1

General Introduction
Chapter 1

The work in thesis focuses on pain and challenging behaviour in advanced dementia. More specifically, it investigates the effectiveness and implementation of a stepwise multidisciplinary and multicomponent intervention for pain and challenging behaviour in patients with advanced dementia residing in nursing homes.

Dementia, challenging behaviour and pain

Dementia is defined as a ‘clinical syndrome due to disease of the brain, usually of a progressive nature, which leads to disturbances of multiple higher cortical functions, including memory, thinking, orientation, comprehension, calculation, learning capacity, language, and judgment’. According to estimates of the World Alzheimer Report 2015, worldwide there are 46.8 million people with dementia, and this number is expected to increase to 74.7 million people by 2030 and to 131.5 million by 2050. Currently, 5-8% of people aged over 60 years have a diagnosis of dementia, rising to over 50% in the 90+ group. For the near future, these estimates seem correct; however, on the longer term these estimates remain debatable. Investigation of these trends over time is challenging, as changes in diagnostic criteria and other methodological variations could affect these estimates of prevalence and incidence. Recent reports suggest an age-specific decline of the incidence rates of dementia in high-income countries, i.e. the risk of being diagnosed with dementia at a certain age appears to decrease slightly. However, no evidence has been found for a decline in incident rates in the Netherlands. Nevertheless, this does not mean that dementia is less prevalent. It is estimated that demographic changes in the coming decades and the increasingly ageing population will lead to a substantial growth in the absolute number of people affected. Currently, in the Netherlands there are approximately 270,000 people with dementia, of whom 70,000 reside in nursing homes. The most common cause of dementia is Alzheimer's Disease; other types include Vascular Dementia, Frontotemporal Dementia and Lewy Body Dementia (although mixed versions are also prevalent).

Challenging behaviour

In all subtypes of dementia, neuropathological changes in the brain are responsible for the decline in function. Besides the deleterious effects on cognition, the neuropathology of dementia is (partially) responsible for numerous other symptoms, such as behavioural disturbances, psychological problems, and the breakdown of language and communication. Symptoms include delusions, hallucinations, agitation/aggression, dysphoria/depression, anxiety, euphoria/elation, apathy/indifference, disinhibition, irritability/lability, aberrant motor behaviour and night-time disturbances. In patients with dementia, up to 80-85% have one or more of these (clinically relevant) symptoms. In addition to these neuropathological changes in the brain, contextual factors, like other health, psychosocial and environmental factors contribute to (or
maintain) an episode of challenging behaviour. The changes in behaviour and emotional/psychological problems have been categorized in many ways. For example, they have been summarized as Behavioural and Psychological Symptoms of Dementia. Alternatively, they have been referred to as neuropsychiatric symptoms or as ‘challenging behaviour’.\(^{11,12,15}\) However, among the general public, memory dysfunction is the best-known symptom; nevertheless, the above-mentioned symptoms have the highest impact on the quality of life\(^{16,17}\) and are one of the main reasons for seeking help and institutionalization.\(^{17,18}\) Furthermore, memory dysfunction is the symptom that most often leads to increased demands on staff resources, increased job-related stress, burnout, and staff turnover; these symptoms are often extremely distressing for both the individual and their caregivers\(^{19-22}\). Therefore, in this thesis, all these symptoms are collectively referred to as ‘challenging behaviour’, as they present a substantial challenge to the individual with dementia, as well as to the informal/formal caregivers that support these women.\(^1\)

**Pain and pain assessment**

A particular challenge in the care of patients with dementia is the presence of pain. The prevalence of pain, particularly chronic pain, is strongly related to age, affecting the oldest population the hardest, with prevalence rates of 72% above age 85 years.\(^{23,24}\) Given these circumstances, pain is very common among people with dementia. Pain in dementia is often expressed through behavioural disturbances. In fact, pain is thought to be one of the most important causes of challenging behaviour.\(^{25}\) However, this causal link is often difficult to identify due to the complexity of the challenging behaviour, which changes over the stages of dementia and is often more frequent in the later stages of the disease.\(^{26}\) Challenging behaviours that arise as a result of pain, such as agitation and aggression\(^{27,28}\), can be extremely distressing for both the individual and their caregiver, and can lead to inappropriate prescribing of antipsychotic medication instead of adequate pain treatment.\(^{29}\) Whilst these medications do have their place in the treatment of severe or persistent psychiatric symptoms, they are also associated with substantial side-effects in persons with dementia, including increased mortality, cerebrovascular events, and falls.\(^{27,30}\)

