Self-management support for patients with incurable cancer and their partners

Schuit, Anouk Suzanne

2022

document version
Publisher's PDF, also known as Version of record

citation for published version (APA)
Schuit, A. S. (2022). *Self-management support for patients with incurable cancer and their partners: The eHealth application Oncokompas and organization of psycho-oncological care*. [PhD-Thesis - Research and graduation internal, Vrije Universiteit Amsterdam].

Self-management support for patients with incurable cancer and their partners

The eHealth application Oncokompas and organization of psycho-oncological care

Anouk Suzanne Schuit

The research presented in this thesis was performed at the Faculty of Behavioral and Movement Sciences, department of Clinical-, Neuro- and Developmental Psychology of the Vrije Universiteit Amsterdam, within the Amsterdam Public Health institute (APH) and Cancer Center Amsterdam (CCA). The research described in this thesis was funded by ZonMw, The Netherlands Organization for Health Research and Development (project no. 844001105).

Cover design: David Schuit & Esther Schuit
Lay-out: Douwe Oppewal
Printed by: Ipskamp Printing, Enschede
ISBN: 978-94-6421-863-3

Financial support for printing this thesis was kindly provided by Opa, Cancer Center Amsterdam and the Faculty of Behavioral and Movement Sciences, Vrije Universiteit Amsterdam.

FSC
www.fsc.org
MIX
Paper from
responsible sources
FSC® C128610

VRIJE UNIVERSITEIT AMSTERDAM

SELF-MANAGEMENT SUPPORT FOR PATIENTS WITH INCURABLE CANCER AND THEIR PARTNERS

The eHealth application Oncokompas and organization of psycho-oncological care

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad Doctor aan
de Vrije Universiteit Amsterdam,
op gezag van de rector magnificus
prof.dr. J.J.G. Geurts,
in het openbaar te verdedigen
ten overstaan van de promotiecommissie
van de Faculteit der Gedrags- en Bewegingswetenschappen
op woensdag 23 november 2022 om 13.45 uur
in de aula van de universiteit,
De Boelelaan 1105

door

Anouk Suzanne Schuit
geboren te Leiderdorp

promotoren:	prof.dr. I.M. Verdonck - de Leeuw prof.dr. W.J.M.J. Cuijpers
copromotor:	dr. C.J.M. Holtmaat

promotiecommissie: prof.dr. M.M. Riper
prof.dr. J.E. Bosmans
prof.dr. A.L. Francke
prof.dr. M. van der Lee
prof.dr. C.C.D. van der Rijt
dr. M.M.H. Lahr

*“We cannot direct the wind,
but we can adjust the sails”*

- Unknown

TABLE OF CONTENTS

1

GENERAL INTRODUCTION

Incurable cancer challenges patients and their partners to deal with cancer related symptoms and concerns, influencing their quality of life. Patients might face physical or psychological symptoms, or have social or existential concerns. Partners of patients with incurable cancer often fulfill different support roles and have to find a balance between their caregiver role, and being a partner. Self-management interventions could support both patients and their partners to deal with cancer and its side-effects in their daily lives.

This thesis focuses on self-management among incurably ill cancer patients and their partners, and the efficacy and cost-utility of the eHealth application Oncokompas in particular. In addition, a perspective of patients on the organization of psycho-oncological care is provided. This thesis concentrates on patients with incurable cancer (i.e., patients who have no curative treatment options) with a life expectancy of at least three months, and their partners.

This first chapter provides background information on cancer and its treatment, followed by current knowledge on psycho-oncological care and self-management applications in particular. The aim and outline of this thesis are presented at the end of this chapter.

LIVING WITH CANCER

Impact of cancer on patients

In the Netherlands, more than 110.000 patients are diagnosed with cancer annually and approximately 45.000 patients die of cancer each year[1,2]. Mortality rates vary considerably for patients with different cancer types. In 2020, most patients died of lung cancer, prostate cancer (men), breast cancer (women), and colorectal cancer[3]. Better treatment options make it possible to live with incurable cancer for a longer period of time[3,4]. For some patients, cancer care focuses on acute illness with short-term outcomes, while others live with cancer as a more stable and chronic condition and are in need of long-term support. In the palliative phase of cancer, several treatments can be provided to patients to prolong life, and to reduce pain or other side effects of cancer: chemotherapy, targeted therapy, immunotherapy, radiation, or surgery[5].

Patients living with incurable cancer often experience many challenges. The most frequently reported physical symptoms are fatigue, pain, lack of energy, weakness and appetite loss[6]. Furthermore, distress and psychological symptoms (e.g., anxiety or depression) are frequently reported among patients with incurable cancer[7]. Also, social consequences are substantial, for example regarding social engagement, social identity and the social network. Many struggle to proceed with their social life as prior to cancer, and feel socially excluded to some extent or feel that cancer has become central in their social life[8]. In addition, patients have to deal with existential challenges, such as being confronted with mortality due to a limited life span[9], feeling hopelessness or having concerns about autonomy[10].

Impact of cancer on patients' partners

Cancer also has a considerable impact on the lives of patients' partners. Partners of patients with cancer often play a major role in caring for their loved one[11–13]; they often provide practical (e.g., transportation, household tasks, managing and coordinating medical care) and emotional support[14]. Although caring for a loved one is often rewarding[14,15], it also can be challenging and caregiving responsibilities are associated with physical, psychological, and social difficulties[12–14,16,17]. In the Netherlands, 5 million people provide informal care to relatives or someone close, of whom 825.000 (16%) provide intensive care (> 8 hours per week) for a long period of time (> 3 months). 9% of the informal caregivers is seriously burdened due to caregiving[18]. Unfortunately, it is not clear how many of those caregivers are partners who are caring for a patient with incurable cancer in particular.

Physical problems often reported by partners include sleep disturbance, fatigue, loss of appetite, loss of physical strength, and weight loss[12]. Caregiving could also impact partners' emotional or mental health[19] and cause psychological distress[11,12,20]. Many partners experience caregiver burden[19,21,22], negatively affecting their quality of life. Caregiver burden can be described as "*the extent to which caregivers perceive that caregiving has an adverse effect on their emotional, social, financial, physical, and spiritual functioning*"[23].

Palliative care

Palliative care is an important and integral part of supportive care (i.e., the prevention and management of symptoms or side-effects of cancer and its treatment across all phases of the cancer experience)[24]. The World Health Organization (WHO) describes palliative care as "*an approach that improves the quality of life of patients and their families who are facing problems associated with life-threatening illness. It prevents and relieves suffering through the early identification and assessment of pain and other problems, whether physical, psychosocial or spiritual*"[25]. Palliative care is valuable at the time of diagnosis of advanced cancer and prior to end of life, but often mistakenly assumed to be a synonym of hospice care[4]. Compared to hospice care, palliative care may be integrated earlier in the cancer trajectory and can be delivered at the same time as disease-directed care. It targets all patients with serious illness; both patients who are receiving life-prolonging therapy and those who are not. Palliative care can be provided in inpatient and outpatient settings[4]. Palliative care also comprises psycho-oncological care, which aims to reduce psychosocial distress and maintain health-related quality of life of patients and their informal caregivers[26].

Due to a growing demand on healthcare resources patients are increasingly expected to adopt an active role in managing their illness and well-being[27]. In addition, many patients want to be in charge of their lives as long as possible, as well as their relatives. Palliative care interventions help patients and their relatives to manage their symptoms. These interventions are often tailored to the individual to maximize their benefits and to ensure affordable and effective care. Tailored web-based applications have the potential to increase self-management skills and to help patients and their relatives to adopt an active role in managing symptoms.

Self-management

Self-management is referred to as "*those tasks that individuals undertake to deal with the medical, role and emotional management of their health condition(s)*"[28]. It concerns several processes including problem solving, decision making, utilizing resources, collaborating in the relationships with healthcare providers, and taking actions to minimize the impact of the disease[29].

Self-management strategies among patients with incurable cancer cover multiple domains. Among others, it includes medicine and pharmacology, and life style changes (e.g., self-administering medication and monitoring symptoms, or adjusting nutrition, diet and exercise). It also comprises taking actions regarding mental health and social support (e.g., the use of mindful self-help strategies, doing meaningful activities and seeking social support from relatives, friends and healthcare professionals). Furthermore, gaining knowledge about the disease, medical decision-making, and navigating through the (medical) system are part of self-management[30,31]. Patients might use various strategies to deal with cancer in their daily lives, depending on their preferences and characteristics.

Interventions targeting self-management behavior in patients often address the development of knowledge and/or skills on the disease and its symptoms, the activation of patients to adopt and sustain new behaviors and the provision of care coordination and support[31] (as for example, a nurse administered educational intervention[32], a web-based collaborative care intervention[33], or consultations with a multidisciplinary supportive care team[34]). Earlier research suggested that when patients' knowledge, skills and confidence to self-manage their disease (i.e., patients' activation levels) are positively affected[35], positive changes in self-management behaviors will follow[36]. eHealth shows positive effects regarding communication between patients, close relatives and healthcare providers and in promoting individualized care, enabling users to take an active role in their own care if they want to[37].

eHealth

eHealth refers to health services and information delivered through the Internet and related technologies to improve health, well-being and healthcare[38,39]. The concept of eHealth is broad; the use of eHealth varies regarding its place in healthcare (e.g., support care delivery, manage care or promote prevention and education), its characteristics (e.g., robotics, wearable devices, virtual reality, personal health records or web-based applications) and its influence on the healthcare system (e.g., wearables versus collaborative decision-making support systems)[39]. Benefits of digital health interventions are 24/7 availability[40], the possibility of tailoring information and advice to users' needs[40], and increased access to care[37].

Behavioral interventions technologies (BITs) are behavioral and psychological interventions designed to affect the actions people undertake regarding their health, and aimed to change behaviors related to health and well-being[39,41]. The amount of clinical support provided to users of BITs varies. Adjunctive BITs are designed as an assistive tool, supplementing or enhancing the care delivered by a healthcare professional. Guided BITs are technologies directing key aspects of care with support from a healthcare professional. Fully automated BITs are delivered direct to the user for self-care, without support of a healthcare professional[42].

eHealth could be a part of a stepped care approach, in which treatment options are organized based on intensity (e.g., including watchful waiting, (guided) self-help, face-to-face therapy, and specialized interventions)[43,44]. In addition, it has the potential to contribute to value-based healthcare (VBHC) by improving overall health and well-being and keeping healthcare costs down. Maintaining quality of life while controlling costs is an important concern for patients, healthcare professionals, and policy makers[45]. VBHC emphasizes goal-directed care, and requires the input of patients and their families as experts regarding their illness experience[46]. Palliative care principles converge with several principles of VBHC[47], focusing on individual patients' values, wishes and goals while considering their quality of life, and allowing patients to actively take part in their healthcare process. It acknowledges the expertise of patients and their caregivers regarding their illness experience[46,48].

In this thesis, the behavioral intervention technology Oncokompas – developed to support users to adopt an active role in managing cancer-related symptoms – is examined among patients with incurable cancer and their partners.

Oncokompas

Initially, the eHealth application Oncokompas was developed to support cancer survivors to adopt an active role in managing their cancer related symptoms. Oncokompas is a fully automated BIT; the web-based application can be accessed by patients themselves, in their own time and at their own pace with 24/7 availability. From 2016 to 2018, the content of Oncokompas was extended, to make the application suitable for use among incurably ill cancer patients and their partners. Oncokompas was developed using the participatory design approach; stakeholders were included in every step of the design process[49].

Oncokompas follows the stepped care principle; it supports users to manage their symptoms on their own, with professional help when needed. It comprises three steps: 1) Measure, 2) Learn, and 3) Act. Within the step 'Measure', users can choose which topics they want to monitor within Oncokompas. Subsequently, patient-reported outcome measures (PROMs) are presented to the user to assess how someone is performing on a certain topic. PROMs can be used to investigate users' views on their symptoms, functional status, and their HRQOL[50]. The step 'Learn' presents an overview of the user's well-being, based on the patient's answers on the PROMs. Well-being scores are presented in red (a topic needs attention and support), orange (a topic could use attention and support), and green (someone is doing well on that topic). Users can read information on their specific symptoms and get tips and tricks on how to work on their symptoms. Lastly, the step 'Act' provides an overview of supportive care options. These options comprise (guided) self-help interventions (for topics with orange scores) and the advice to contact a general practitioner or medical specialist (for topics with red scores).

Previous studies showed that Oncokompas is considered feasible among survivors of head and neck cancer and survivors of breast cancer with an adoption grade of 64% and 75% respectively, and a mean satisfaction score of 7.3 and 7.6[51,52]. Among cancer survivors, Oncokompas did not improve the amount of knowledge, skills, and confidence for self-management[53]. However, the application improved HRQOL and tumor-specific symptom burden[53]. In addition, a study on the cost-utility of Oncokompas among cancer survivors showed that it is not more expensive than usual survivorship care[54]. A pilot study on the feasibility of self-management support delivered by nurses in the home setting, with Oncokompas integrated as eHealth component, showed that patients positively assessed Oncokompas as a self-management intervention. However, usage of the intervention was low and Oncokompas had no significant effect on patient activation or HRQOL[55]. Based on these findings, it was hypothesized that Oncokompas may be more beneficial in incurably ill cancer patients with longer life expectancy regarding patient activation and HRQOL, and as fully automated behavioral intervention technology.

Aim of this thesis

The overall aim of this thesis was to provide insight into the role of the web-based self-management intervention Oncokompas in palliative care, targeting patients with incurable cancer and their partners. To gain insight in patients' experiences with Oncokompas and their self-management strategies to cope with cancer in their daily life, a qualitative study was conducted to evaluate Oncokompas. Furthermore, patients' perspectives on organizing psycho-oncological cancer care, including eHealth, were investigated. Two randomized controlled trials (RCTs) were conducted to determine the efficacy and cost-utility of the eHealth application Oncokompas among incurably ill cancer patients and partners of incurably ill cancer patients.

