Summary

For many patients cancer pain is an important source of concern. Particularly in the outpatient setting, pain management is a major challenge. In response to and in line with developments in healthcare, supporting self-management and implementing eHealth could be meaningful for these patients as well. This project was initiated for the development and evaluation of an eHealth intervention for outpatients with moderate to severe cancer pain. The aim of the intervention was to support self-management in order to improve pain control and quality of life. In that context a number of studies were conducted and are presented in this thesis.

Chapter 1

In this chapter the general introduction for this thesis is described. Background information regarding cancer pain is provided. Moreover, a description of regular care informs about the methods that are used to detect, assess, and treat pain complaints. It is well known that inadequate pain relief can be attributed to different barriers. Existing interventions and further recommendations are shared. In that context, the concepts 'self-management' and 'eHealth' are clarified. This chapter ends with the objectives and outline of this thesis.

Chapter 2

This chapter contains a systematic literature review with a meta-analysis that was conducted to determine the prevalence of cancer pain; the prevalence of moderate to severe cancer pain; and the determinants that are associated with cancer pain. A total of 122 articles were selected and categorised into groups based on disease stage: patients after finishing curative treatment (group 1); patients receiving anti-cancer treatment, with curative or palliative intention (group 2); patients with advanced, metastatic and/or terminal disease (group 3); all patients regardless of their disease stage (group 4).

Pain is prevalent in 39.5% of the patients in group 1; in 55.0% of the patients in group 2; in 66.4% of the patients in group 3; and in 50.7% of the patients in group 4. Patients in group 3 experience significantly more pain compared to patients in group 1 and 2. Patients in group 2 experience significantly more pain compared to patients in group 1. Moderate to severe pain is prevalent in 27.6% of patients in group 1; in 32.4% of patients in group 2; in 51.9% of patients in group 3; and in 33.1% of the patients in group 4. Patients in group 3 experience significantly more moderate to severe pain compared to patients in group 1 and 2.

Studies from Asia show higher prevalence rates compared to studies from Europe. Patients with prostate cancer report less pain compared to patients with head-neck,

lung-, and breast cancer. Patients with a limited performance status experience more pain compared to patients with a normal performance status. Recall periods of a month or a year result in higher pain prevalence rates compared to recall periods of a week or a point in time. Age, race or data collection method are not associated with pain prevalence. Cancer pain continues to be a significant problem.

Chapter 3

The match between wishes and needs of patients and health professionals is essential for successful eHealth interventions. Intervention development was carried out based on key principles of user centred design (UCD) and is reported on in this chapter. A multidisciplinary team was composed; a co-creative and iterative process was initiated; researchers and technicians collaborated to concretise conceptual ideas; patients and health professionals were consulted to gain input and evaluate output; prototypes were used to visualise solutions; and user and technical requirements were formulated, specified, and prioritised.

The outcome of this process is an intervention consisting of a home visit, a mobile application for patients, a web application for nurses, and follow-up activities. During the home visit the nurse performs a pain assessment, checks pain medication, and provides information about pain. The main researcher gives instructions about the application and discusses expectations. Throughout the intervention period, patients make use of the intervention on a daily basis. Pain is monitored every morning and evening by means of a diary; medication intake is registered with a personalised day schedule; a graph with pain intensity scores and mediation intakes provides insight; information about pain is presented in knowledge sessions; in case of questions or remarks there is contact with the nurse via text messages.

Nurses enter the web application every workday and take note of completed diaries, medication intakes, and text messages. The nurse informs the treating physician, when needed and on a regular basis. Nurses can rely upon advices of the pain specialist or multidisciplinary team. This advice is reported to the treating physician who decides on follow-up.

Chapter 4

Small-scale feasibility evaluation in everyday life is a crucial step in the development and testing of complex interventions and is dealt with in this chapter. In the current study, thirteen patients and three nurses made use of the intervention with a follow-up of 4 weeks.

Questionnaire findings show that patients learned to use the application quickly, practiced tasks easily, and liked to work with the application. Average completion rates, as recorded in server logs, were 76.8% for pain monitoring, 50.4% for

medication monitoring, and 100% for education sessions. Important in terms of feasibility is that most patients kept monitoring regardless of low or high pain intensity scores. Interviews reveal that patients valued and made use of different intervention components. Some indicate that the diaries create some kind of awareness each time; others preferred the reminders in order to not forget their medication; still others were enthusiastic about the nurse who is always looking over their shoulder.