Especially in the more advanced stages of the disease, detection of pain is difficult due to severe cognitive and communication problems.\(^{31}\) As a result, commonly used self-report assessment tools are often either not valid and/or not reliable, and are also difficult to use. However, **assessment of pain** is the prerequisite for appropriate **pain treatment**. Pain assessment requires an understanding of the neurobiology of the pain experience
and the behavioural expression of pain\textsuperscript{32}, together with knowledge of the clinical assessment instruments.\textsuperscript{33-35} Therefore, it is recommended to combine different assessment techniques to detect pain in dementia.\textsuperscript{36} These techniques include observation of both verbal (e.g. ‘calling out’) and non-verbal (e.g. frowning, agitation) behaviour, with physical examination\textsuperscript{37} that can focus on musculoskeletal conditions, such as arthritis and osteoporosis, respiratory and urinary tract infection, injury from falls, orofacial pain, and pressure ulcers.\textsuperscript{25} A similar complexity applies to the treatment of chronic pain in dementia, which justifies a combination of a non-pharmacological and a pharmacological approach.\textsuperscript{38,39} Particularly in the advanced stages of dementia, with a high prevalence of multi-morbidity and polypharmacy, non-pharmacological interventions may have safety benefits.\textsuperscript{38}

To summarize: both pain and challenging behaviour are highly prevalent in dementia\textsuperscript{40}, and the entanglement between the two makes their relationship (as well as their assessment and treatment) complex and difficult for caregivers.\textsuperscript{25,41,42} However, a literature review that preceded the start of this thesis, revealed that only one intervention was available that specifically acknowledges this complexity.\textsuperscript{43} This implies that there is a considerable demand for useful guidelines, protocols, etc., to help caregivers deal with these complex and challenging situations.

**Serial Trial Intervention (STI)**

The only intervention that acknowledges this complexity of both assessment and treatment of pain in the advanced stages of dementia, and combines non-pharmacological and pharmacological interventions for pain, unmet needs and challenging behaviour, is the Serial Trial Intervention (STI)\textsuperscript{44}, developed by Christine Kovach in the USA. The STI is designed to assess and manage unmet needs in residents with advanced dementia who are no longer able to clearly or consistently communicate pain and other unmet needs through spoken language. The STI directs nurses to respond to these behavioural symptoms by implementing multiple levels of assessment and treatment. It allows nurses to tailor both assessment and treatment components to the individual resident. The steps are designed to identify and treat the underlying problem and, when an underlying problem is not readily apparent, trials of non-pharmacological treatments, pharmacological treatments and/or consultation are implemented.\textsuperscript{44,45} In a randomised controlled trial (RCT), Kovach et al. show that this intervention (applying a stepwise protocol in patients with dementia in nursing homes in the USA) can decrease discomfort and expressions of challenging behaviour.\textsuperscript{46,47} Moreover, they also show that this stepwise intervention supports and assists healthcare professionals to handle these complex problems and challenges.\textsuperscript{48}
However, the organisation, availability and level of education of the staff, as well as the availability of additional resources, differ across settings and countries. Therefore, to apply this method in the Netherlands, the STI had to be translated and adapted for the Dutch language and the Dutch nursing home care setting. The Dutch version of the STI is called ‘STApgewijs Onbegrepen gedrag en Pijn bij dementie de baas! (STA OP!’.

Nursing home care setting
Although the exact definition of a ‘nursing home’ differs between countries, generally, a nursing home is seen as a facility that admits mainly older people who require assistance with (instrumental) activities of daily living and have identifiable health needs. They provide 24-hour, 7-days/week functional support in a domestic-styled environment, which can be organised in traditional large-scale units, small-scale units, or in more innovative settings (such as a care farm). The multidisciplinary and complex long-term care for residents with advanced dementia or ‘psychogeriatric care’ is delivered on specialised care units, while care for residents with chronic physical problems is delivered on somatic units. In addition, Dutch nursing homes also provide short-term care and services, such as geriatric rehabilitation.

The nursing staff provides most of the 24-hour care: in the Netherlands, this consists mainly of: i) persons with a vocational education plus 2-3 years training as a certified nurse assistant (‘verzorgende’; Dutch qualification level 3), or ii) nurse assistants (‘Helpende’; Dutch qualification level 2), and (sometimes) iii) registered nurses with 4-years vocational training (‘MBO-verpleegkundige’; Dutch qualification level 4) or a Bachelor’s degree (HBO-verpleegkundige; Dutch qualification level 6).