Outline of this thesis

In chapter 2, patients' perspectives on the organization of psycho-oncological care are presented. Chapter 3 to 9 concern the eHealth application Oncokompas. In chapter 3, an overview is provided of Oncokompas. Chapter 4 describes the study protocol of the RCT among patients with incurable cancer. The results of the RCT to investigate the efficacy of Oncokompas among incurably ill cancer patients are described in chapter 5. Chapter 6 focuses on the cost-utility of Oncokompas among these patients. The findings of an interview study on patients' experiences with Oncokompas and their self-management strategies are presented in chapter 7. Chapter 8 describes the study protocol of the randomized controlled trial among partners of patients with incurable cancer. The results of this RCT are described in chapter 9. Finally, chapter 10 presents a general discussion on the studies provided in this thesis, with their strengths and limitations, suggestions for future research, and implications in practice.

REFERENCES

1. IKNL. Cijfers over kanker. Available from: https://iknl.nl/nkr-cijfers. (accessed March 20, 2022)
2. CBS. The Netherlands in numbers: infographics inspired by 36 questions. 2021. Available from: https://longreads.cbs.nl/the-netherlands-in-numbers-2021/what-do-people-die-of-on-an-average-day/. (accessed March 20, 2022)
3. KWF kankerbestrijding. Oncopolicy. 2022. Available from: https://www.kwf.nl/en/oncopolicy. (accessed April 30, 2022)
4. Lo SS, Buss MK. What is the difference between supportive and palliative care? ASCO News June. 2019, 3.
5. Kanker.nl. Behandelingen in de palliatieve fase. Available from: https://www.kanker.nl/gevolgen-van-kanker/niet-meer-beter-worden/palliatieve-zorg/behandelingen-in-de-palliatieve-fase. (accessed May 8, 2022)
6. Teunissen SCCM, Wesker W, Kruitwagen C, de Haes HCJM, Voest EE, de Graeff A. Symptom Prevalence in Patients with Incurable Cancer: A Systematic Review. J Pain Symptom Manage. 2007;34(1):94–104.
7. Vogt J, Beyer F, Sistermanns J, Kuon J, Kahl C, Alt-Epping B, et al. Symptom Burden and Palliative Care Needs of Patients with Incurable Cancer at Diagnosis and During the Disease Course. Oncologist. 2021;26(6):e1058–e1065.
8. van Roij J, Brom L, Youssef-El Soud M, van de Poll-Franse L, Raijmakers NJH. Social consequences of advanced cancer in patients and their informal caregivers: a qualitative study. Support Care Cancer. 2019;27(4):1187–1195.
9. Tarbi EC, Meghani SH. A concept analysis of the existential experience of adults with advanced cancer. Nurs Outlook. 2019;67(5):540–557.
10. Vehling S, Kissane DW. Existential distress in cancer: Alleviating suffering from fundamental loss and change. Psychooncology. 2018;27(11):2525–2530.
11. Pitceathly C, Maguire P. The psychological impact of cancer on patients' partners and other key relatives: A review. Eur J Cancer. 2003;39(11):1517–1524.
12. Stenberg U, Ruland C, Miaskowski C. Review of the literature on the effects of caring for a patient with cancer. Psychooncology. 2010;19(10):1013–25.
13. Lund L, Ross L, Petersen MA, Groenvold M. Cancer caregiving tasks and consequences and their associations with caregiver status and the caregiver's relationship to the patient: A survey. BMC Cancer. 2014;14(1):1–13.
14. Girgis A, Lambert S, Johnson C, Waller A, Currow D. Physical, Psychosocial, Relationship, and Economic Burden of Caring for People With Cancer: A Review. J Oncol Pract. 2013;9(4):197–202.
15. Li Q. B, Loke AY. The positive aspects of caregiving for cancer patients: A critical review of the literature and directions for future research. Psychooncology. 2013;22(11):2399–2407.
16. Given BA, Given CW, Sherwood P. The challenge of quality cancer care for family caregivers. In Semin Oncol Nurs. 2012;28(4):205–212.
17. Shaffer KM, Jacobs JM, Nipp RD, Carr A, Jackson VA, Park ER, et al. Mental and physical health correlates among family caregivers of patients with newly-diagnosed incurable cancer: a hierarchical linear regression analysis. Support Care in Cancer. 2017; 25(3): 965-971.
18. de Boer A, de Klerk M, Verbeek-Oudijk D, Plaisier I. Blijvende bron van zorg. Rijksoverheid. 2020. Available from: www.scp.nl. (accessed April 28, 2022)
19. Given BA, Given CW, Kozachik S. Family Support in Advanced Cancer. CA Cancer J Clin. 2001;51(4):213–231.
20. Arora A. Caregiver Distress in Cancer. In: Suggestions for Addressing Clinical and Non-Clinical Issues in Palliative Care. 2021. Cascella & Stones. IntechOpen.

21. van Roij J, Brom L, Sommeijer D, van de Poll-Franse L, Raijmakers N. Self-care, resilience, and caregiver burden in relatives of patients with advanced cancer: results from the eQuiPe study. Support Care Cancer. 2021;29(12):7975–7984.
22. Sun V, Raz DJ, Kim JY. Caring for the informal cancer caregiver. Curr Opin Support Palliat Care. 2019;13(3):238–242.
23. Zarit SH, Todd PA, Zarit JM. Subjective burden of husbands and wives as caregivers: a longitudinal study. Gerontologist. 1986;26(3):260–266.
24. Olver I, Keefe D, Herrstedt J, Warr D, Roila F, Ripamonti CI. Supportive care in cancer—a MASCC perspective. Support Care Cancer. 2020;28(8):3467–3475.
25. WHO. Palliative care. 2022. Available from: https://www.who.int/news-room/fact-sheets/detail/palliative-care. (accessed April 30, 2022)
26. Weber D, Gruendel M, Mehnert A. Psycho-oncology and Palliative Care: Two Concepts That Fit into Comprehensive Cancer Care. In: Palliative Care in Oncology. 2015;1–308. Springer, Berlin, Heidelberg.
27. Fitzmaurice C, Allen C, Barber RM, Barregard L, Bhutta ZA, Brenner H, et al. Global, regional, and national cancer incidence, mortality, years of life lost, years lived with disability, and disability-adjusted life-years for 32 cancer groups, 1990 to 2015: A Systematic Analysis for the Global Burden of Disease Study Global Burden. JAMA Oncol. 2017;3(4):524–548.
28. McCorkle R, Ercolano E, Lazenby M, Schulman-Green D, Schilling LS, Lorig K, et al. Self-management: Enabling and empowering patients living with cancer as a chronic illness. CA Cancer J Clin. 2011;61(1):50–62.
29. Schulman-Green D, Martin F, Alonzo A, Grey M, McCorkle R, Redeker NS, et al. Process of Self-management in Chronic Illness. J Nurs Scholarsh. 2012;44(2):136–144.
30. van Dongen SI, de Nooijer K, Cramm JM, Francke AL, Oldenmenger WH, Korfage IJ, et al. Self-management of patients with advanced cancer: A systematic review of experiences and attitudes. Palliat Med. 2020;34(2):160–178.
31. Budhwani S, Wodchis WP, Zimmermann C, Moineddin R, Howell D. Self-management, self-management support needs and interventions in advanced cancer: A scoping review. BMJ Support Palliat Care. 2019;9(1):12–25.
32. Yates P, Edwards H, Nash R, Aranda S, Purdie D, Najman J, et al. A randomized controlled trial of a nurse-administered educational intervention for improving cancer pain management in ambulatory settings. Patient Educ Couns. 2004;53(2):227–237.
33. Steel JL, Geller DA, Kim KH, Butterfield LH, Spring M, Grady J, et al. Web-based collaborative care intervention to manage cancer-related symptoms in the palliative care setting. Cancer. 2016;122(8):1270–1282.
34. Schofield P, Ugalde A, Gough K, Reece J, Krishnasamy M, Carey M, et al. A tailored, supportive care intervention using systematic assessment designed for people with inoperable lung cancer: A randomised controlled trial. Psychooncology. 2013;22(11):2445–2453.
35. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. Health Serv Res. 2004;39(4p1):1005–1026.
36. Hibbard JH, Mahoney ER, Stock R, Tusler M. Do increases in patient activation result in improved self-management behaviors? Health Serv Res. 2007;42(4):1443–1463.
37. Widberg C, Wiklund B, Klarare A. Patients' experiences of eHealth in palliative care: an integrative review. BMC Palliat Care. 2020;19(1):1–14.
38. Eysenbach G. What is e-health? Journal of Medical Internet Research. 2001;3(2):e20.
39. Van Gemert-Pijnen L, Kelders SM, Kip H, Sanderman R. eHealth Research, Theory and Development. A Multidisciplinary Approach. New York: Routledge; 2018.
40. Aapro M, Bossi P, Dasari A, Fallowfield L, Gascón P, Geller M, et al. Digital health for optimal supportive care in oncology: benefits, limits, and future perspectives. Support Care Cancer. 2020;28(10):4589–4612.

41. Mohr DC, Schueller SM, Montague E, Burns MN, Rashidi P. The behavioral intervention technology model: An integrated conceptual and technological framework for ehealth and mhealth interventions. J Med Internet Res. 2014;16(6):e3077.
42. Hermes EDA, Lyon AR, Schueller SM, Glass JE. Measuring the implementation of behavioral intervention technologies: Recharacterization of established outcomes. J Med Internet Res. 2019;21(1):e11752.
43. Krebber AMH, Jansen F, Witte BI, Cuijpers P, de Bree R, Becker-Commissaris A, et al. Stepped care targeting psychological distress in head and neck cancer and lung cancer patients: A randomized, controlled trial. Ann Oncol. 2016;27(9):1754–1760.
44. O'Donohue W, Draper C. Stepped Care and e-Health. 2010.New York. Springer.
45. Owens DK, Qaseem A, Chou R, Shekelle P. High-Value, Cost-Conscious Health Care: Concepts for Clinicians to Evaluate the Benefits, Harms, and Costs of Medical Interventions. Ann Intern Med. 2011;154(3):174–180.
46. Mold J. Goal-Directed Health Care: Redefining Health and Health Care in the Era of Value-Based Care. Cureus. 2017;9(2):1–9.
47. Sampaio SGDSM, Motta LB Da, Caldas CP. Value-based medicine and palliative care: how do they converge? Expert Rev Pharmacoeconomics Outcomes Res. 2019;19(5):509–515.
48. Karazivan P, Dumez V, Flora L, Pomey MP, Del Grande C, Ghadiri DP, et al. The patient-as-partner approach in health care: A conceptual framework for a necessary transition. Acad Med. 2015;90(4):437–441.
49. van Gemert-Pijnen JEWC, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res. 2011;13(4):e1672.
50. Black N. Patient reported outcome measures could help transform healthcare. BMJ. 2013;346:1–5.
51. Duman-Lubberding S, van Uden-Kraan CF, Jansen F, Witte BI, van der Velden LA, Lacko M, et al. Feasibility of an eHealth application "OncoKompas" to improve personalized survivorship cancer care. Support Care Cancer. 2016;24(5):2163–2171.
52. Melissant HC, Verdonck-de Leeuw IM, Lissenberg-Witte BI, Konings IR, Cuijpers P, Van Uden-Kraan CF. 'Oncokompas', a web-based self-management application to support patient activation and optimal supportive care: a feasibility study among breast cancer survivors. Acta Oncol . 2018;57(7):924–934.
53. van der Hout A, van Uden-Kraan CF, Holtmaat K, Jansen F, Lissenberg-Witte BI, Nieuwenhuijzen GAP, et al. Role of eHealth application Oncokompas in supporting self-management of symptoms and health-related quality of life in cancer survivors: a randomised, controlled trial. Lancet Oncol. 2020;21(1):80–94.
54. van der Hout A, Jansen F, van Uden-Kraan CF, Coupé VM, Holtmaat K, Nieuwenhuijzen GAP, et al. Cost-utility of an eHealth application 'Oncokompas' that supports cancer survivors in self-management: results of a randomised controlled trial. J Cancer Surviv. 2021;15(1):77-86.
55. de Veer AJ, Slev VN, Pasman HR, Verdonck-De Leeuw IM, Francke AL, van Uden-Kraan CF. Assessment of a structured self-management support intervention by nurses for patients with incurable cancer. Oncol Nurs Forum. 2020;47(3):305–317.

2

ORGANIZING PSYCHO-ONCOLOGICAL CARE FOR CANCER PATIENTS: THE PATIENT'S PERSPECTIVE

Anouk S. Schuit
Karen Holtmaat
Valesca van Zwieten
Eline J. Aukema
Lotte Gransier
Pim Cuijpers
Irma M. Verdonck-de Leeuw

Frontiers in Psychology 2021;12:625117

ABSTRACT

Background: Cancer patients often suffer from psychological distress during or after cancer treatment, but the use of psycho-oncological care among cancer patients is limited. One of the reasons might be that the way psycho-oncological care is organized, does not fit patients' preferences. This study aimed to obtain detailed insight into cancer patients' preferences regarding the organization of psycho-oncological care.

Methods: 18 semi-structured interviews were conducted among cancer patients. Patients completed psycho-oncological treatment between 2015 and 2020 at the psychology department in a general hospital or a center specialized in psychological cancer care in the Netherlands. The interview comprised questions related to preferences regarding the institute where to receive treatment, the psychologist who provides treatment, and the type of treatment, as well as questions related to experienced barriers and facilitators to receive psycho-oncological care. Interviews were digitally recorded and transcribed verbatim. Data were analyzed individually by two coders into key issues and themes.

