by the recent introduction of national quality indicators [254]. However, nursing home quality indicators have been found not to reflect the needs of people with dementia. Although people with dementia are nursing homes most prevalent residents [252].

Asante et al. [287] proposed that quality care in Swiss nursing homes is produced intentionally by frontline staff and requires leaders to act in a person-centred manner towards staff members and people with dementia. They characterised nursing homes as complex adaptive systems that require leaders to unify frontline staff behind a vision—a process that is equally complex.

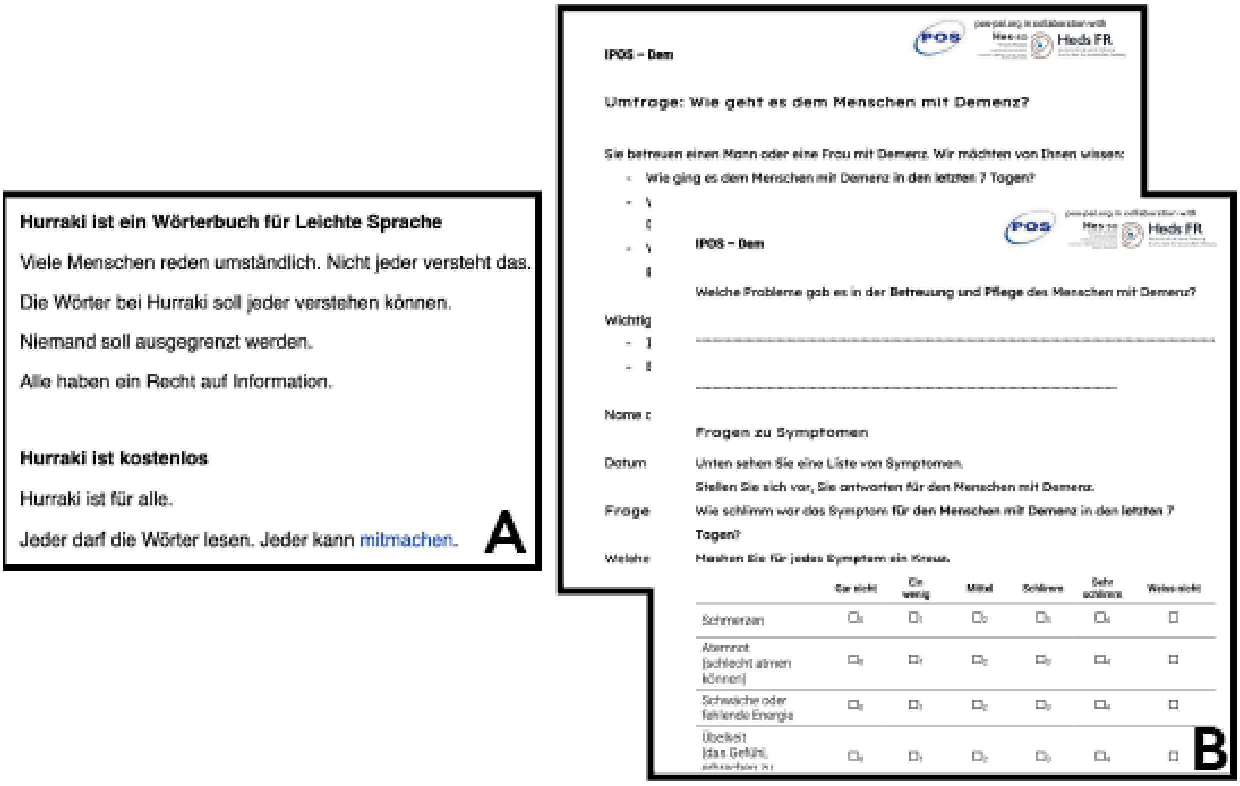
The recurrent theme across these studies undertaken in Switzerland is the promotion of PCC in Swiss nursing homes. This involves overcoming the barriers related to staffing, discrimination and procedural complexities. Moreover, there is a clear need for guidance in prioritising care tasks and improving palliative and end-of-life care. Therefore, considering the unique configuration of Swiss nursing homes and the pressing need to enhance PCC within these settings, the current thesis has offered an essential contribution to the ongoing discussion and investigation. The complex nursing intervention developed during the present thesis acknowledges and addresses the specific complexities, such as diverse staffing and funding models, as well as the localised governance of nursing homes. With clusters in 10 cantons, the overarching trial contributes to a nuanced understanding of effectively promoting PCC in the Swiss nursing home context.

Moreover, the adapted instruments and concepts from the present thesis suggest ways to overcome the identified barriers and improve end-of-life care for people with dementia, which is a prevalent population living in Swiss nursing homes [30]. Ultimately, the overarching trial interventions' second active component—person profiles—affirms the value of adaptive leadership in nursing homes, uniting frontline staff and family members behind a shared vision of quality care. In essence, by focusing on these aspects, the current work is not just contributing to academic discourse, but it is also potentially enhancing the lived experiences of people with dementia who reside in Swiss nursing homes, along with improving the lives of their family members.

7.7 Strengths and Limitations

The overarching trial recruited and engaged a substantial number of nursing homes in the German-speaking part of Switzerland. According to Kim and Park's 2017 review [46], only one study [288] with sample sizes and time to follow-up similar to the overarching trial we propose in Chapter 6 has been identified. The valuable research data generated during the overarching trial will be subject to multiple future publications beyond those already published and made openly accessible once the SW-CRT analysis is finally completed and published.

With the easy-read development in the current thesis [57], a major concept has been identified and adapted for a clinical measure that is intended to be used by all grades and differently skilled frontline staff in nursing homes. The easy-read's benefits may be transferred to future research projects and underpin patient and public involvement and engagement (PPIE) endeavours. Through the easy-read approach, nursing science may be made more relevant to clinical practice, and its contents and findings may be better transferable to clinical practice. Although using the easy-read version may reduce the cognitive load on any group of readers, it has been warned that the particular look of easy-read German can elicit adverse reactions from recipients who do not require modified texts to understand them [289]. Easy-read German may evoke, for example, the feeling of not being taken seriously in readers with high reading competences.