In addition, typical for Dutch nursing homes is that they employ specialised elderly care physicians to provide and coordinate medical care. Furthermore, most nursing homes also employ other healthcare professionals, such as psychologists, physiotherapists and occupational therapists. Altogether, these professionals form the multidisciplinary care team, which provides continuous long-term care in these homes. However, in order to meet the complex (care) needs of nursing home residents with advanced dementia and challenging behaviour and/or with pain, enhancing the knowledge and competencies of both nursing staff and other healthcare professionals is of considerable importance.

Aims and research questions
The overall aim of this thesis is to investigate the implementation and effectiveness of the stepwise, multidisciplinary and multicomponent intervention for pain and challenging behaviour in dementia, the STA OP! (acronym for the adapted and translated version of the STI).
Chapter 1

The main research questions addressed in this thesis are:
1. What is the current state-of-the-art with respect to challenges related to pain management in dementia?
2. What is the current state of evidence regarding the effectiveness of interventions targeting pain on the outcome ‘behaviour’, and interventions targeting behaviour on the outcome ‘pain’, in dementia?
3. Does implementation of the STA OP! lead to a reduction of pain and improvement of pain management in residents with advanced dementia?
4. Does implementation of the STA OP! lead to fewer expressions of challenging behaviour, better mood, and less use of antipsychotics in residents with advanced dementia?
5. With regard to the implementation process of the STA OP! intervention:
   a. What are the experiences of healthcare professionals with implementation of STA OP! and its actual use in daily practice?
   b. Is STA OP! delivered and implemented as intended at the level of the team and of the individual resident/professional?
   c. What facilitating or impeding factors are associated with implementation at the level of the organisation, the team, or the individual resident/professional?

Outline of this thesis
To answer the first two research questions, two literature studies were conducted. To investigate research questions 3 and 4, a cluster RCT was performed involving nursing home residents with advanced dementia, and with pain and/or challenging behaviour; to examine the final question, a process evaluation was performed alongside the cluster RCT in which we describe in detail the implementation process of the STA OP!

Chapter 2 discusses the evidence from relevant and recent literature regarding the challenges of pain management in dementia. The review focuses on four main perspectives that are critical to this discussion, i.e. 1) The biological perspective: the effect and consequences of neuropathological changes in dementia on pain; 2) The assessment perspective: the challenges of pain assessment in dementia; 3) The organisational and educational aspects that challenge pain management in dementia; and 4) Pain management in practice. Chapter 3 provides a comprehensive overview

2 When studying complex multicomponent interventions, it is important to investigate how and to what extent the intervention is implemented, and to identify and understand the factors that facilitate or impede implementation, since care innovations do not automatically find their way into practice. In order to describe the implementation process of the STA OP! intervention, we added a new research question to the five described in the study protocol (Chapter 3). Due to the addition of this question, the limited funding and the renewed regulations regarding PhD theses, we skipped the questions included in the study protocol a) if use of STA OP! resulted in a change in the use of non-pharmacological comfort interventions, b) if the effect of the intervention was moderated by the Apo-E4 status of the patient, and c) if the use of STA OP! led to a change in the quality of life in patients with dementia. The latter item is part of a thesis on the quality of life in advanced dementia.
of the current state of evidence regarding the effectiveness of interventions targeting pain on the outcome behaviour, and the effectiveness of interventions targeting behaviour on the outcome pain, in dementia. In Chapter 4 we describe the design of the STA OP! study, a cluster RCT that investigates the effectiveness of the stepwise multidisciplinary and multicomponent intervention for pain and challenging behaviour in advanced dementia. Chapters 5 and 6 report the results of the cluster RCT. Chapter 5 focuses on the effects of the intervention on challenging behaviour, symptoms of depression and psychotropic medication use, and Chapter 6 reports the effects of the intervention on pain, pain management, and pain medication. Chapter 7 describes in detail the implementation process of the STA OP! intervention, i.e. whether the intervention was implemented as planned, and the facilitating/impeding factors, as well as the experiences of healthcare professionals regarding implementation of the intervention and its usage in daily practice. The last chapter of this thesis, Chapter 8, presents a summary and general discussion of the results of the studies described in this thesis. General findings are put into context, methodological considerations and clinical implications are addressed, and some recommendations are made for future studies.
REFERENCES