Results: Regarding the institute, easy accessibility and prompt availability of psychol-oncological care were considered important. Regarding the psychologist, most participants had a strong preference to be treated by a psychologist specialized in cancer or other somatic diseases. Individual face-to-face therapy was preferred above other types of treatment. Several barriers were mentioned to receive psycho-oncological treatment, among which poor accessibility to psycho-oncological care, lack of knowledge on the possibilities for psycho-oncological treatment, and stigma. Most frequently mentioned facilitators were being assertive to ask for help, having a good relationship with the healthcare professional, and the integration of psycho-oncological support within medical cancer care.

Conclusions: From the patient's perspective, the organization of psycho-oncological care for cancer patients should focus on easy accessibility and availability, delivered by specialized psychologists, and integration in medical cancer care. Online and group therapy are acceptable, but individual face-to-face therapy is preferred. It is warranted to increase awareness on psycho-oncological care targeting both patients and healthcare providers.

Keywords: patient preferences, supportive care, psychological care, psycho-oncological care, cancer distress

BACKGROUND

Many cancer patients suffer from psychological distress due to physical, psychological and social challenges related to their disease, negatively affecting their quality of life[1–3]. Although prevalence rates of distress in cancer patients vary among studies[1,2,4–6], rates of up to 50% have been reported[1] and many patients need psycho-oncological care (PC)[7,8]. Research has shown that cancer patients' need for PC should be an important aspect of cancer care[9–11]. PC aims to improve patients' quality of life by promoting their well-being and decreasing psychological distress[12]. Previous studies have shown beneficial effects of PC on distress and quality of life[13–17]. However, it is also known that cancer patients with psychological distress do not often use PC[18–20]. One of the reasons may be that the way PC is organized does not fit patients' preferences. In this paper PC is defined as professional psycho-oncological care for cancer patients provided by health psychologists by means of counselling and/or psychotherapy.

Previous studies investigating preferences regarding PC were often conducted among people with psychological problems in the general population. Preferences can relate to different aspects of psychological treatment, such as activity preferences (e.g., desires about the treatment type; individual, couple or family, or group), therapist preferences (e.g., therapist's personality characteristics) and treatment preferences (e.g., psychotherapy or self-help interventions)[21]. Complying to these preferences leads to better adherence and outcomes due to stronger therapeutic alliance, and enhanced patient-provider communication[21–24].

Integrating PC into cancer care services comes with challenges on patient, provider and institutional level[25]. Earlier research among cancer patients focused primarily on their need for PC[7–10], but less on the organization of PC from patients' perspective; why they prefer certain types of care and what facilitates or hinders the access to PC according to patients on patient, provider, and institutional level. Reasons for not using PC, on patient level, are that many patients prefer to manage their symptoms on their own and believe that their distress is not severe enough to receive PC[26,27]. Dealing with symptoms on your own could be a good strategy, since stepped care (including watchful waiting and self-care as first steps) was found to be (cost)effective[28,29]. In stepped care, patients not benefitting from self-care and low-intensity interventions are offered to "step-up" to professional PC. However, on provider level, and outside a stepped care context, a lack of knowledge of PC among both patients and physicians is found to be a barrier to receive PC[26,30,31]. On institutional level, it may be difficult for patients to find their way within the complex healthcare system and to know where to find PC. In the Netherlands, PC for cancer patients can be provided at different locations; in the hospital (e.g., by psychologists at the Department of Psychology), primary care (e.g., by mental health workers), or specialized centers for psychological cancer care (e.g., by psychologists)[32]. PC can also be provided as different types: face-to-face, individually, remotely (e.g., online therapy), together with a partner or other relatives, in a group, or blended (i.e., blending different types of care)[33]. In the Netherlands, the maximum acceptable waiting time for PC is 14 weeks[34]. PC is often reimbursed by health insurance companies[35].

Since the number of cancer patients is increasing annually[36], a growing need for PC is expected in the coming years[37]. Better knowledge is needed on cancer patients' preferences regarding the organization of PC. This will enable patient-centered care, which emphasizes individual patient preferences, needs and values[38,39]. Therefore, the aim of this qualitative study was to gain more understanding of the preferences regarding the organization of PC among cancer patients who received PC in the past, and the barriers and facilitators they experienced to receive PC.

METHODS/DESIGN

Recruitment and study sample

Between February 2019 and June 2020, adult cancer patients were recruited who completed psycho-oncological treatment at the Department of Psychiatry and Medical Psychology in a general hospital (OLVG) or at a center specialized in psychological cancer care (Ingeborg Douwes Centrum (IDC)), both located in Amsterdam, the Netherlands. Patient referrals to IDC occurred both from hospitals and primary care centers in Amsterdam and surrounding areas. Patient referrals to the Department of Psychiatry and Medical Psychology in the hospital occurred by the physician, general practitioner (GP), or nurse specialist in the hospital.

Patients were eligible if they were 18 years or older, able to communicate in Dutch, were treated for cancer (any type and stage, treatment modality, or treatment intent), and received their psycho-oncological care prior to participation in the study (either before, during, or after cancer treatment).

Patients were screened for eligibility by the psychologist who provided their psychological treatment. Reasons not to approach patients were patients being too ill, privacy reasons, the nature of the psychological symptoms (severe post-traumatic stress disorder or changed psychopathology), and having mental disabilities. Patients were selected based on completion of their psychological treatment; at first patients were selected who finished their treatment recently. Subsequently, the time frame of completion was broadened further back in time (up until data saturation had been reached). All patients received their psychological treatment up to four years prior to study participation.

Eligible patients received a letter with information on the study. Interested patients were asked to return the reply card to the researcher of the Vrije Universiteit Amsterdam (AS) to express their interest in the study. Subsequently, they were contacted by phone to give them the opportunity to ask questions and to schedule the interview with this researcher (AS).

Interview

A semi-structured interview scheme was used, consisting of two main topics (preferences and experiences, e.g., barriers and facilitators to receive PC) with related questions (Table 1). Flexibility was allowed in the order in which questions were asked. Topics and related questions were derived from the literature and the clinical experience of the research team. After three interviews the research team discussed whether the interview scheme had to be adapted; minor changes were made in the formulation of some sub questions. Participants were asked to provide information about their cancer diagnosis, psycho-oncological treatment and sociodemographic characteristics at the start of the interview.

Table 1. Interview topics

Topics	Key questions
Preferences	– What are your preferences regarding the setting of care (e.g., location and type of psychologist)? – What are your preferences regarding the type of professional support (face to face/group sessions/online therapy)? – What were other preferences regarding the psychological care you wanted to receive?
Experiences	– Which barriers did you experience or what could be barriers when looking for psychological support? – Which facilitators did you experience or what could facilitate receiving psychological support?

Interviews were conducted by a PhD-student (AS) trained in qualitative research methods. No relationship between the interviewer and the participants was established prior to study commencement. Participants were interviewed at the location of their preference; e.g., at their homes, their workplace, or at the Vrije Universiteit Amsterdam. This study was conducted partly during the lockdown in the Netherlands (March-May 2020) due to the COVID-19 pandemic; due to safety procedures concerning COVID-19, three interviews were conducted by phone. All interviews were recorded with an audio device and transcribed verbatim. Transcripts were not returned to the participants for comments or corrections.

Data analysis

Data was analyzed using Atlas.ti (version 8). The transcripts of the interviews were analyzed by two coders independently (AS and VvZ), using thematic analysis[40]. Data-analysis ran parallel to data collection. First, the coders read the transcripts to get familiar with the data. Then, two coders analyzed the data individually, coding citations into key issues and themes, derived from the data. Findings were discussed in consensus meetings in which differences were resolved and a thematic framework was created. Two independent persons (IVdL and KH) were involved for advice, when there were doubts during the consensus meetings. All quotes extracted from the interviews, provided in this paper, were translated from Dutch into English. Information in quotes that could lead to a person's identification was removed to ensure respondents' privacy.

In this paper the consolidated criteria for reporting qualitative research (COREQ) were followed to report about the study[41]. The study was approved by the Medical Ethical Committee of OLVG hospital, Amsterdam (18.178 PPPSC). All participants provided written informed consent before the start of the interview.

RESULTS

Study population

In total, 85 patients were invited to participate: 26 by OLVG (31%) and 59 by IDC (69%), of whom 67 (79%) were not willing to participate (not willing to talk about the disease (n = 2), being too ill to participate (n = 1), no reason provided (n = 64)). A total of 18 patients were interviewed (7 patients via OLVG, 11 patients via IDC), after which no additional information of value was obtained and data saturation had been reached. The duration of the interviews lasted 44-136 minutes (median 64). The majority of the participants was female (72%) and received PC at IDC (61%). The mean age of participants was 47 years (SD 13.1). Table 2 shows an overview of the participant characteristics.

Table 2. Participant characteristics (n = 18)

	n (%)
Sex	
Male	5 (28)
Female	13 (72)
Age at interview (in years)	
Mean (SD)	47 (13.1)
Minimum	24
Maximum	64
Marital status	
Single	1 (6)
Having a relationship/Living together	6 (33)
Married	8 (44)
Widow(er)	1 (6)
Divorced	2 (11)
Children	
Yes	10 (56)
No	8 (44)
Highest level of education completed	
Academic education	9 (50)
Higher education	7 (39)
Secondary education	2 (11)
Current employment	
Paid job	14 (78)
No paid job	4 (22)
Received psychological treatment in	
Psychology department within hospital (OLVG)	7 (39)
Psychological cancer care center (IDC)	11 (61)
Cancer diagnosis*	
Breast cancer	9 (50)
Colorectal cancer	3 (17)
Head and neck cancer	2 (11)
Hematological cancer	4 (22)
Unknown	1 (6)
Time since cancer diagnosis	
1 – 3 years	11 (61)
3 – 5 years	5 (28)
> 5 years	2 (11)
Time since psychological treatment	
< 1 year	4 (22)
1 – 3 years	11 (61)
3 – 5 years	3 (17)

* One participant was diagnosed with both breast cancer and colorectal cancer. Therefore, this total percentage does not add up to 100.

Most participants who received PC at OLVG or at IDC had finished their cancer treatment but still had regular follow-up sessions with their physician. Some were still undergoing cancer treatment during PC.

Table 3. Preferences regarding the institute and psychologist

Key issues	Themes
Preferences related to	
Institute	Short term availability of PC
	Accessibility: – Short travelling time to location – (Free) car parking facilities – Prefer to receive medical and psychological care at same location
	Institution is specialized in PC – Curiosity about what a specialized center has to offer – Easier to fit in; everyone has cancer
	Personal feelings and experiences: – Feeling comfortable at the location where to receive PC – Experiences during medical cancer treatment (when receiving PC in the hospital)
Psychologist	Professional distance to the psychologist: – Easier to explain difficult topics – Easier to show emotions – Psychologist is able to put things into other perspectives
	Experienced in cancer/other physical diseases: – Psychologist must have knowledge about the psychological impact of diseases (e.g., cancer), the healthcare environment and about psychological mechanisms • Not having to explain things which are self-evident when having a serious illness (e.g., cancer)
	Gender: – Same gender due to gender related physical symptoms
	Age: – Being the same age category could make it easier to feel connected to the psychologist
	Professional with lots of work experience
	Good relationship with psychologist

Preferences

Participants described three categories related to their preferences regarding the organization of PC: the institute, the psychologist (Table 3), and the type of PC (Table 4).

Table 4. Advantages and disadvantages per type of care

	Advantages	**Disadvantages**
Individual PC	– One-on-one setting with psychologist (having undivided attention of the psychologist) – Possible to bring relatives to therapy	NM*
PC in groups	– Talking to people who understand your situation and have similar problems – Sharing experiences and advice how to cope with cancer related symptoms – Learning to accept confronting circumstances	– Too burdensome to hear about other patients' problems – Makes you conscious that you have (had) cancer – Feeling disappointed when peers drop-out – Difficult to connect with peers with different age – Having the feeling that it is not relevant for other peers to listen to your experiences – Having concerns about privacy – Not being able to be your true self – Difficult to express yourself when not feeling comfortable in a group – Less time available per person
Online therapy / blended therapy	– Available 24/7 – Available at your own home – Saving travelling time – No waiting lists – Suitable for less complicated needs – Extra support besides face-to-face support – Available in different languages	– Relatively unknown area – Lack of social contact makes it difficult to communicate: • Nonverbal signals and emotions are less visible • No in-depth conversations • No direct support from psychologist – Easier to get distracted or to avoid therapy – Disturbing when technology does not work properly (e.g., during videoconferencing) – Having concerns about privacy – Not suitable for all patients (dyslexia, visual problems) – Not wanting to follow therapy in your home environment

* NM = none mentioned

Preferences regarding the institute

The majority of the patients treated at IDC were not yet familiar with the existence of a center specialized in PC for cancer patients until their healthcare professional suggested a referral to IDC. In some cases, patients were recommended to receive PC at IDC by acquaintances (e.g., colleagues). The main reasons for participants to receive PC in the hospital instead of in a center specialized in PC for cancer patients were shorter waiting lists or practical reasons.

Short-term availability of support and **accessibility of the location** (e.g., short travelling time and car parking facilities) were considered important when choosing where to receive PC. Also, familiarity with the location was mentioned to prefer receiving medical and psychological care at the same location (i.e., the hospital). Some participants preferred an institute **specialized in PC**, due to curiosity or because it felt easier to fit in, because everyone treated here has or had cancer.

In addition, **personal feelings and experiences** were important; patients want to feel comfortable at the institute where they receive care and – when receiving PC in the hospital – the experiences during cancer treatment often play a major role in deciding where to receive PC:

> *"I felt more comfortable to be treated at IDC. Because it is a neutral environment. The hospital, that's the place where you've experienced some bad things. It feels better to go to a different place."*

Preferences regarding the psychologist

Most participants preferred to receive PC by a **psychologist experienced in supporting patients with somatic diseases, or cancer in particular**. Many people indicated that it was important to receive PC from a psychologist with knowledge about the psychological impact of somatic diseases (e.g., cancer):

> *"Firstly, you can connect more easily [with the psychologist], because you think 'that person understands how things in the hospital work'. Secondly, it is easier for her to give tips and tricks because she knows how the medical world works and how things work for patients who experienced stressful events in their life. I didn't want to go to a psychologist 'just around the corner'."*

Some participants (more often those who received PC in the hospital), indicated that they did not prefer a psychologist especially trained in treating cancer patients over a psychologist specialized in treating patients in general.