Hurraki ist ein Wörterbuch für Leichte Sprache

Viele Menschen reden umständlich. Nicht jeder versteht das.

Die Wörter bei Hurraki soll jeder verstehen können.

Niemand soll ausgegrenzt werden.

Alle haben ein Recht auf Information.

Hurraki ist kostenlos

Hurraki ist für alle.

Jeder darf die Wörter lesen. Jeder kann mitmachen.

IPOS – Dem

Umfrage: Wie geht es dem Menschen mit Demenz?

Sie betreuen einen Mann oder eine Frau mit Demenz. Wir möchten von Ihnen wissen:
- Wie ging es dem Menschen mit Demenz in den letzten 7 Tagen?

Wichtig

Name

Datum

Frage

Welche

IPOS – Dem

Welche Probleme gab es in der **Betreuung** und **Pflege** des Menschen mit Demenz?

Fragen zu Symptomen

Unten sehen Sie eine Liste von Symptomen.

Stellen Sie sich vor, Sie antworten für den Menschen mit Demenz.

Wie schlimm war das Symptom **für den Menschen mit Demenz** in den letzten 7 Tagen?

Machen Sie für jedes Symptom ein Kreuz.

	Gar nicht	Ein wenig	Mittel	Schlimm	Sehr schlimm	Weiss nicht
Schmerzen	☐	☐	☐	☐	☐	☐
Atemnot (schlecht atmen können)	☐	☐	☐	☐	☐	☐
Schwäche oder fehlende Energie	☐	☐	☐	☐	☐	☐
Übelkeit (das Gefühl,	☐	☐	☐	☐	☐	☐

Figure 14: Comparison of Common German Easy-Read Text (A) and IPOS-Dem (B)

***Panel A:** Screenshot and reprint from Hurraki, published under CC BY 3.0 via Hep Hep Hurra e.v.*

During the cognitive interviewing, adverse reactions to the presentation of easy-read text was not an issue raised by the participants [57]. However, the specific layout of the easy-read texts (as shown in Panel A of Figure 14) has been obscured by the questionnaire structure (As shown in Panel B of Figure 14).

7.7.1 IPOS-Dem as an Outcome Measure in a Trial

On the one hand, it was possible to start psychometric development and testing for the IPOS-Dem and derive some evidence on its measurement properties. The reliability study in Chapter 5, however, has exemplified the issue of poor inter-rating reliability of the newly developed measure, while IPOS-Dem was used as a clinical measure and secondary outcome measure in the overarching trial [2]. This may be considered a limitation. This decision was taken because evidence from the UK indicated the impact and potential for change in nursing homes [40]. Furthermore, with QUALIDEM, the overarching trial is underpinned by a relatively strong primary outcome measure [214] for which further reporting on its measurement properties could also be derived from the data collected.

7.7.2 Stratification and Sociodemographics

During planning of the overarching trial, a brief dementia staging measure like the Functional Assessment Staging tool [201] was not available in German, so dementia stage and diagnosis (if documented) had to be derived from the nursing homes RAI or BESA Data [2], which often resulted in missing information. Furthermore, the inability to link the assessment with the assessor for each IPOS-Dem assessment limited the possibility of meaningfully stratifying the data analysis by frontline staff grade and skill. Hence, the stratification of the data analysis by dementia type and severity may be limited. Although worthwhile comparisons to other language regions and datasets could be undertaken, as discussed above, this was, however, different from the primary aim of the overarching trial. Aspirations like these would have removed the research further from clinical practice. It was hypothesised that collecting additional variables would have led to the disengagement of the frontline staff and clinical champions because of questionnaire fatigue and issues with trust in data protection procedures, as discussed above. These elements should be revised and incorporated more succinctly in future studies in this field.

7.8 Implications for Research, Practice and Policy

7.8.1 Research Implications

As mentioned, overarching trial has generated a considerable amount of research data. With pending further analysis, symptom and problem trajectories will be compared with other disease groups and other nursing home research. For nursing science, understanding shared decision-making, learning and communication needs in frontline staff and family members may be developed from the future analysis of intervention nurse person profile memos. Despite the pressing need for sound PROMS posited by SRAN, only a fraction of IPOS-Dem's measurement properties have been explored and described. Further research will focus on concurrent and convergent validity, comparing IPOS-Dem with QUALIDEM, MIDOS and the Minimum Dataset routine data [259]. The promotion of an easy-read version in PPIE, as discussed above, may be further tested and implemented in research. In future projects, the easy-read version may enable engagement with more diverse populations beyond people with dementia.

7.8.2 Clinical Practice

The easy-read version of IPOS-Dem may be a valuable tool to support implementation and foster knowledge translation in clinical practice. The high fluctuation and proportion of overseas personnel in nursing homes lends itself to high-quality written information for clinical practice. With the speed of knowledge development in medicine and nursing, the need for accessible and high-quality communication among frontline staff and other staff may also be high and increasing. This may be addressed by purposefully using easy-read translation in onsite education and day-to day communication, regardless of who is providing the information.

Although the IPOS-Dem may hold merit to enable all frontline staff and family members to talk about and capture their observations during day-to-day care for people with dementia, based on its poor measurement properties, it cannot be recommended as a clinical decision-making tool. A handbook may be developed and adapted to easy-read German for the Swiss nursing home context. As outlined in Chapter 5, QUALIDEM has improved regarding inter-rater reliability because a handbook has been developed. Furthermore, the public availability of the measure and a handbook has been taken as an important determinant of acceptability and feasibility [290] in clinical practice on a systemic level.