Nurses were positive about the intervention, though had to get used to a new way of working. They had to rely on eHealth rather than face to face, on patients who had to provide them with the right information, and on treating physicians who had to consider their advises. In general study results confirm feasibility of the intervention in every day practice. Provided that substantive and technical adjustments were made, the intervention had the potential to contribute to self-management (support) of cancer pain.

Chapter 5

This chapter describes the protocol of a large-scale randomised and controlled study to compare self-management support with care as usual. The study would include an effect, cost, and process evaluation and was initially planned and organised as follows:

'Recruitment of the necessary 174 patients is performed via outpatient oncology clinics and inpatients oncology wards of one academic and one regional hospital. Patients are eligible when they are diagnosed with cancer (all stages of the disease), have moderate to severe pain (NRS ≥4 for >2 weeks), and a life expectancy of >3 months. Random allocation (1:1) assigns patients to either the intervention or control group. Patients in the intervention group will receive self-management support by means of the eHealth intervention; patients in the control group will receive care as usual. The intervention is delivered by registered nurses specialised in pain and palliative care.

Effect measurements for both groups will be carried out with questionnaires at baseline (T0), after 4 weeks (T1), and after 12 weeks (T2). Pain and quality of life are primary outcomes. Secondary outcomes are knowledge, self-efficacy, anxiety and depression, and medication use. The final questionnaire contains also questions for the cost evaluation. Data for the process evaluation will be gathered continuously in both groups during the study using logbooks, log files, and checklists. After the intervention, semi-structured interviews will be performed with patients in the intervention group and at the end of the study a focus group interview with nurses.'

Chapter 6

This chapter presents the results of the randomised and controlled study and particularly provides insight into the course of the study and process outcomes. Eventually, three phases can be distinguished.

The study kicked off in two centres (phase 1a) and was then extended to four centres (phase 1b) with at random allocation to the intervention or control group. Because the intervention was performed as part of the medical treatment contract, treating physicians were designated to recruit patients. In practice recruitment was often delegated to the nursing staff. Printed folders and recruitment cards were offered; screening lists and a trial agency were used; presentations and recruitment updates were distributed. Despite all efforts, inclusion rates continued to lag behind. The most important reason for treating physicians not to recruit was 'not being eligible', the most frequent mentioned reason for patients not to participate was 'being too ill'. Different factors probably affected recruitment including the recruitment strategy, the research design, the type of intervention, and the patient sample.

Because of low inclusion numbers, possible selection bias, and high dropout rates the study was continued with allocation to the intervention group only (phase 2). A total of 66 patients gave informed consent and 54 patients actually started. Patients were on average 62.4 years, 59.3% was male and 83.3% received anti-tumour treatment with palliative intent. Ultimately, 47 patients filled out the in-between measurement and 32 patients completed the entire study period. Due to the final protocol amendment, the focus of the study shifted from a comparison between the eHealth intervention and care as usual to the impact of the eHealth intervention. As a consequence process outcomes were more valuable and received more attention.

Based on semi-structured interviews with 21 patients and a focus group interview with four nurses, experiences have been inventoried. Some variation was seen both in the implementation of the home visit as well as in the selection of follow-up activities, partly caused by the situation of patients and the work routines of nurses. Patients appreciated the introduction and nurses were positive about the pragmatic approach. Technical flaws made the applications slow or stalling at times. In general, patients were satisfied, which is reflected in the average completion rates of pain monitoring (78.8%), medication monitoring (65.5%), and education sessions (100%). Patients differ in their answers as to what extent the intervention supported them in their self-management, though confirm in many cases that the intervention helped them in increasing awareness, taking medication on time, getting insight, learning about pain and the treatment of pain, and discussing pain with their treating physician. Nurses underline that this or a similar intervention could complement usual care for outpatients with cancer pain. Notwithstanding these positive findings, no conclusions can be drawn yet regarding clinical effectiveness of the intervention based on effect outcomes, due to the small sample size and the protocol amendments.

Chapter 7

Finally, the general discussion provides a reflection on the main findings and addresses some methodological considerations that focus on the measurement and assessment of cancer pain; the focus on patients and their needs and wishes; and the evaluation of eHealth interventions. Moreover, theoretical considerations are discussed in terms of the definition of self-management; intervention components of self-management support; and the operationalisation of self-management. The chapter concludes with some implications for practice, research, and policy.