Personal factors also played a role when it came to preferences for a psychologist; wanting to be treated by a psychologist with the same (female) **gender** due to specific physical symptoms, or with the same (young) **age category** were both mentioned, such as the wish to be treated by a psychologist with **a lot of work experience** (which was not further specified).

Participants described the added value of visiting a psychologist. They appreciated the **professional distance to their psychologist**, making it easier to discuss difficult topics than with family or friends. People said it was easier to show their emotions to a psychologist than to relatives:

> *"It is very difficult to see people feeling sad about you. Especially the people very close to you. [...] When I felt bad, I said I was feeling fine. But to [name psychologist] I could just tell 'Well, I'm doing very badly'. Not that she doesn't care, but she is just not personally affected."*
>
> *"Over there [with the psychologist] I can be scared, I can also admit that I'm scared and that I'm afraid to die, and that I feel sad. But to your friends and family you always pretend to be strong, because you don't want them to feel bad."*

Participants appreciated the psychologist helping them to see things from other points of view. They also thought it was important to have a **good relationship** with the psychologist.

Preferences regarding the type of care

Although all participants received individual PC, everyone was asked to reflect on advantages and disadvantages of various types of PC (Table 4). Some participants also received other types of PC in their past (not always related to cancer), such as group therapy sessions.

Individual PC

Most participants preferred individual PC because it enabled them to talk about their problems in a one-on-one setting, while having the undivided attention of the psychologist. Additionally, being able to bring their relative(s) to their therapy sessions was appreciated.

PC in groups
Participants reflected on group therapy sessions. Although most participants recognized that people might benefit from group therapy, the majority did not prefer this type of care.

Participants described that it could be pleasant to talk to people who understand your situation, because this puts things into perspective and enables you to share experiences. Furthermore, it would be helpful for learning to accept confronting circumstances (e.g., when a peer passes away during therapy).

However, people mentioned that it would be too burdensome to hear about other patients' problems and that it could be confronting because it makes you more aware that you have (had) cancer. Being disappointed when peers drop-out of the group therapy was also mentioned not to prefer group therapy. Furthermore, having the feeling that sharing your experiences would not be useful for others and having privacy issues – not feeling safe enough to share confidential issues – were mentioned. It would also be hard to express yourself when not feeling comfortable. In addition, difficulties to connect with peers due to age differences and less time available per person were described as other disadvantages of group therapy.

Online therapy
For most participants online therapy was a relatively unknown area (only one participant received PC during the COVID-19 pandemic, which made online therapy mandatory due to safety reasons). Participants reflected on different types of online therapy; guided therapy through videoconferencing or blended therapy with online and offline exercises, guided by a psychologist. They wondered how to be certain you communicate with an experienced psychologist and if the same psychologist will return every session during the therapy. They also thought online therapy would make it more difficult to communicate, because there is no direct contact with the psychologist:

> *"With online therapy the psychologist cannot see the emotions. When you have a conversation, someone can see the emotions [...]. They can see through your eyes whether you are doing badly, or through your posture [...] Online, [...] when things are difficult in the session – I would just shut down my laptop. When you are with each other in a room, you cannot avoid it."*

Participants indicated they would get distracted during online therapy or avoid therapy when it gets emotional or too time consuming. Furthermore, they noticed privacy concerns and thought online therapy would not be suitable for all patients (for example online exercises, when having visual problems or dyslexia). Not wanting to have therapy in your home environment and being disturbed when the technology does not work properly, were other disadvantages mentioned.

Some participants were curious about online support. Described benefits of online therapy were 24/7 availability of some forms of online therapy and availability at your own home. It could be offered directly – there are no waiting lists for this type of care – and be available in different languages to make it easier for non-natives. Participants described that it could be especially useful for patients with less complicated care needs. It was also considered useful when online therapy is available besides individual face-to-face therapy, as blended care.

Experiences in receiving PC

Participants mentioned several barriers and facilitators on patient, provider and institutional level, when reflecting on their experiences to receive their preferred PC (Table 5). Almost all participants expressed their satisfaction with the PC they received. Participants indicated the importance to offer tailored support. The barriers and facilitators that were mentioned related to participants' specific experiences and their suggestions for improvement.

Table 5. Barriers and facilitators to receive PC

Key issues	**Themes**	
	Barriers	**Facilitators**
Patient level		
Patients' personal characteristics	– Being less assertive – Feeling burdened to contact healthcare professional in hospital when having new questions about the disease and its symptoms – Preferring to work on mental health on your own (without support of psychologist) because you do not like to ask for help – Not recognizing your need for help	– Being assertive to ask for PC – Daring to be vulnerable – Allowing yourself to get PC
Patients' motivation or personal reasons	– Having no earlier experience with PC (in general) – Having negative experience with PC in the past – Having to explain the "cancer story"	– Being aware of healthcare support network due to own profession – Having experience with PC (in general) – Wanting to use own experiences to help others – Wanting to be able to explain to yourself and others what happens with you mentally when having cancer
Stigma about PC	– Confronting to be labeled as a 'depressed person' – Feels like personal failure to seek for PC – Going to a psychologist has negative associations in social environment – Psychologist has negative image	– Pleasant that there is a place available especially for cancer patients
Medical treatment as priority	– Medical treatment is often the first priority for patients and physicians	NM
Time investment	– Not willing to give up spare time to receive PC	NM
Role of social environment	NM	– Getting stimulated by people in social environment to find PC

Provider level		
Relationship with healthcare professional	NM	– Easier to discuss psychological symptoms with familiar healthcare professional – Having a good relationship with healthcare professional
Role of healthcare professionals	– Not being aware of PC options – Not asking enough questions to get the patient to the appropriate type of care – Lack of time during consultation in the hospital makes it difficult to talk about psychosocial symptoms – Not receiving tailored information on PC options	– Normalize psychosocial symptoms and talk about psychosocial impact of cancer on daily life – Formulate PC needs from patient's perspective – Offer tailored support to patients (e.g., more intensive support when necessary and tailored information about supportive care options) – Increase patients' recognition of their own symptoms
Taboos	– Certain topics are difficult to discuss with healthcare professional (e.g., sexuality issues)	NM
Institutional level		
Accessibility to PC	– Not knowing where to start to find PC – PC is often provided by another institute than medical treatment – Waiting lists for PC – Contact with healthcare professionals in hospital is less intensive when medical treatment is finished, making it more difficult to discuss psychological symptoms in between follow-up appointments – Unawareness about reimbursement or financial issues holding patients back to receive PC – Having to legitimize your need for help continuously – Care process of psychologists is not tailored to the individual (e.g., general questionnaires used for the intake procedures)	– A central point of contact within the hospital • With knowledge of the patient's personal situation • Where patients can turn to when having questions – An easily accessible contact outside working hours
PC as an integrated part of cancer care	– Forcing someone to seek support could have opposite effect (i.e., patients resisting support)	– Normalizing psychological impact of cancer diagnosis – Making it easier for patients to accept PC – Informing patients in early stage of the cancer trajectory about available PC options – More attention to the need of PC (e.g., during follow-up period) – Implementing a voluntarily intake interview

* NM = none mentioned

Barriers

On patient level, barriers related to **patients' motivation and personal characteristics**. Having no earlier experience with PC or having negative experiences with PC in the past, and not wanting to explain "the cancer story" again, could be barriers to find or receive PC.

Some participants indicated wanting to cope with their mental health on their own first, without psychological help. Sometimes people prefer to solve their problems on their own and specialized care is not necessary (e.g., stepped care). However, participants also mentioned not liking to ask for help. It is more difficult to get to PC when you do not admit your need for support. Furthermore, not being assertive enough daring to ask for PC when you need it, could be a barrier. This also accounts when you feel burdened to contact the healthcare professional in the hospital when having new cancer related questions.

Stigma attached to psychological support was described as a barrier to ask for PC due to different reasons: it is confronting to be labeled as "depressed person", it feels like a personal failure to ask for PC, and going to a psychologist provokes negative reactions from the social environment:

> *"When I say I go to a psychologist, because I have important questions for myself, then people say 'Are you confused, or do you have a burn-out?'"*

Prejudices about the image of psychologist could also be a hurdle to overcome:

> *"I always tried to keep myself away from psychological support. Because I think those people [psychologists] are weird, they have these difficult looks on their face, and they ask 'What do you think?'. [...] I had that prejudice during the period I was sick, and also afterward."*

It was mentioned that accurate timing of PC is important, because initially **medical treatment was prioritized by patients and healthcare professionals**. Some participants indicated that shortly after the cancer diagnosis medical treatment was their first priority, being in a survival mode. They could not think about the psychological impact of cancer and also their physicians focused on medical treatment initially. Offering PC too early could counteract in accepting PC and minimize its benefits. A barrier related to **time investment** was the unwillingness to give up spare time for PC.

Barriers on provider level related to the **role of healthcare professionals** (physicians, nurse specialists, or GPs); healthcare professionals not being aware of PC options or not asking enough questions to refer the patient to the appropriate type of care. Furthermore, participants indicated that they had no overview in information about psychosocial supportive care options (including PC). Also, certain topics are difficult to discuss with healthcare professionals due to **taboos on that topic** (e.g., sexuality issues) or lack of time during consultations with the physician, which makes it difficult to talk about the psychosocial aspects of having cancer. However, the majority said that when they specifically asked their healthcare professional to get psychological support, they were referred to PC.

Lastly, barriers on institutional level to receive PC related to **the accessibility of psychological care**. Participants did not know where to start finding PC due to the organization of healthcare in the Netherlands (e.g., arranging a referral from your GP and searching by yourself for a location to receive PC).

Furthermore, waiting lists for psychological care limited the access to PC. In addition, participants described that contact with healthcare professionals in the hospital gets less intensive when cancer treatment is finished, making it more difficult to discuss psychosocial symptoms that occur after treatment. PC being provided by another institute than the cancer treatment could also be a barrier. Furthermore, people mentioned that the access to mental healthcare is not tailored to the individual (e.g., filling in general questionnaires used for intake procedures).

Unawareness of financial reimbursement or having financial issues could also be barriers to receive PC; having no knowledge about the financial aspects of healthcare and not knowing that certain PC could be reimbursed by your healthcare insurance could hold people back from finding PC, thinking it is too expensive. Another barrier mentioned was (continuously) having to legitimize a need for PC:

> *"It disturbs me that – the psychology department is not the most approachable department of the hospital. I think that this could discourage potential patients. What bothers me most, is that I when wanted support for the second time – That you basically get a service check, as you get for your car, which I already passed the first time. So, every time you have a new question, you have to get interrogated again."*

Facilitators

On patient level, **patients' motivation** and their **personal characteristics** could also serve as facilitators to receive PC. Wanting to use your own experiences to help others and being able to explain (to yourself and others) what happens to you mentally when having cancer, were personal motivations to find PC. Being aware of the healthcare support network due to participants' profession and having earlier experience with psychological support also facilitates the access to PC. Being assertive, daring to be vulnerable, and allowing yourself to receive PC are personal characteristics making it easier to receive the preferred PC:

> *"If I didn't mention that I wanted to go to that specific place, then he [the GP] would have said, just go to a psychologist. I don't know if I would have been ended up at the IDC. I think that it matters if you are assertive and if you know your way within the healthcare system."*
>
> *"They [healthcare professionals in the hospital] continuously asked, if you want support for this, you can just tell us. But I thought it wasn't necessary [...] and then I thought, you know what, I will allow myself this, because it already sucks too much. It is available and maybe it can help me."*

Furthermore, people's **social environment plays a major role** to receive PC by stimulating patients to ask for PC when they need help. Also, specialized institutes for cancer patients facilitate the access to PC, with the potential to reduce **stigma**; it is pleasant for patients to know that there is a place especially for cancer patients to receive PC.

A facilitator on provider level was the **relationship with the healthcare professional** (e.g., the physician or GP). Participants said it was easier to discuss psychological symptoms with a familiar healthcare professional. **Healthcare professionals, such as the physician, nurse specialist or GP, also have a role organizing the referral to PC.** When there is more attention to the psychosocial impact of cancer on daily life in general, it would be easier to discuss psychological issues with the healthcare professional. Furthermore, it would help when healthcare professionals formulate supportive care needs from the patient's perspective and help patients to recognize their psychological symptoms. Raising awareness could facilitate looking for PC. Participants explained that tailored care is essential in PC, which means less intensive care (e.g., tailored information about supportive care options) when possible and more intensive care (e.g., therapy by a professional) when necessary.

Regarding facilitators on institutional level, people specifically mentioned **easy accessibility** as an important facilitator. It would facilitate the access to PC when there is a central point of contact within the hospital, familiar with patients' personal situation, where they can turn to when having questions.

Participants indicated that **integration of PC in the cancer care process** would help to get to the preferred PC. This could normalize the psychological impact of cancer and could make it easier to accept PC. It would also help to inform patients at an early stage of the cancer trajectory about PC options. In addition, implementing a voluntary intake interview and having more attention for the psychological care needs during the follow-up trajectory could also support finding PC.

DISCUSSION

This study investigated the organization of PC from the perspective of Dutch cancer patients who received PC in the past. Patients' preferences regarding PC related to the institute where to receive care, the psychologist and type of care. They recalled experiences that did or did not facilitate the access to PC, and reported their thoughts on what would facilitate or hinder access to PC, categorized on patient, provider and institutional level. Focusing on facilitators and resolving barriers – while taking into account patients' preferences – in the organization of PC may support patients to timely get to their preferred PC. In this way, high-quality PC can be ensured, despite increasing demands.