7.8.3 Policy Implications

Given the utility of measures like IPOS-Dem in fostering a needs-based approach to patient care, there is a clear case for policymakers to advocate for their use. In practice, this could involve promoting training programmes for frontline staff specialised in dementia care to increase proficiency in these measures and observations, thereby enriching the care plan with comprehensive nursing data.

At the core of the present thesis' findings lies the centrality of PCC in the work with people with dementia. As such, it is incumbent upon policymakers to spur the adoption of PCC in various healthcare settings, particularly in nursing homes. Moreover, our study has underscored the necessity for further enhancement of palliative and end-of-life care for people with dementia. This could be achieved through the review and subsequent refinement of existing standards and guidelines to cater more effectively to the unique needs of people with dementia and the nursing homes they live in.

Addressing staffing issues is another vital area of policy intervention, with the need for better staffing models in nursing homes being an area of particular concern. Policymakers should ensure that adequate resources are allocated to nursing homes and that frontline staff are given ample time and support to provide, coordinate and reflect on care in an effective manner. The pivotal role of frontline staff in caring and care is further emphasised by their possession of tacit knowledge gained through direct patient interaction. Policies and guidelines must be drafted to respect and actively incorporate this caring knowledge into care planning and decision-making processes. This could empower frontline staff to advocate more confidently and precisely for the needs of people with dementia, leading to enhanced patient outcomes.

The evidence presented in the current thesis also shows the inherent complexity of nursing homes, which operate as adaptive systems requiring perceptive leadership capable of unifying the staff behind a shared vision of caring quality. As a result, policies should be designed to acknowledge this complexity and support the leaders and institutions within these settings. Finally, the recognition and prioritisation of people with dementia's needs are critical. Coupled with frontline staff empowerment, this emphasis on the person with dementia could offer a relatively simple yet effective pathway to shift care processes and routines in nursing homes towards PCC within the multifaceted and linguistically diverse context of Swiss nursing homes.

7.9 Conclusion

With the development of IPOS-Dem and its application in the overarching trial, major priority areas for Swiss nursing research are addressed. In summary, the current thesis and overarching trial successfully engaged a substantial number of people with dementia living in 23 nursing homes across German-speaking Switzerland. This can be attributed to the chosen easy-read approach. People with dementia living in nursing homes, are a vulnerable and hard to access population, therefore the results of this thesis project can also be considered a major contribution to the research on this population. Furthermore engaging the staff and family members to reflect on person-centred outcomes with IPOS-Dem helps to develop person centred practice and nursing science in the context of nursing homes.

Further research will describe the effect of the developed intervention and tested during the overarching trial, providing additional information on the measurement properties of the measures used. Adopting an easy-read approach in collaboration with ProInfirmis (the Swiss league for people with learning disabilities) for the cultural adaption and translation of the IPOS-Dem measure to the Swiss nursing homes will be extended in future projects. The involvement of people with dementia and their family members is essential in furthering person-centred practice. This need for involvement also holds true for research practice, which is reflected in the rising amount of patient and public involvement and engagement initiatives. The presented easy-read principles bear methodic potential for future patient and public involvement and engagement projects within this context.

Based on the studies presented in this thesis. IPOS-Dem has the potential to improve caring for people with dementia. IPOS-Dem can be recommended for research purposes. For clinical practice the development of a manual to help discern the different symptoms can be recommended. Further work on the psychometric evaluation of IPOS-Dem is needed and will be derived from the dataset generated during the overarching trial.

However, thoughtful application of IPOS-Dem and subsequent discussion and coordination as proposed in Chapter 3 and Chapter 6 has the potential to improve care for people with dementia and their families. The proposed programme can also improve the science of care and caring for older vulnerable populations, particularly people with dementia, which is a global public health priority.

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[294] F. Angeli, P. Verdecchia, G. Vaudo, S. Masnaghetti, and G. Reboldi, “Optimal use of the non-inferiority trial design,” *Pharmaceutical Medicine*, vol. 34, no. 3, pp. 159–165, Jun. 2020, doi: 10.1007/s40290-020-00334-z.

8 Appendices

8.I Rationale and Guidance for using Easy-Read in the Swiss-German Nursing Home Context

Easy-read is a further development of plain language. Easy-read enhances text accessibility and readability for people with and without reading difficulties compared to plain language. Easy-read has recommendations for, e.g., word difficulty and precision, use of numbers in the text and sentence length [165]. International resources for easy-read are available from https://www.inclusion-europe.eu/easy-to-read/ and for plain language at the European Publications Office [168]. To develop easy-read text with certified translators in Switzerland, I recommend approaching ProInfirmis, who offer help, resources and access to personnel in the three languages https://www.buero-leichte-sprache.ch/. Another review of health information post-COVID-19, such as that conducted by Stableford et al. fifteen years ago [166], would be due. Learnings from the public health information campaigns describing diverse health procedures ranging from simple to complex (e.g., hand-washing or MRNA vaccines) may have significantly impacted the landscape of health information [291]. Still, Stableford et al.'s treatise on plain language is quite comprehensive and holds true for easy-read as well. In Chapter 4, I argue for applying easy-read in assessment instruments based on Papadokus' findings [163]. They evaluated half of the patient-centred outcome measures used in cancer care as lacking regarding readability and understandability.

Furthermore, our initial discussions with frontline staff members for conceptual clarifications showed that some wording was quite involved in the German IPOS-Dem [57]. However, the easy-read approach may have merit in any frontline staff and patient-facing communication. My argument was based on the following assumptions and contextual factors:

1. Up to 70% of people working in Swiss nursing homes have a migratory background and learnt German as a second (or third…) language [66], [54], [292].
2. Swiss nursing homes employ a heterogenous staff mix in caring and care with a wide variety of educational backgrounds, skewed away from tertiary and secondary education [8], [66].
3. It is harder to learn to communicate in German if everyone around you speaks Allemanic dialects [54], [292].
4. The general proportion of people with reading and writing difficulties remains constant between 15 and 20 % of the working population [164].