The results of this study replicate existing findings, although our study sample targets a specific patient group. Many participants preferred individual therapy over group therapy, consistent to findings of earlier research[42,43]; patients appreciate having undivided attention of the therapist and sometimes fear to expose themselves in front of others, to get lost in a group, or have concerns about privacy. Our study participants described that online therapy would be acceptable although face-to-face therapy was preferred, which is consistent with other studies investigating online therapy[44,45]. Previous studies described anonymity of Internet-based interventions being an advantage compared to formal mental health services, which are often still stigmatized[44,46]. Perceived disadvantages of online therapy described in earlier research, such as lack of empathy and trust, absences of body language, and being unable to motivate yourself, were also described by participants in our study, as applies for advantages of online therapy such as having no waiting lists and 24/7 availability[44]. Patients that often use the Internet to improve their health are three times more likely to prefer Internet-based psychological interventions[44]. However, despite the relatively young age group in our study which in general frequently uses the Internet[47], most participants were unfamiliar with online therapy (most participants finished their psychological treatment before the COVID-19 pandemic). It has been reported that the COVID-19 pandemic seems to be great catalyst for implementation of online therapy, forcing patients and health professionals to get used to e-mental health[48]. Furthermore, some patients mentioned that they would like a psychologist of the same gender and age, which corresponds to previous studies[49–51], for example due to the nature of their presenting problem. However, there is no clear evidence on whether client-counsellor similarity affects therapeutic outcomes[49,50].

Patients experienced several barriers to receive PC at their preferred setting, of which some are related to non-fulfillment of certain preferences. Barriers to initiate and continue mental health treatment on patient level, among which lack of availability and stigma, were mentioned in the literature before[46,52–54]. In addition, some participants in our study mentioned that they initially preferred to self-manage psychological problems, a finding that was also documented by Baker-Glenn et al. (2011)[55]. Using the stepped care model might be interesting for these patients since previous studies revealed the positive impact of screening patients for distress followed by further assessment, appropriate referral and treatment, which could lead to improved patient outcomes[11,29,56]. On provider level and consistent to our findings, lack of time of healthcare professionals to discuss psychosocial problems with their patients also has been mentioned as barrier in previous research[30]. Furthermore, on institutional level, continuity of care is necessary to ensure easy access to mental health services[57], in which primary care plays an important role. In our study, patients reported that finding a location to receive PC by yourself could make it difficult to find your way to PC. In the Netherlands, cancer patients can be referred to PC by hospital care providers (e.g., physicians), but often referral is made by their GP (almost 40%)[58].

Integrating PC as a standard part of cancer care could be a solution to facilitate the access to PC for cancer patients[59], for example using the collaborative care approach which stimulates health professionals from both medical and psychological settings to provide integrated care, usually coordinated by a practice team or care manager[25]. As described by our study participants, healthcare professionals could normalize the psychosocial impact of cancer on patients' daily life and offer tailored support and information to patients to guide them to appropriate PC that matches their preferences. Communication skills training for healthcare professionals to integrate the discussion about psychological symptoms in their daily practice was already found to be effective[30,60,61]. An open discussion about symptoms with the healthcare professional is important to let patients know that their psychosocial needs are important alongside with their medical needs[30,61]. Integrating PC as standard part of cancer care will come with challenges[25], also because the number of cancer diagnoses is increasing annually. To reduce the pressure on psycho-oncological and medical healthcare services, the further implementation of the stepped care model could be a solution, which was found to be (cost-)effective to reduce distress and health-related quality of life and emphasized the importance of screening for distress in clinical practice[28,29].

This study provides detailed insight into the perspectives of cancer patients with respect to the organization of PC. Strengths of the study were that we included patients who received and completed psychological treatment and were thus experienced. A large variety in socio-demographic characteristics was noticed during the interviews, which suggests an appropriate level of diversity among the target group (i.e., patients with distress). However, some limitations could be addressed too, which suggest to interpret the results with caution. Information on patients' socio-demographics and cancer diagnosis was self-reported (the research team had no access to medical records) and some patients received their psychological treatment four years prior to the interview, meaning that recall bias cannot be ruled out completely. Furthermore, we did not systematically collect data on participants' psychiatric diagnosis, or type and format of psychological treatment.

This study used a self-selecting convenience sample, which affects generalizability and could cause selection bias which is inevitable with this recruitment method. It is possible that patients with psychological distress who did not receive psychological treatment or patients who were not treated by a psychologist specialized in cancer or other somatic diseases – who were not interviewed in this study – have other preferences regarding PC. Further research should examine why these patients did not receive PC. Some other aspects could also have affected the representativeness of our sample. Firstly, participants were treated in two centers within Amsterdam, The Netherlands. Therefore, the results could not be generalized to other hospitals or other countries. Secondly, although we aimed to recruit both patients treated with curative and palliative intent, all patients indicated their prognosis was good. However, patients' preferences may change when they get sicker[38]. Lastly, our sample contained a relatively high percentage of women (72%) and most participants were highly educated (89%). In addition, the mean age of our sample (47 years) was lower than the average age of the cancer population, which could be explained by the positive association between having distress and a younger age and/or being female[62,63]. Another explanation could be that older patients generally have a higher disease burden and therefore are less motivated to participate in an interview study.

In conclusion, from the patient's perspective, the organization of PC should focus on easy accessibility and availability, delivered by specialized psychologists, and integration in medical cancer care. Online and group therapy are acceptable, but individual face-to-face therapy is preferred. It is warranted to increase the awareness on the benefits and possibilities of PC targeting both patients and healthcare providers.

REFERENCES

1. Mehnert A, Hartung TJ, Friedrich M, Vehling S, Brähler E, Härter M, et al. One in two cancer patients is significantly distressed: Prevalence and indicators of distress. Psychooncology. 2018;27(1):75–82.
2. Zabora J, Brintzenhofeszoc K, Curbow B, Hooker C, Piantadosi S. The prevalence of psychological distress by cancer site. Psychooncology. 2001;10(1):19–28.
3. Marco DJT, White VM. The impact of cancer type, treatment, and distress on health-related quality of life: cross-sectional findings from a study of Australian cancer patients. Support Care Cancer. 2019;27(9):3421–3429.
4. Herschbach P, Keller M, Knight L, Brandl T, Huber B, Henrich G, et al. Psychological problems of cancer patients: A cancer distress screening with a cancer-specific questionnaire. Br J Cancer. 2004;91(3):504–11.
5. Hoffman KE, McCarthy EP, Recklitis CJ, Ng AK. Psychological Distress in Long-term Survivors of Adult-Onset Cancer. Arch Intern Med. 2009;169(14):1274–1281.
6. Götze H, Brähler E, Gansera L, Polze N, Köhler N. Psychological distress and quality of life of palliative cancer patients and their caring relatives during home care. Support Care Cancer. 2014;22(10):2775–2782.
7. Smith A, Hyde YM, Stanford D. Supportive care needs of cancer patients: A literature review. Palliat Support Care. 2015;13(4):1013–1017.
8. Wang T, Molassiotis A, Chung BPM, Tan JY. Unmet care needs of advanced cancer patients and their informal caregivers: a systematic review. BMC Palliat Care. 2018;17(1):1–29.
9. Brix C, Schleussner C, Füller J, Roehrig B, Wendt TG, Strauss B. The need for psychosocial support and its determinants in a sample of patients undergoing radiooncological treatment of cancer. J Psychosom Res. 2008;65(6):541–548.
10. Faller H, Weis J, Koch U, Brähler E, Härter M, Keller M, et al. Perceived need for psychosocial support depending on emotional distress and mental comorbidity in men and women with cancer. J Psychosom Res. 2016;81:24–30.
11. Merckaert I, Libert Y, Messin S, Milani M, Slachmuylder JL, Razavi D. Cancer patients' desire for psychological support: Prevalence and implications for screening patients' psychological needs. Psychooncology. 2010;19(2):141–149.
12. Jacobsen PB, Wagner LI. A new quality standard: The integration of psychosocial care into routine cancer care. J Clin Oncol. 2012;30(11):1154–1159.
13. Faller H, Schuler M, Richard M, Heckl U, Weis J, Kuffner R. Effects of psycho-oncologic interventions on emotional distress and quality of life in adult patients with cancer: Systematic review and meta-analysis. J Clin Oncol. 2013;31(6):782–793.
14. Osborn RL, Demoncada AC, Feuerstein M. Psychosocial interventions for depression, anxiety, and quality of life in cancer survivors: Meta-analyses. Int J Psychiatry Med. 2006;36(1):13–34.
15. Linden W, Girgis A. Psychological treatment outcomes for cancer patients: What do meta-analyses tell us about distress reduction? Psychooncology. 2012;21(4):343–350.
16. Rehse B, Pukrop R. Effects of psychosocial interventions on quality of life in adult cancer patients: Meta analysis of 37 published controlled outcome studies. Patient Educ Couns. 2003;50(2):179–186.
17. Kalter J, Verdonck-de Leeuw IM, Sweegers MG, Aaronson NK, Jacobsen PB, Newton RU, et al. Effects and moderators of psychosocial interventions on quality of life, and emotional and social function in patients with cancer: An individual patient data meta-analysis of 22 RCTs. Psycho-Oncology. 2018;27: 1150–1161.
18. Faller H, Weis J, Koch U, Brähler E, Härter M, Keller M, et al. Utilization of professional psychological care in a large German sample of cancer patients. Psychooncology. 2017;26(4):537–543.

19. Tondorf T, Grossert A, Rothschild SI, Koller MT, Rochlitz C, Kiss A, et al. Focusing on cancer patients' intentions to use psychooncological support: A longitudinal, mixed-methods study. Psychooncology. 2018;27(6):1656–1663.
20. Kowalski C, Ferencz J, Singer S, Weis I, Wesselmann S. Frequency of psycho-oncologic and social service counseling in cancer centers relative to center site and hospital characteristics: Findings from 879 center sites in Germany, Austria, Switzerland, and Italy. Cancer. 2016;122(22):3538–3545.
21. Swift JK, Callahan JL, Cooper M, Parkin SR. The impact of accommodating client preference in psychotherapy: A meta-analysis. J Clin Psychol. 2018;74(11):1924–1937.
22. Swift JK, Callahan JL, Ivanovic M, Kominiak N. Further examination of the psychotherapy preference effect: A meta-regression analysis. J Psychother Integr. 2013;23(2):134–145.
23. Swift JK, Callahan JL. The Impact of Client Treatment Preferences on Outcome: A Meta-Analysis. J Clin Psychol. 2009;65(4):368–381.
24. Lindhiem O, Bennett CB, Trentacosta CJ, McLear C. Client preferences affect treatment satisfaction, completion, and clinical outcome: A meta-analysis. Clin Psychol Rev. 2014;34(6):506–517.
25. Fann JR, Ell K, Sharpe M. Integrating psychosocial care into cancer services. J Clin Oncol. 2012;30(11):1178–1186.
26. Mosher C, Winger J, Hanna N, Jalal S, Fakiris A, Einhorn L, et al. Barriers to Mental Health Service Use and Preferences for Addressing Emotional Concerns among Lung Cancer Patients. Psychooncology. 2014;23(7):812–819.
27. Clover KA, Mitchell AJ, Britton B, Carter G. Why do oncology outpatients who report emotional distress decline help? Psychooncology. 2015;24(7):812–818.
28. Jansen F, Krebber AMH, Coupé VMH, Cuijpers P, De Bree R, Becker-Commissaris A, et al. Cost-utility of stepped care targeting psychological distress in patients with head and neck or lung cancer. J Clin Oncol. 2017;35(3):314–324.
29. Krebber AMH, Jansen F, Witte BI, Cuijpers P, de Bree R, Becker-Commissaris A, et al. Stepped care targeting psychological distress in head and neck cancer and lung cancer patients: A randomized, controlled trial. Ann Oncol. 2016;27(9):1754–1760.
30. Dilworth S, Higgins I, Parker V, Kelly B, Turner J. Patient and health professional's perceived barriers to the delivery of psychosocial care to adults with cancer: A systematic review. Psychooncology. 2014;23(6):601–612.
31. Mosher CE, Duhamel KN, Rini CM, Li Y, Isola L, Labay L, et al. Barriers to mental health service use among hematopoietic SCT survivors. Bone Marrow Transplant. 2010;45(3):570–579.
32. Integraal Kankercentrum Nederland. Detecteren behoefte psychosociale zorg. Oncoline. 2017: 1–85. Available from: http://www.oncoline.nl/detecteren-behoefte-psychosociale-zorg. (accessed January 1, 2019)
33. Jaspers J, Van Middendorp H. Psychosociale zorg bij chronische ziekten. Houten: Bohn Stafleu van Loghum; 2010.
34. GGZ Nederland. Q & A Wachttijden Geestelijke Gezondheidszorg en Verslavingszorg. 2018. Available from: https://www.ggznederland.nl/uploads/assets/Q&Awachttijden_2019_KORT_definitief.pdf. (accessed February 3, 2021)
35. Rijksoverheid. Wie vergoedt mijn hulp bij psychische problemen? Available from: https://www.rijksoverheid.nl/onderwerpen/geestelijke-gezondheidszorg/vraag-en-antwoord/vergoeding-ggz. (accessed February 10, 2021)
36. Integraal Kankercentrum Nederland. Cijfers over kanker. Nederland Integraal Kankercentrum. 2014. Available from: https://www.cijfersoverkanker.nl/kerncijfers-over-kanker-49.html. (accessed January 1, 2019)
37. Zegers M, Heijmans M, Rijken M. Ondersteuningsbehoeften van (ex-) kankerpatiënten en de rol van de huisarts. NIVEL; 2010. 92.

38. Epstein RM, Peters E. Beyond information: Exploring patients' preferences. JAMA. 2009;302(2):195–197.
39. Loiselle CG, Brown TL. Increasing access to psychosocial oncology services means becoming more person-centered and situation-responsive. Support Care Cancer. 2020;1–3.
40. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77–101.
41. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. Int J Qual Heal Care. 2007;19(6):349–357.
42. Shechtman Z, Kiezel A. Why do people prefer individual therapy over group therapy? Int J Group Psychother. 2016;66(4):571–591.
43. Arch JJ, Vanderkruik R, Kirk A, Carr AL. A closer lens: Cancer survivors' supportive intervention preferences and interventions received. Psychooncology. 2018;27(5):1434–1441.
44. Wallin EEK, Mattsson S, Olsson EMG. The Preference for Internet-Based Psychological Interventions by Individuals Without Past or Current Use of Mental Health Treatment Delivered Online: A Survey Study With Mixed-Methods Analysis. JMIR Ment Heal. 2016;3(2):e25.
45. Griffiths F, Lindenmeyer A, Powell J, Lowe P, Thorogood M. Why are health care interventions delivered over the internet? A systematic review of the published literature. J Med Internet Res. 2006;8(2):e10.
46. Andrade LH, Alonso J, Mneimneh Z, Wells JE, Al-Hamzawi A, Borges G, et al. Barriers to mental health treatment: Results from the WHO World Mental Health surveys. Psychol Med. 2014;44(6):1303–1317.
47. CBS StatLine. Internet; toegang, gebruik en faciliteiten. 2019. Available from: https://www.cbs.nl/nl-nl/cijfers/detail/83429NED?dl=35852. (accessed Oct 28, 2020)
48. Wind TR, Rijkeboer M, Andersson G, Riper H. The COVID-19 pandemic: The 'black swan' for mental health care and a turning point for e-health. Internet Interv. 2020;20.
49. Furnham A, Swami V. Patient preferences for psychological counsellors: Evidence of a similarity effect. Couns Psychol Q. 2008;21(4):361–370.
50. Blow AJ, Timm TM, Cox R. The role of the therapist in therapeutic change: Does therapist gender matter? J Fem Fam Ther. 2008;20(1):66–86.
51. Landes SJ, Burton JR, King KM, Sullivan BF. Women's preference of therapist based on sex of therapist and presenting problem: An analog study. Couns Psychol Q. 2013;26(3–4):330–342.
52. Tucker JR, Hammer JH, Vogel DL, Bitman RL, Wade NG, Maier EJ. Disentangling self-stigma: Are Mental illness and help-seeking self-stigmas different. J Couns Psychol. 2013 Oct;60(4):520–531.
53. Clement S, Schauman O, Graham T, Maggioni F, Evans-Lacko S, Bezborodovs N, et al. What is the impact of mental health-related stigma on help-seeking? A systematic review of quantitative and qualitative studies. Psychol Med. 2015;45(1):11–27.
54. Boerema AM, Kleiboer A, Beekman ATF, van Zoonen K, Dijkshoorn H, Cuijpers P. Determinants of help-seeking behavior in depression: A cross-sectional study. BMC Psychiatry. 2016;16(1):1–9.
55. Baker-Glenn EA, Park B, Granger L, Symonds P, Mitchell AJ. Desire for psychological support in cancer patients with depression or distress : validation of a simple help question. Psychooncology. 2011;531:525–531.
56. Carlson LE. Screening alone is not enough: the importance of appropriate traige, referral, and evidence-based treatment of distress and common problems. J Clin Oncol. 2013;31(29):3616–3617.
57. Mitchell AJ, Vahabzadeh A, Magruder K. Screening for distress and depression in cancer settings: 10 lessons from 40 years of primary-care research. Psychooncology. 2011;20(6):572–584.
58. Krul S, Docter M, Brouwer-Dudok de Wit C, Verdonck-de Leeuw IM. Psychological care in cancer patients and their caregivers: Who gets help, why, when, and how? Neth J Psychol. 2012;67:36–42.

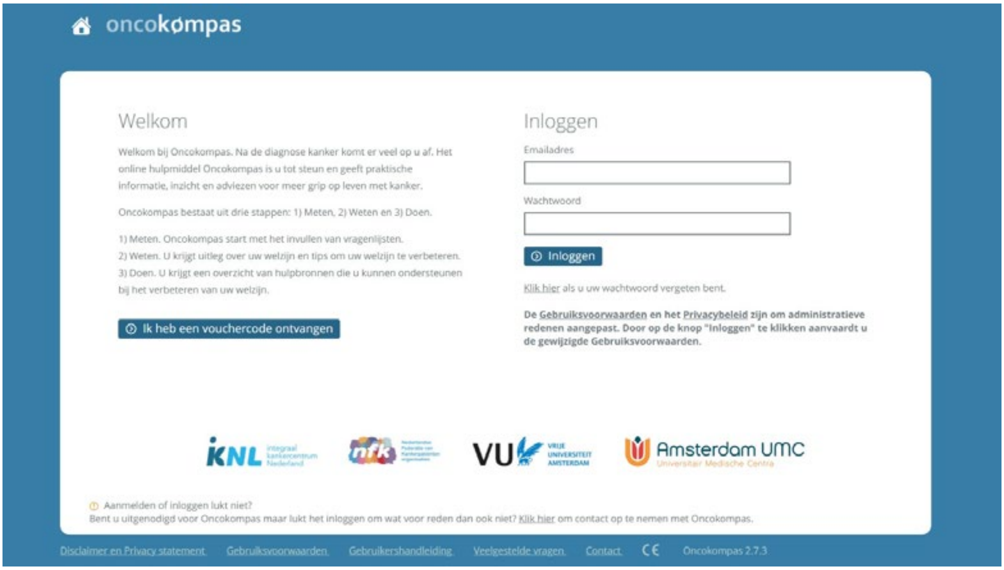
59. Berman R, Davies A, Cooksley T, Gralla R, Carter L, Darlington E, et al. Supportive Care: An Indispensable Component of Modern Oncology. Clin Oncol. 2020;32:781-788.
60. Moore, Rivera S, Bravo-Soto G, Olivares C, Lawrie T. Communication skills training for healthcare professionals working with people who have cancer. Cochrane Database Syst Rev Commun. 2018;(7):CD003751.
61. Holland J. Why Psychosocial Care is Difficult to Integrate into Routine Cancer Care: Stigma is the Elephant in the Room. J Natl Compr Cancer Netw. 2010;8(4):362–366.
62. Zebrack B, Isaacson S. Psychosocial care of adolescent and young adult patients with cancer and survivors. J Clin Oncol. 2012;30(11):1221–1226.
63. Weis J, Hönig K, Bergelt C, Faller H, Brechtel A, Hornemann B, et al. Psychosocial distress and utilization of professional psychological care in cancer patients: An observational study in National Comprehensive Cancer Centers (CCCs) in Germany. Psychooncology. 2018;27(12):2847–2854.

3

INTERMEZZO ONCOKOMPAS

Oncokompas is an eHealth self-management application supporting users to adopt an active role in managing their own health and healthcare. Oncokompas comprises three steps: ‘Measure’, ‘Learn’, and ‘Act’. Based on patient-reported outcome measures (PROMs) (Measure), users get tailored information and advice (Learn), and a personalized overview of supportive care options (Act). The development of Oncokompas started in 2010. First, Oncokompas was developed for cancer survivors in general. Subsequently, extra tumor specific modules were developed targeting survivors of head and neck cancer, colorectal cancer, lymphoma, breast cancer, and melanoma. From 2016 till 2018 Oncokompas was extended to make the content of the application suitable for patients with incurable cancer and their partners.

Users get an invitation to activate their Oncokompas account by e-mail. After creating an account, users can log-in to Oncokompas at any time on their tablet or PC. Figure 1 shows a screenshot of the login screen of Oncokompas. When users log in into the application, they are asked to complete a general questionnaire. This questionnaire is used to select relevant topics for a specific user. For example, when someone is retired, no work-related topics will be presented to this user.



Welkom bij Oncokompas. Na de diagnose kanker komt er veel op u af. Het online hulpmiddel Oncokompas is u tot steun en geeft praktische informatie, inzicht en adviezen voor meer grip op leven met kanker.

Oncokompas bestaat uit drie stappen: 1) Meten, 2) Weten en 3) Doen.

1) Meten. Oncokompas start met het invullen van vragenlijsten.
2) Weten. U krijgt uitleg over uw welzijn en tips om uw welzijn te verbeteren.
3) Doen. U krijgt een overzicht van hulpbronnen die u kunnen ondersteunen bij het verbeteren van uw welzijn.

Klik hier als u uw wachtwoord vergeten bent.

De Gebruiksvoorwaarden en het Privacybeleid zijn om administratieve redenen aangepast. Door op de knop "Inloggen" te klikken aanvaardt u de gewijzigde Gebruiksvoorwaarden.

Bent u uitgenodigd voor Oncokompas maar lukt het inloggen om wat voor reden dan ook niet? Klik hier om contact op te nemen met Oncokompas.

Figure 1. Login screen of Oncokompas (in Dutch)

Measure

After completion of the general questionnaire, an overview of all topics is provided in the component ‘Measure’ (Figure 2 and 3). Topics relate to different domains of quality of life: physical, psychological, social functioning, and existential issues. Users can choose by themselves which topics they want to address. Figure 4 and 5 present an overview of all topics developed for incurably ill cancer patients and their partners, respectively. The screenshots presented in figure 6-15 are screenshots of the version of Oncokompas for patients. The version of Oncokompas for partners of incurably ill cancer patients looks different in terms of colors (green background) compared to patients (blue background), but otherwise follows the same structure (‘Measure’, ‘Learn’, and ‘Act’).

Figure 2. The topic overview in Oncokompas for patients

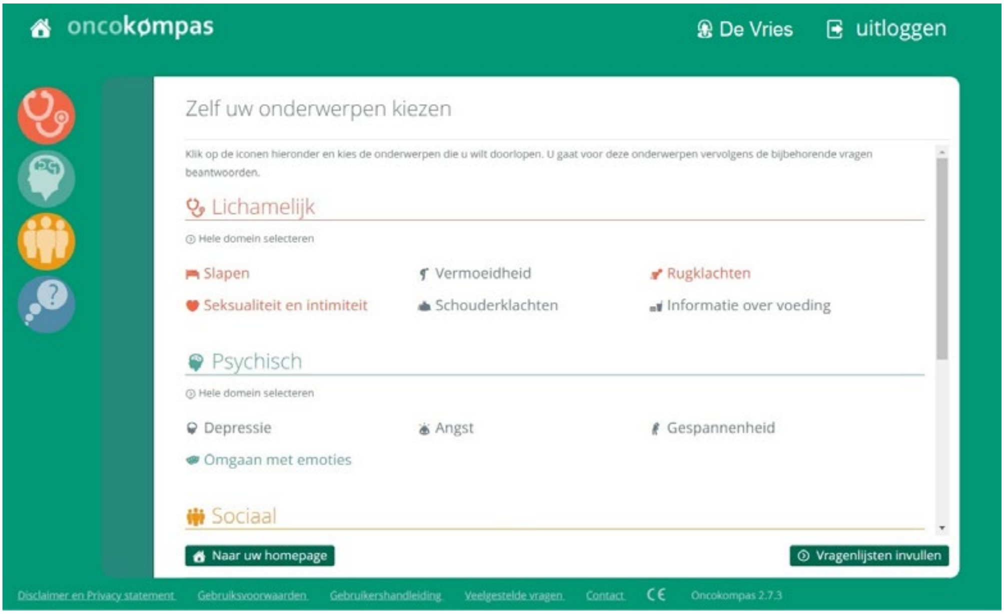
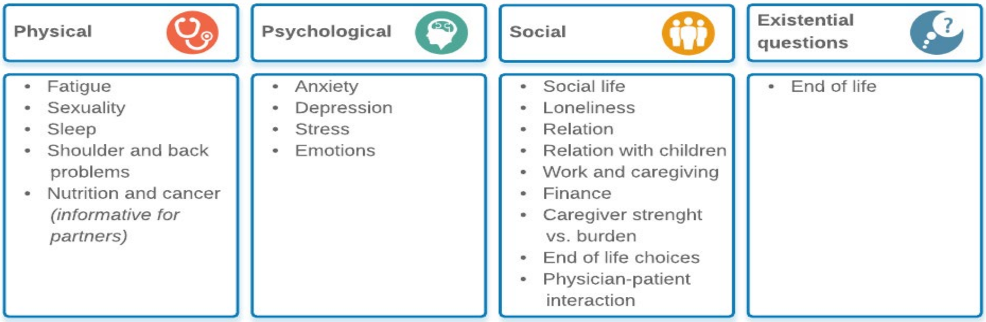

Klik op de iconen hieronder en kies de onderwerpen die u wilt doorlopen. U gaat voor deze onderwerpen vervolgens de bijbehorende vragen beantwoorden.