As I learnt during the training, our primary outcome measure, QUALIDEM, suffered similar issues to IPOS-Dem. For example, multiple independent frontline staff in the study repeatedly asked about the relatively uncommon formulation describing self-isolating behaviour *"…schottet sich selbst ab"*. These experiences and anecdotes truly informed my fierce advocacy for easy-read. Since I am not doing a PhD in sociolinguistics, I refrained from further examining the argumentation (the most indepth work on the language support needs in Swiss Nurses imho has been done by Konstantinou et al. [292]). However, as Stableford et al. [166] notes:

> 'Creating stellar plain language materials is an acquired skill that requires knowledge and experience. It is both an art and a science, requiring the ability to simultaneously think about the cognitive, emotional, and visual appeal of the piece as well as applying research-based strategies to ensure a truly easy-to-read and understand print material.'

In conclusion, I strongly want to encourage the reader to engage with the resources cited above. By working on making your communication, written or spoken more accessible, you not only facilitate your own personal development but also contribute to the broader goal of inclusion. As the thesis author, I highlight the importance of clear and effective communication and urge you to prioritize easy-read in your future projects for the benefit of all.

8.II Literature Review Search Strategies

8.II.a Pubmed

Search number	Query	Sort By	Filters
5	#1 AND #2 AND #3 AND #4		Systematic Review
4	#1 AND #2 AND #3		Review, Systematic Review
3	(nursing home) OR (long term care facilities) OR (residential care) OR (care home)		Review, Systematic Review
2	education OR staff knowledge OR training OR collaboration OR person-centred OR person centered OR palliative OR quality of care OR caring OR needs OR quality of life		Review, Systematic Review
1	Dementia OR Alzheimer* OR Vascular dementia OR Lewy body OR Frontotemporal OR Cognitive Impairment		Review, Systematic Review

8.II.b Cochrane

Search Name: Date Run: 2022/07/15 22:28:31 Comment:

ID	Search	Hits
#1	(Dementia OR Alzheimer* OR Vascular dementia OR Lewy body OR Frontotemporal OR Cognitive Impairment):ti,ab,kw (Word variations have been searched)	41588
#2	education OR staff knowledge OR training OR collaboration OR person-centred OR person centered OR palliative OR quality of care OR caring OR needs OR quality of life (Word variations have been searched)	703738
#3	(nursing home) OR (long term care facilities) OR (residential care) OR (care home) (Word variations have been searched)	38498
#4	#1 AND #2 AND #3 (Word variations have been searched)	3994
#5	#4 NOT (Pharmaceutical OR Medication OR Pharmacotherapy*)	

with Cochrane Library publication date from Jan 2010 to present, in Cochrane Reviews

8.II.c CINAHL

#	Query	Limiters/Expanders	Last Run Via	Results
S4	((nursing home) OR (long term care facilities) OR (residential care) OR (care home) (Word variations have been searched)) AND (S1 AND S2 AND S3)	Expanders - Apply equivalent subjects Search modes - Boolean/ Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	5,843
S3	(nursing home) OR (long term care facilities) OR (residential care) OR (care home) (Word variations have been searched)	Expanders - Apply equivalent subjects Search modes - Boolean/ Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	73,792
S2	education OR staff knowledge OR training OR collaboration OR person-centred OR person centered OR palliative OR quality of care OR caring OR needs OR quality of life	Expanders - Apply equivalent subjects Search modes - Boolean/ Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	1,766,361
S1	(Dementia OR Alzheimer* OR Vascular dementia OR Lewy body OR Frontotemporal OR Cognitive Impairment)	Expanders - Apply equivalent subjects Search modes - Boolean/ Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	142,128

8.III Summary of Reviews Included in Chapter 2

Table 20: Included Study Characteristics for Chapter Two

Authors	**Date**	**Aim**	**Method**	**Main Findings / Results**
Abbott, Noren, Whear *et al.*	2019	Summarise experiences of stakeholders of interactions with robopets & their effect on people with dementia	Random effects meta-analysis, Best fit framework synthesis	Refined logic model for robopet interventions. Evidence for effects on loneliness, agitation but not on other aspects of physical mental health.
Backhaus, Hoeck, de Vries *et al.*	2020	Describe interventions to foster family member inclusion in nursing home care.	Narrative Summary	Interventions primarily aim to improve family-staff interactions while family-resident or family-family engagement seemed less of an aim. No actual increases in the engagement of family members reported.
Birkenhäger-Gillesse, Boudewijn, Achterberg *et al.*	2018	Effects of psychosocial interventions on neuropsychiatric symptoms, & psychotropic drug prescription rates.	Fixed-effects & random-effects meta-analysis	Psychosocial interventions, with culture-change component substantially reduce the rate of antipsychotics administered (RR 0.65, 95% CI 0.57 to 0.73). Educational programmes less effective (RR 1.50, 95% CI 0.49 to 4.64).
Costello, Walsh, Cooper *et al.*	2019	Analyze the prevalence of burnout in nursing home frontline staff caring for people with dementia. Examine risk factors.	Random-effects meta-analysis	No burnout or psychological stress in frontline staff. Strong associations between burnout or stress & poor work environments, that don’t allow for discussion of care needs, poor teamwork & leadership support.
Gonella, Mitchell, Bavelaar *et al.*	2022	Describe family member support interventions during end of life care for people with dementia living in nursing homes.	Convergent integrated synthesis	Fronline staff should have regular conversations with family caregivers and offer them enough time and space for private conversations. Family Members may benefit from specialized psychoeducational programs that are adapted to their individual requirements.
Kim & Park	2017	Analyze the effectiveness of Patient-centred care for people with dementia.	Random-effects meta-analysis	Reduced agitation in people with dementia with short intervention approaches (SMD: 0.513; 95% CI: –0.994 to –0.032). Reductions in depression or improvements in the quality of life in people with dementia require long-term interventions and studies (SMD: 0.191; 95% CI: 0.079 to 0.302)

Authors	Date	Aim	Method	Main Findings / Results
Kormelnick, Janus, Smalbrugge *et al.*	2021	Examine the implementation of complex interventions for managing neuropsychiatric symptoms in people with dementia living in nursing homes.	Deductive thematic analysis with CIFR	Strong leadership and support are critical to success. Suboptimal implementation of these complex interventions often limit their effectiveness. Many challenging contextual factors in long-term care institutions.
Ma, Zhao, Wan *et al.*	2020	Describe frontline staff views & values regarding antipsychotics administration in people with dementia living in nursing homes.	Inductive content analysis	Need for changes to the organisational culture, and the provision of relevant training may be of great value. The complexity of behaviour that challenges the frontline staff results in many barriers to reducing the administration of antipsychotics in people with dementia
Morris, Horne, McEvoy *et al.*	2018	Evaluate effectiveness & acceptability of communication training interventions for frontline staff working with people with dementia & family members of people with dementia.	Inductive content analysis	Most training interventions improve communication and knowledge. Skills-based, practical simulation exercises were critical in the most effective interventions.
O'Donnell, Holland & Swarbrick	2022	Describe nursing home frontline staff's strategies to manage neuropsychiatric symptoms of people with dementia.	Three stage thematic analysis	Frontline staff knowingly describes psychotropic medicines as a "quick fix" to handle challenging behaviour or to finish duties on time. Limitations in the setting, such as the exclusion of people with dementia from participating in PCC due to insufficient staffing numbers and cost restrictions. Lack of cooperation amongst the differently skilled and different grades of frontline staff hinders non-pharmacological care interventions.
Rees, Tuijt, Burton *et al.*	2019	Describe self-management support interventions for people with dementia having multiple contditions.	Data driven convergent synthesis	Theory of self management support needs. Family caregivers view empowerment as a component of their caring responsibilities and look for ways to help dementia patients maintain control. The empowerment of family caregivers is best supported by healthcare practitioners' ability to identify when cognition alterations have occurred.
Tsai, Browne & Inder	2021	Analyze the effectiveness of frontline staff interventions to manage & assess pain in people with dementia.	Fixed-effects meta-analysis	Projects solely implementing a routine pain assessment tool showed no effect on nurses' analgesic management (Mean Difference of

Authors	Date	Aim	Method	Main Findings / Results
				0.35 [95% CI –0.30, 1.00], p = .292, and I2 = 91%)
Walsh, Dennehy, Sinnott *et al.*	2017	Describe influences on the prescription of antipsychotics for people with dementia living in nursing homes.	Meta-ethnographic synthesis	“The aim of improving care” for residents is a priority for everyone involved. The options for managing BPSD were generally perceived to be binary (antipsychotic prescribing or non-pharmacologic interventions) with the former considered to be a shortcut. A lack of empowerment at all levels of the healthcare team and among family members acts as a barrier to informed decision-making regarding antipsychotic prescribing. Fragmentation between different levels of care creates confusion surrounding roles and responsibilities, which can lead to inappropriate care plans.

***Abbreviations**: Behavioural psychiatric symptoms of dementia (BPSD), Consolidated Framework for Implementation Research (CIFR), confidence interval (CI), p-value (p), percentage of variance (I2), person centred care (PCC), relative risk (RR), standardized mean difference (SMD)*

8.IV Overarching trial intervention intent, hypothesis and description

In the person profile component of the intervention, the intervention nurse can lead systematic trans- inter- and interprofessional case learning and reflection. We theorised it to reinforce and role-model the *prerequisites* dimension of the Person-Centred Care framework Figure 2 as well as modifying the *care environment* components of *shared decision-making systems* and *power sharing* directly by providing exemplary moderation and communication techniques grounded in concrete observations and the tacit knowledge of all participants. Person profiling is an improved version of a prior, well-received intervention [1] that was designed to support particular care process modifications that have been previously described by Dr Ellis-Smith [40] and re-presented in Figure 1 back in Chapter 1. Within the nursing home contexts, the IPOS-Dem instrument structure facilitated a concrete, systemic approach and steered the conversation themes.

We hypothesised that a significant improvement in caring quality as measured by QUALIDEM (i.e. a positive effect, $p < 0.05$, in a two-tailed hypothesis test) could be achieved.

However, the literature has not yet described a minimally important clinical difference for the QUALIDEM instrument (our primary outcome measure). Therefore, the heuristic of ‘half a standard deviation’ may be used [293]. Regarding the QUALIDEM total score, this would calculate an improvement of 10.8 percentage points from baseline to follow-up. Our trial is powered according to the details in Section 6.4.9 and should be sufficiently powered to detect an effect of a five percentage point increase in the QUALIDEM total score. Still, it can be debated if a non-inferiority trial would be the better choice in this population where one would expect the people with dementia’s quality of life and caring quality to stagnate or deteriorate over time [294].

8.V Pain Interventions in Dementia

F. Spichiger et al., 'Pain interventions for people with dementia: a quasi-experimental study', BMC Palliative Care, vol. 21, no. 1, p. 228, Dec. 2022, doi: 10.1186/s12904-022-01118-9

8.V.a Background

Due to the complexity of the provision of care for people with dementia, pain assessment and management is still considered to be lacking. An optimal way to support frontline staff in providing pain assessment and management for people with dementia living in nursing homes has not yet been identified. The success of supporting interventions seems dependent on contextual factors in the nursing homes. This study, therefore, analyzes the feasibility of a nurse-led training intervention, using repeated on-site case studies, in modifying pain intensity and frequency in people with dementia.