Figure 3. The topic overview in Oncokompas for partners

Physical	Psychological	Social	Existential questions
• Diarrhea • Constipation • Lack of appetite • Nausea • Stoma related problems • Weight • Nutritional drinks • Probe feeding • Oral problems • Swallowing • Pain • Fatigue • Sleep • Dyspneu • Lymphedema • Daily functioning • Sexuality • Body image • Skin problems • Side effects • Choice support	• Anxiety; ◦ for death ◦ for suffering • Depression • Stress • Emotions	• Social life • Loneliness • Relation • Relation with children • Relation with adult children • Work • Finance • Single and cancer • Meaningful activities • End of life choices • Physician-patient interaction	• Meaning • End of life

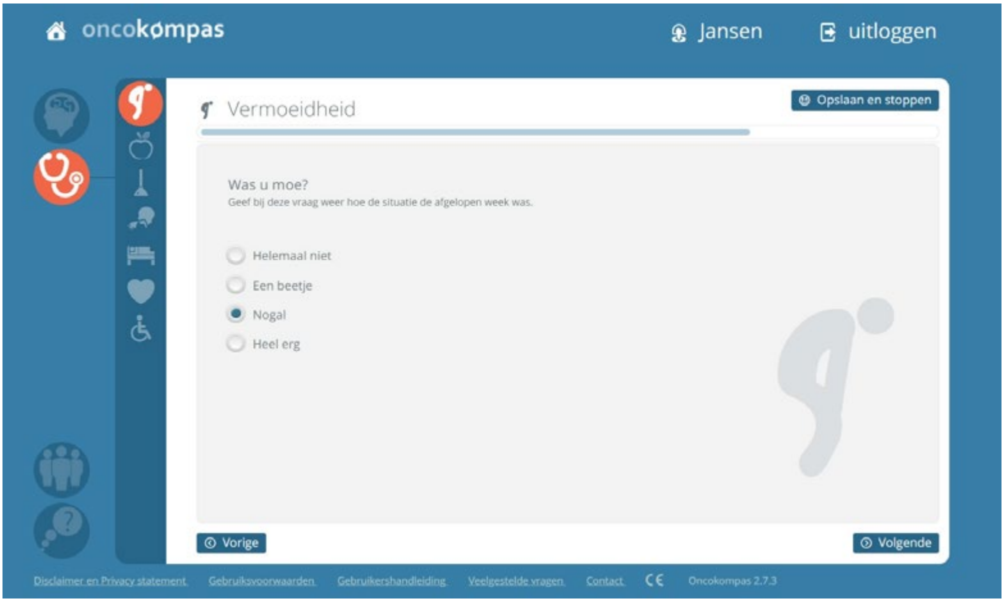
Figure 4. Overview of all topics covered in Oncokompas for patients with incurable cancer



Physical	Psychological	Social	Existential questions
• Fatigue • Sexuality • Sleep • Shoulder and back problems • Nutrition and cancer *(informative for partners)*	• Anxiety • Depression • Stress • Emotions	• Social life • Loneliness • Relation • Relation with children • Work and caregiving • Finance • Caregiver strenght vs. burden • End of life choices • Physician-patient interaction	• End of life

Figure 5. Overview of all topics covered in Oncokompas for partners of patients with incurable cancer

After selecting the topic(s) a user wants to address, the user is asked to complete a few screening questions for each of the selected topics (Figure 6). The answers of the user are processed real-time and processed by the algorithms in Oncokompas to determine which follow-up patient-reported outcome measures (PROMs) are presented to the user. All algorithms are based on evidence-based cut-off scores, Dutch practical guidelines and/or consensus of teams of experts in the field of oncology and palliative care.



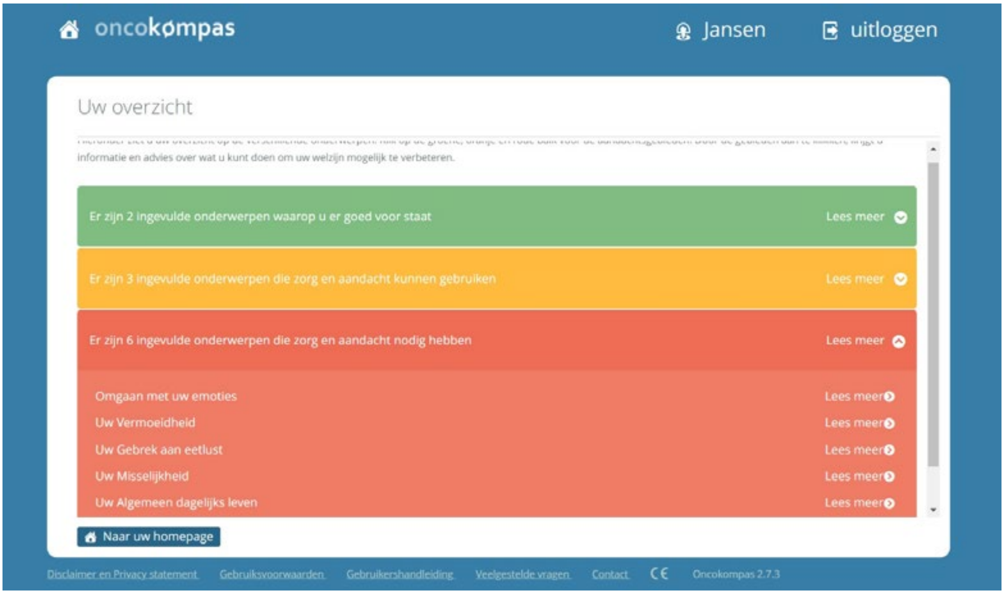
Was u moe?
Geef bij deze vraag weer hoe de situatie de afgelopen week was.

- ○ Helemaal niet
- ○ Een beetje
- ● Nogal
- ○ Heel erg

Figure 6. Example of a question within the topic ‘Fatigue’

Learn

Users’ answers on the PROMs are processed real-time and linked to tailored feedback in the ‘Learn’ component. Users get an overview of their overall well-being on topic level, using a 3-color system (red, orange and green). A green score means that the user is doing well on this topic, an orange score means that this topic could use attention and support, and a red score means that this topic needs attention and support (Figure 7). Users can read information per topic (Figure 8 and 9). For certain topics, Oncokompas draws attention to clusters of interrelated symptoms (Figure 9).



Uw overzicht

informatie en advies over wat u kunt doen om uw welzijn mogelijk te verbeteren.

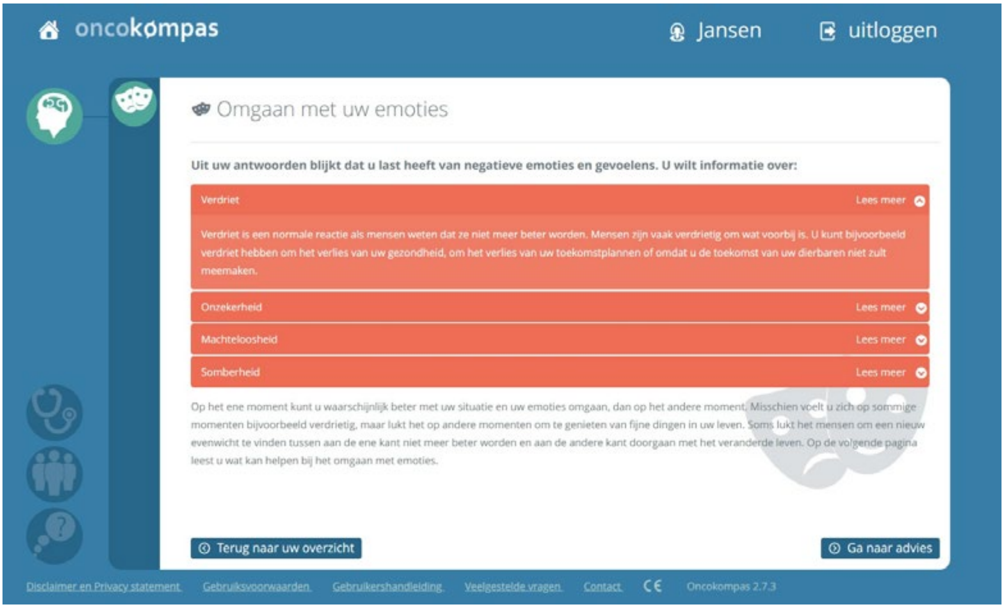
Er zijn 2 ingevulde onderwerpen waarop u er goed voor staat

Er zijn 3 ingevulde onderwerpen die zorg en aandacht kunnen gebruiken

Er zijn 6 ingevulde onderwerpen die zorg en aandacht nodig hebben

- Omgaan met uw emoties
- Uw Vermoeidheid
- Uw Gebrek aan eetlust
- Uw Misselijkheid
- Uw Algemeen dagelijks leven

Figure 7. Overview of the well-being scores on topic level



Omgaan met uw emoties

Uit uw antwoorden blijkt dat u last heeft van negatieve emoties en gevoelens. U wilt informatie over:

Verdriet

Verdriet is een normale reactie als mensen weten dat ze niet meer beter worden. Mensen zijn vaak verdrietig om wat voorbij is. U kunt bijvoorbeeld verdriet hebben om het verlies van uw gezondheid, om het verlies van uw toekomstplannen of omdat u de toekomst van uw dierbaren niet zult meemaken.

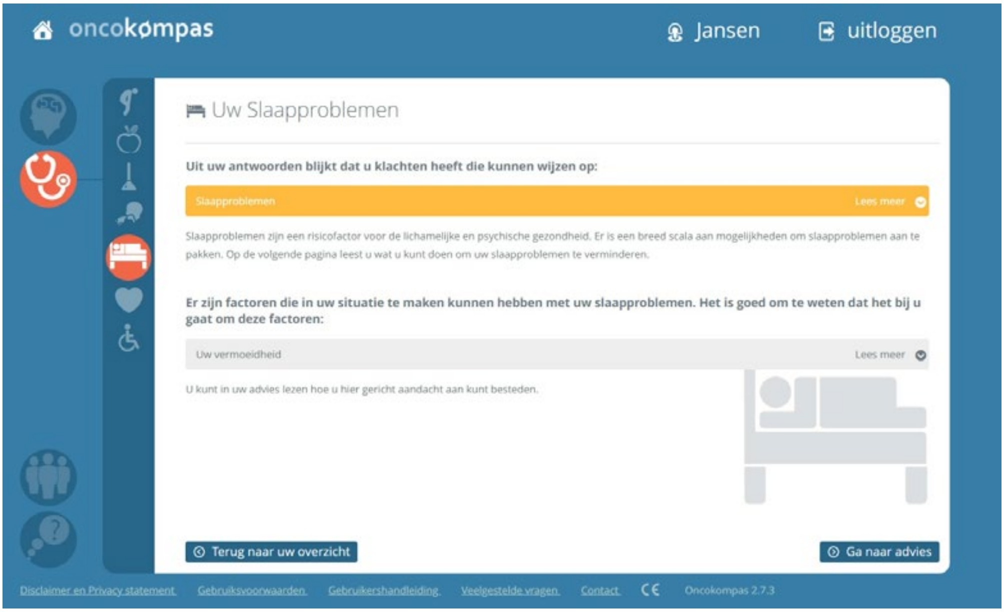
Onzekerheid

Machteloosheid

Somberheid

Op het ene moment kunt u waarschijnlijk beter met uw situatie en uw emoties omgaan, dan op het andere moment. Misschien voelt u zich op sommige momenten bijvoorbeeld verdrietig, maar lukt het op andere momenten om te genieten van fijne dingen in uw leven. Soms lukt het mensen om een nieuw evenwicht te vinden tussen aan de ene kant niet meer beter worden en aan de andere kant doorgaan met het veranderde leven. Op de volgende pagina leest u wat kan helpen bij het omgaan met emoties.

Figure 8. Information on the topic ‘Emotions’



Uit uw antwoorden blijkt dat u klachten heeft die kunnen wijzen op:

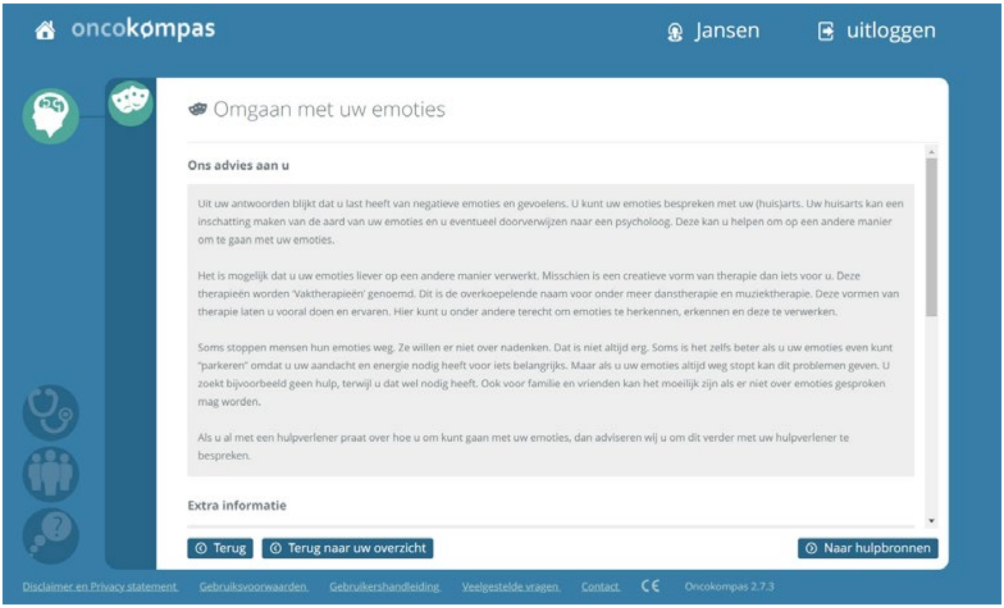
Slaapproblemen zijn een risicofactor voor de lichamelijke en psychische gezondheid. Er is een breed scala aan mogelijkheden om slaapproblemen aan te pakken. Op de volgende pagina leest u wat u kunt doen om uw slaapproblemen te verminderen.

Er zijn factoren die in uw situatie te maken kunnen hebben met uw slaapproblemen. Het is goed om te weten dat het bij u gaat om deze factoren:

U kunt in uw advies lezen hoe u hier gericht aandacht aan kunt besteden.

Figure 9. Information on the topic ‘Sleeping problems’

The ‘Learn’ component concludes with personalized self-care advice, including tips and tools to support users to improve their symptom burden by themselves (Figure 10 and 11).