8.V.b Methods

Using a quasi-experimental design, we undertook a multi-center study of nurse-led training in pain management, with subsequent on-site case studies. Healthcare workers from 3 nursing homes assessed pain in 164 residents with dementia over 147 days. We used mixed-effect growth curve models with spline regression to analyze the data.

8.V.c Results

We found that on-site case studies support frontline staff with pain management and assessment. Repeated reflection in case studies led to significantly longer pain free intervals (from 4.7 at baseline to 37.1 days at second follow-up) and decreased frequency of pain events (OR 0.54 at first follow-up and 0.43 at second follow-up). However no trends regarding pain intensity could be found. Therefore, on-site case studies may be valuable for improving pain frequency and pain-free intervals over time.

8.V.d Conclusion

This feasibility study shows the potential of on-site support for frontline nursing home staff. On-site case studies may also affect health outcomes in people with dementia. However, the complexity of dementia care necessitates the management of a broader range of needs.

8.V.e Trial registration

The study was retrospectively registered on the tenth of January 2017 with the German registry of clinical trials (DRKS00009726).

8.VI Action, Actor, Context, Target, Times in the Trial

Table 21: Description of Intervention Elements

Intervention Component	Action	Actor	Context	Target	Time
Training Workshop	Provide training in the use of the outcome measures IPOS-Dem and QUALIDEM, 'mini-GCP'	CNS trained in geriatric and palliative care[A]	Nursing home meeting rooms	Frontline staff (e. g. nursing associates, registered nurses)[B]	Before baseline and at the beginning of each step (i.e. every three months) until cross-over
	Provide training in the use of the outcome measures IPOS-Dem and QUALIDEM the use of REDCap, Consent procedures & 'mini-GCP'	CNS trained in geriatric and palliative care[A]	Online or in a 1:1 meeting in the respective LTCF	Clinical champion[B]	Before baseline
	Provide training in the use of the outcome measure IPOS-Dem	CNS trained in geriatric and palliative care[A]	Nursing home meeting rooms	People with dementia's family members	Before baseline and at the beginning of each step (i.e. every three months) until cross-over
Symptoms and Concerns Assessment	Write and send reminders of pending assessments	Research staff[A]	Via email	Clinical champion[B]	Weekly
	Weekly planning of pending assessment conduct	Clinical champion[B]	According to local protocol	Frontline staff[B]	Weekly
	Identify and assess symptoms and concerns using IPOS-DEM	Frontline staff[B]	In day-to day practice	People with dementia living in respective LTCFs	Monthly
	Identify and assess symptoms and concerns using IPOS-DEM	People with dementia's family members	During visits	People with dementia living in respective LTCFs	Monthly if possible
Person Profiles	Agree on consecutive person-profile meeting coordinates (i.e. room, date, time)	Intervention nurse[A]	Via email and/or telephone	Clinical champion[B]	At baseline
	Communicate invitation to person profiles	Clinical champion[B]	According to local protocol	Frontline staff[B], family members	Monthly
	Provide support and advice with developing a person centred care plan	Intervention nurse[A]	Nursing home units	Frontline staff[B], with family members if possible	Monthly
	Conduct ad-hoc collaborative case analysis on person centred care plan	Intervention nurse[A]	Nursing home units	Frontline staff[B], with family members if possible	Monthly

Intervention Component	Action	Actor	Context	Target	Time
	implementation issues and strategies				
	Provide support and advice with developing a person centred care plan	Intervention nurse[A]	Nursing home units	People with dementia’s family members	Monthly if possible
	Conduct ad-hoc collaborative case analysis on person centred care plan implementation issues and strategies	Intervention nurse[A]	Nursing home units	People with dementia’s family members	Monthly if possible

[A] *Employed by the research institution,* [B] *Employed by the respective nursing home*

Abbreviations: *Clinical nurse specialist (CNS), good clinical practice (GCP); Integrated Palliatiative Care Outcome Scale for People with Dementia (IPOS-Dem); long-term care facility (LTCF)*

8.VII Adaption and Translation Supplementary Table

Original IPOS-Dem	**Group Discussion**	**Agreement**			
		C	**S**	**E**	**CE**
Please write clearly Person's name Person's number Date (dd/mm/yyyy)	"Person with dementia" was considered most appropriate.	Good	Complete	Complete	Complete
Q1: What have been the person's main problems over the past week?	• In the Swiss-German version of IPOS-Dem, "person/people with dementia" instead of "person affected" was used. • Therefore, the terms "person/people with dementia" are replaced in the S-GER version. • "Over the past week" is replaced in the S-GER version with "the last 7 days" in a novel introduction.	Good	Fair	Complete	Complete
Not existent in the original version.	• Two free-text questions have been added in the German version and reused for the S-GER version.	Complete	Good	Complete	Complete
Q2. Please select one box that best describes how the person has been affected by each of the following symptoms over the past week.	• A sentence was added to explain how to rate how much the person with dementia has been affected by the symptom and not how strong the symptom was. • Therefore, the added sentence was also left in the Swiss-GER version.	Good	Complete	Complete	Fair
Answer possibilities: not at all, slightly, moderately, severely, overwhelmingly, cannot assess.	• Used common words to enhance readability.	Good	Complete	Complete	Fair
Shortness of Breath	Example was needed.	Complete	Complete	Complete	Complete
Nausea (feeling sick/vomiting)	Reduced wordiness to enhance readability.	Complete	Complete	Complete	Complete
Poor appetite	Adding "Don't want to eat" was considered a better fit.	Complete	Fair	Complete	Complete
Dental problems or problems with dentures	The wording has slightly changed from the German to the Swiss-German version, but not from English to German.	Good	Fair	Complete	Fair
Drowsiness (sleepiness)	The change to a descriptive phrase helps with readability.	Good	Complete	Complete	Good
Poor mobility (trouble walking, cannot leave the bed, falls)	The selection of common words improved readability.	Good	Good	Complete	Fair
Skin breakdown (redness, skin tearing, pressure damage)	We considered "biting" as an often-used slang word for itching, but it was deemed confusing.	Good	Fair	Complete	Fair
Difficulty communicating	An easy language explanation in brackets is consistent with other items and helps with readability.	Complete	Complete	Complete	Complete
Sleeping problems	The change to the descriptive phrase helps with readability.	Good	Complete	Complete	Fair
Hallucinations (seeing or hearing things not present) and/or delusions (fixed false beliefs)	The selection of common words improved readability.	Complete	Complete	Complete	Complete
Agitation (restless, irritable, aggressive)	Explanation of the term was left out in the GER version and also in the S-GER version.	Complete	Complete	Complete	Complete

Original IPOS-Dem	**Group Discussion**	**Agreement**			
Wandering (as a result of distress or putting person at risk)	In Swiss-German, the term “distress” is not used in the nursing home/ care home setting.	Complete	Complete	Complete	Complete
Answer possibilities: not at all, occasionally, sometimes, most of the time, always, cannot assess.	The selection of common words improved readability.	Good	Complete	Complete	Fair
Q3: Has s/he been feeling anxious or worried?	Worried can be left off because, in the S-GER version, the term “agitated” is more precise to the English meaning.	Complete	Complete	Complete	Complete
Q4: Have any of his/her family been anxious or worried about the person?	• “Friends” needed to be added because of the family nursing concept. Family and friends are considered one group accordingly. • The word “worried” was left off because it has the same meaning as being anxious in Swiss-German.	Complete	Complete	Complete	Complete
Q5: Do you think s/he felt depressed?	• The selection of common words improved readability. • Participants in the forward translation for the Swiss-German IPOS-Dem felt that “or” needs to be included because “sad” and “depressed” have two different German meanings within the same overarching topic: feeling sad.	Complete	Complete	Complete	Complete
Q5b: Lost interest in things s/he would normally enjoy?	The change to a descriptive phrase helps with readability.	Fair	Complete	Complete	Good
Q6: Do you think s/he felt at peace?	The change to a descriptive phrase helps with readability and consistency.	Complete	Complete	Complete	Complete
Q7: Has s/he been able to interact positively with others (e.g., staff, family, residents)?	The change to a descriptive phrase helps with readability and consistency.	Good	Complete	Fair	Complete
Q7b: Can s/he enjoy activities appropriate for his/her level of interest and abilities?	This question has been left off in the GER version and also in the S-GER version.	N/A	N/A	N/A	N/A
Q8: Has his/her family had as much information as desired?	This question has been left off in the GER version and also in the S-GER version.	N/A	N/A	N/A	N/A
Not existent in the original version. Was s/he irritated or aggressive?	The change to a descriptive phrase helps with readability and consistency.	Complete	Complete	Complete	Good
Q9: Have practical problems been addressed? (e.g., hearing aids, foot care, glasses, diet)	This question caused the most translation problems (forward and backward) because the meaning is different in S-GER.	Complete	Fair	Complete	Complete
Not existent in the original version. Q9b: If not: What was the reason?	It helps to consider Q9 in day-to-day practice.	Complete	Fair	Complete	Complete
What was the person’s last weight and the date s/he was last weighed? Weight: … kg Date: …/…/…	This question has been left off in the GER version and also in the S-GER version. It is usually captured in minimum datasets.	N/A	N/A	N/A	N/A

Supplementary Material A: Level of Agreement Regarding Concepts, Content, Experience and Semantics During Phase Four - Expert Review.

Complete agreement: all eight expert group members agreed; Good agreement: six to seven members agreed; Fair agreement: five members agreed. ***Abbreviations:*** *C: Conceptual; CE: Content equivalence; E: Experiential; GER: German; N/A: Not available; S: Semantic; S-GER: Swiss-German. Reprinted from supplemental material to [57], published by SPRINGER under CC BY 4.0*

8.VIII Cluster-wise Sociodemographics Table

Because this table works much better (sortable, searchable) in its interactive online version published with the article [58] the jury and I decided to remove it from here. Navigate to DOI: 10.1371/journal.pone.0286557.s001 to find an interactive html version of this table.

8.IX Additional IPOS-Dem Item Characteristics

This table works much better (sortable, searchable) in its interactive online version published with the article [58] and is only here for completions sake. Navigate to DOI: 10.1371/journal.pone.0286557.s002 to find an interactive html version of this table.

#	Item	vars	n	miss	pct_n	mean	sd	median	trimmed	mad	min	max	range	skew	kurtosis	se	IQR	cor	discrimination	difficulty
1	*Pain*	1	462	26	0.05	1.27	1.05	1	1.18	1.48	0	4	4	0.56	−0.3	0.05	2	0.42	0.42	0.32
2	*Shortness of breath*	2	474	14	0.03	0.24	0.61	0	0.08	0	0	4	4	2.97	9.73	0.03	0	0.27	0.27	0.06
3	*Weakness*	3	476	12	0.02	1.47	1.09	1	1.41	1.48	0	4	4	0.42	−0.43	0.05	1	0.57	0.57	0.37
4	*Nausea*	4	460	28	0.06	0.23	0.63	0	0.07	0	0	4	4	3.26	12	0.03	0	0.37	0.37	0.06
5	*Vomiting*	5	472	16	0.03	0.1	0.43	0	0	0	0	4	4	5.52	34.24	0.02	0	0.3	0.3	0.02
6	*Poor appetite*	6	473	15	0.03	0.77	1.02	0	0.59	0	0	4	4	1.29	1.04	0.05	1	0.55	0.55	0.19
7	*Constipation*	7	456	32	0.07	0.67	0.9	0	0.52	0	0	4	4	1.32	1.3	0.04	1	0.45	0.45	0.16
8	*Sore or dry mouth*	8	443	45	0.09	0.43	0.87	0	0.22	0	0	4	4	2.27	4.95	0.04	0.5	0.47	0.47	0.1
9	*Drowsiness*	9	473	15	0.03	1.53	1.16	1	1.45	1.48	0	4	4	0.44	−0.56	0.05	1	0.55	0.55	0.38
10	*Poor mobility*	10	478	10	0.02	1.24	1.38	1	1.05	1.48	0	4	4	0.78	−0.74	0.06	2	0.52	0.52	0.31
11	*Sleeping Problems*	11	461	27	0.06	0.81	1.03	0	0.63	0	0	4	4	1.17	0.53	0.05	1	0.5	0.5	0.19
12	*Diarrhoea*	12	459	29	0.06	0.32	0.71	0	0.15	0	0	4	4	2.67	7.75	0.03	0	0.27	0.27	0.08
13	*Dental Problems*	13	453	35	0.07	0.57	1.02	0	0.33	0	0	4	4	1.92	2.96	0.05	1	0.42	0.42	0.13
14	*Swallowing problems*	14	473	15	0.03	0.49	0.98	0	0.24	0	0	4	4	2.2	4.17	0.05	1	0.49	0.49	0.12
15	*Skin breakdown*	15	478	10	0.02	0.99	1.1	1	0.83	1.48	0	4	4	0.93	−0.07	0.05	2	0.38	0.38	0.25
16	*Difficulty communicating*	16	479	9	0.02	1.59	1.4	1	1.5	1.48	0	4	4	0.36	−1.15	0.06	3	0.61	0.61	0.4
17	*Hallucinations and/or delusions*	17	438	50	0.1	0.78	1.14	0	0.56	0	0	4	4	1.32	0.63	0.05	1	0.47	0.47	0.17
18	*Agitation*	18	482	6	0.01	1.72	1.29	2	1.65	1.48	0	4	4	0.23	−1	0.06	2	0.56	0.56	0.43
19	*Wandering*	19	475	13	0.03	1.26	1.4	1	1.07	1.48	0	4	4	0.69	−0.91	0.06	2	0.42	0.42	0.31
20	*Anxious or worried*	20	480	8	0.02	1.78	1.08	2	1.8	1.48	0	4	4	−0.1	−0.68	0.05	2	0.6	0.6	0.45
21	*Family anxious or worried*	21	384	104	0.21	1.55	1.33	1	1.44	1.48	0	4	4	0.42	−0.95	0.07	2	0.42	0.42	0.36
22	*Felt Depressed*	22	456	32	0.07	1.54	0.99	2	1.53	1.48	0	4	4	0.04	−0.68	0.05	1	0.55	0.55	0.39
23	*Lost interest*	23	414	74	0.15	1.1	1.16	1	0.97	1.48	0	4	4	0.7	−0.64	0.06	2	0.54	0.54	0.27
24	*Inner peace*	24	418	70	0.14	1.52	0.94	1	1.49	1.48	0	4	4	0.59	−0.08	0.05	1	0.46	0.46	0.36
25	*Able to interact*	25	481	7	0.01	1.5	1.27	1	1.42	1.48	0	4	4	0.35	−1.06	0.06	3	0.52	0.52	0.37
26	*Irritable or agressive*	26	481	7	0.01	1.36	1.04	1	1.3	1.48	0	4	4	0.17	−0.87	0.05	2	0.49	0.49	0.34
27	*Practical matters*	27	454	34	0.07	1.4	1.13	1	1.3	1.48	0	4	4	0.56	−0.4	0.05	1	0.36	0.36	0.34

Supplementary Material B: Item characteristics.

This file shows additional item characteristics for the easy-read IPOS-Dem and complements Table 12. Reprinted from supplemental material to [58], published by PLOS under CC BY 4.0

8.X Ethics approval

Kanton Zürich
Kantonale Ethikkommission

Prof. Dr. med. Konrad E. Bloch
Präsident Abteilung B

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Dekanat für Forschung und Entwicklung
Prof. Dr. Andrea Koppitz
Route des Arsenaux 16a
1700 Fribourg

21. Oktober 2022 / ere

Verfügung der Kantonalen Ethikkommission Zürich

Wesentliche Änderung

Eingereicht am	11.10. und 19.10.2022
BASEC-Nr.	2019-01847
Projekttitel	Burden of disease of people with dementia in nursing homes measured by IPOS-Dem: a stepped-wedge cluster randomized controlled trial
Gesuchsteller/in	Prof. Dr. Andrea Koppitz, HedS Fribourg
Zentrum	Prof. Dr. Andrea Koppitz, HedS Fribourg

Entscheid

Die Bewilligung wird erteilt.
Allfällige weitere Bewilligungspflichten sind zu beachten (siehe Hinweise im Anhang).

Entscheidverfahren

☐ vereinfachtes Verfahren ☒ Präsidialentscheid

Gebühren
Betrag: CHF 250.- Tarifcode: 3.3.1
Gemäss der geltenden Gebührenordnung von swissethics.

Rechtsmittelbelehrung

Gegen diesen Beschluss kann innert 30 Tagen, von der Mitteilung an gerechnet, beim Regierungsrat des Kantons Zürich schriftlich Rekurs eingereicht werden.
Die Rekursschrift muss einen Antrag und dessen Begründung enthalten. Der angefochtene Entscheid ist beizulegen oder genau zu bezeichnen. Die angerufenen Beweismittel sind genau zu bezeichnen und soweit möglich beizulegen.

Kopie an

☐ Sponsor
☐ Swissmedic
☐ Bundesamt für Gesundheit
☒ beteiligte Ethikkommissionen : EK NZ, EK OS
☐ andere:

i.V.

Prof. Dr. med. Konrad E. Bloch
Präsident

Dr. med. Peter Kleist
Geschäftsführer

Anhang: - Liste der eingereichten Dokumente