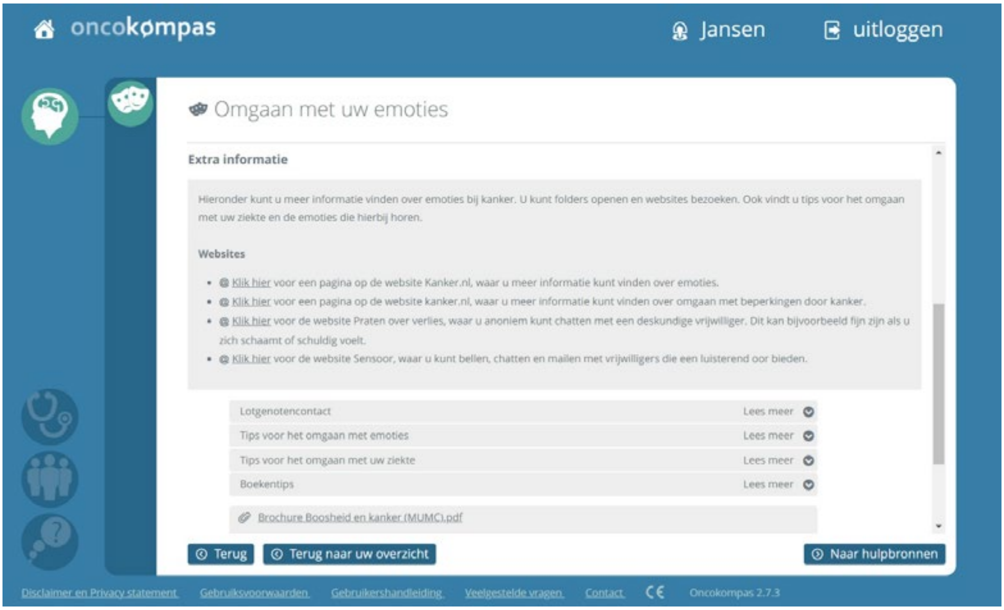
Uit uw antwoorden blijkt dat u last heeft van negatieve emoties en gevoelens. U kunt uw emoties bespreken met uw (huis)arts. Uw huisarts kan een inschatting maken van de aard van uw emoties en u eventueel doorverwijzen naar een psycholoog. Deze kan u helpen om op een andere manier om te gaan met uw emoties.

Het is mogelijk dat u uw emoties liever op een andere manier verwerkt. Misschien is een creatieve vorm van therapie dan iets voor u. Deze therapieën worden 'Vaktherapieën' genoemd. Dit is de overkoepelende naam voor onder meer danstherapie en muziektherapie. Deze vormen van therapie laten u vooral doen en ervaren. Hier kunt u onder andere terecht om emoties te herkennen, erkennen en deze te verwerken.

Soms stoppen mensen hun emoties weg. Ze willen er niet over nadenken. Dat is niet altijd erg. Soms is het zelfs beter als u uw emoties even kunt "parkeren" omdat u uw aandacht en energie nodig heeft voor iets belangrijks. Maar als u uw emoties altijd weg stopt kan dit problemen geven. U zoekt bijvoorbeeld geen hulp, terwijl u dat wel nodig heeft. Ook voor familie en vrienden kan het moeilijk zijn als er niet over emoties gesproken mag worden.

Als u al met een hulpverlener praat over hoe u om kunt gaan met uw emoties, dan adviseren wij u om dit verder met uw hulpverlener te bespreken.

Figure 10. Personalized advice the topic ‘Emotions’



Omgaan met uw emoties

Extra informatie

Hieronder kunt u meer informatie vinden over emoties bij kanker. U kunt folders openen en websites bezoeken. Ook vindt u tips voor het omgaan met uw ziekte en de emoties die hierbij horen.

Websites

- Klik hier voor een pagina op de website Kanker.nl, waar u meer informatie kunt vinden over emoties.
- Klik hier voor een pagina op de website kanker.nl, waar u meer informatie kunt vinden over omgaan met beperkingen door kanker.
- Klik hier voor de website Praten over verlies, waar u anoniem kunt chatten met een deskundige vrijwilliger. Dit kan bijvoorbeeld fijn zijn als u zich schaamt of schuldig voelt.
- Klik hier voor de website Sensoor, waar u kunt bellen, chatten en mailen met vrijwilligers die een luisterend oor bieden.

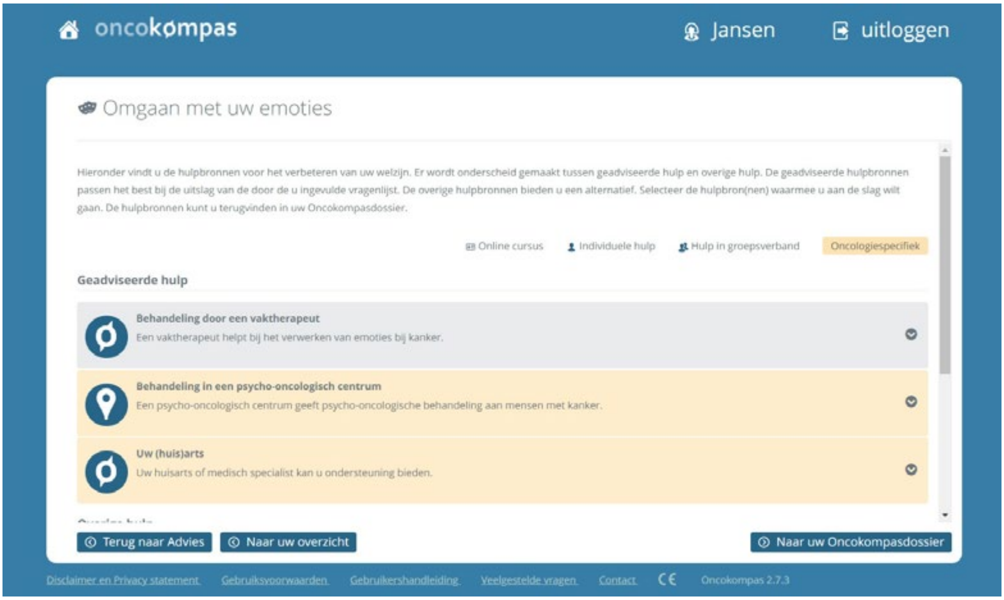
Lotgenotencontact — Lees meer
Tips voor het omgaan met emoties — Lees meer
Tips voor het omgaan met uw ziekte — Lees meer
Boekentips — Lees meer

Brochure Boosheid en kanker (MUMC).pdf

Figure 11. Personalized advice the topic ‘Emotions’, including links to related websites and tips to support the user to take action on his/her symptom burden

Act

In the ‘Act’ component, Oncokompas provides users a personalized overview of supportive care options, based on their health status, personal characteristics and preferences (Figure 12 and 13). Topics with orange scores focus on (guided) self-help interventions. Topics with red scores include the advice to contact a general practitioner or medical specialist.



Omgaan met uw emoties

Hieronder vindt u de hulpbronnen voor het verbeteren van uw welzijn. Er wordt onderscheid gemaakt tussen geadviseerde hulp en overige hulp. De geadviseerde hulpbronnen passen het best bij de uitslag van de door de u ingevulde vragenlijst. De overige hulpbronnen bieden u een alternatief. Selecteer de hulpbron(nen) waarmee u aan de slag wilt gaan. De hulpbronnen kunt u terugvinden in uw Oncokompasdossier.

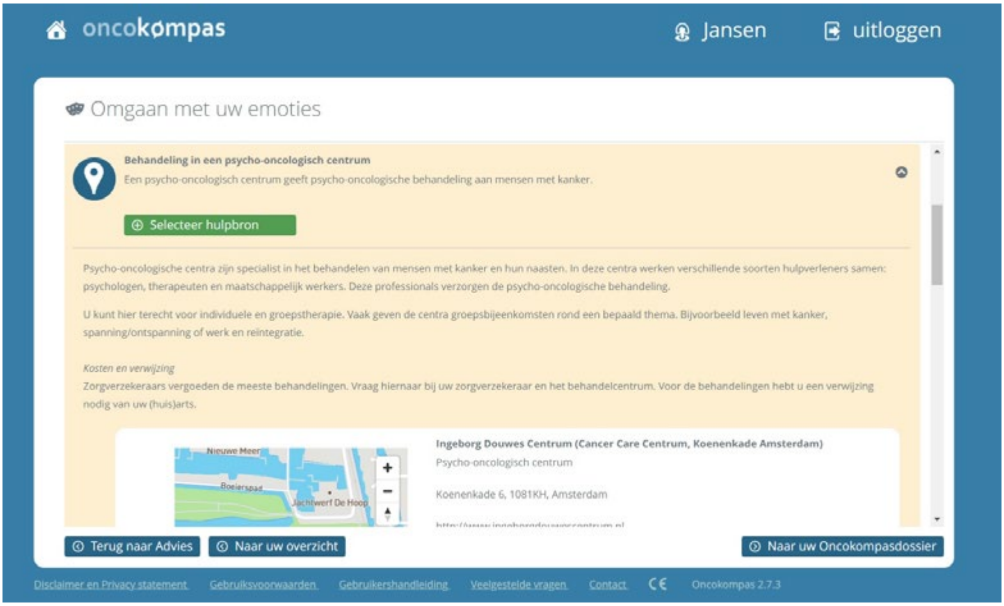
Geadviseerde hulp

Behandeling door een vaktherapeut
Een vaktherapeut helpt bij het verwerken van emoties bij kanker.

Behandeling in een psycho-oncologisch centrum
Een psycho-oncologisch centrum geeft psycho-oncologische behandeling aan mensen met kanker.

Uw (huis)arts
Uw huisarts of medisch specialist kan u ondersteuning bieden.

Figure 12. Overview of the supportive care options



Omgaan met uw emoties

Behandeling in een psycho-oncologisch centrum
Een psycho-oncologisch centrum geeft psycho-oncologische behandeling aan mensen met kanker.

Psycho-oncologische centra zijn specialist in het behandelen van mensen met kanker en hun naasten. In deze centra werken verschillende soorten hulpverleners samen: psychologen, therapeuten en maatschappelijk werkers. Deze professionals verzorgen de psycho-oncologische behandeling.

U kunt hier terecht voor individuele en groepstherapie. Vaak geven de centra groepsbijeenkomsten rond een bepaald thema. Bijvoorbeeld leven met kanker, spanning/ontspanning of werk en reintegratie.

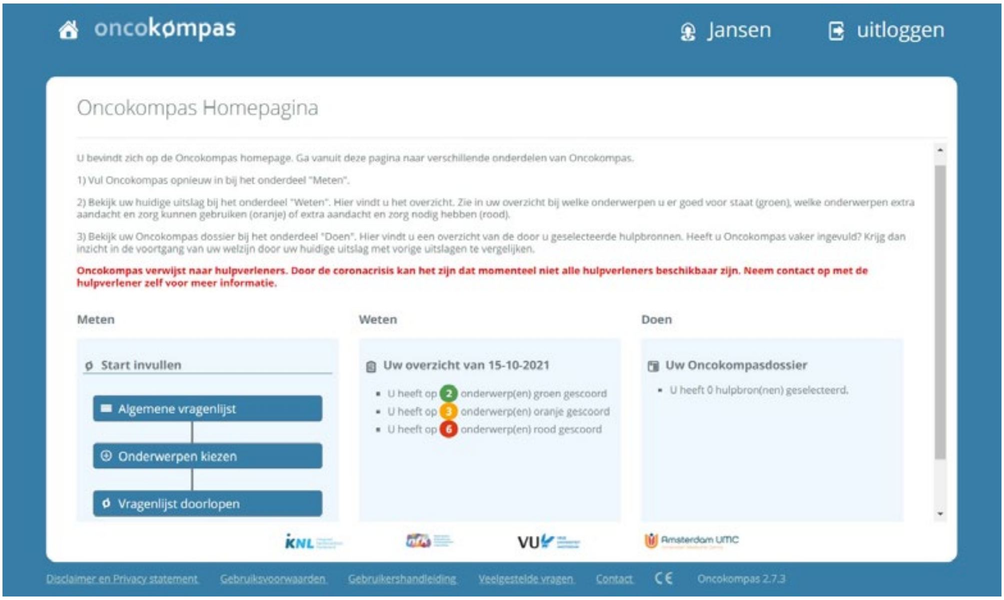
Kosten en verwijzing
Zorgverzekeraars vergoeden de meeste behandelingen. Vraag hiernaar bij uw zorgverzekeraar en het behandelcentrum. Voor de behandelingen hebt u een verwijzing nodig van uw (huis)arts.

Ingeborg Douwes Centrum (Cancer Care Centrum, Koenenkade Amsterdam)
Psycho-oncologisch centrum

Koenenkade 6, 1081KH, Amsterdam

Figure 13. Each supportive care option is further explained when a user clicks on the supportive care option

Once users have created an account, they can use Oncokompas multiple times. When logging into the application, users arrive on the homepage of Oncokompas (Figure 14). Each time a user wants to monitor his or her symptoms, Oncokompas starts with the component 'Measure'. Oncokompas provides an overview of scores on the topics over time in the Oncokompas dossier (Figure 15).



Oncokompas Homepagina

U bevindt zich op de Oncokompas homepage. Ga vanuit deze pagina naar verschillende onderdelen van Oncokompas.

1) Vul Oncokompas opnieuw in bij het onderdeel "Meten".

2) Bekijk uw huidige uitslag bij het onderdeel "Weten". Hier vindt u het overzicht. Zie in uw overzicht bij welke onderwerpen u er goed voor staat (groen), welke onderwerpen extra aandacht en zorg kunnen gebruiken (oranje) of extra aandacht en zorg nodig hebben (rood).

3) Bekijk uw Oncokompas dossier bij het onderdeel "Doen". Hier vindt u een overzicht van de door u geselecteerde hulpbronnen. Heeft u Oncokompas vaker ingevuld? Krijg dan inzicht in de voortgang van uw welzijn door uw huidige uitslag met vorige uitslagen te vergelijken.

Oncokompas verwijst naar hulpverleners. Door de coronacrisis kan het zijn dat momenteel niet alle hulpverleners beschikbaar zijn. Neem contact op met de hulpverlener zelf voor meer informatie.

Meten

Start invullen

Weten

Uw overzicht van 15-10-2021

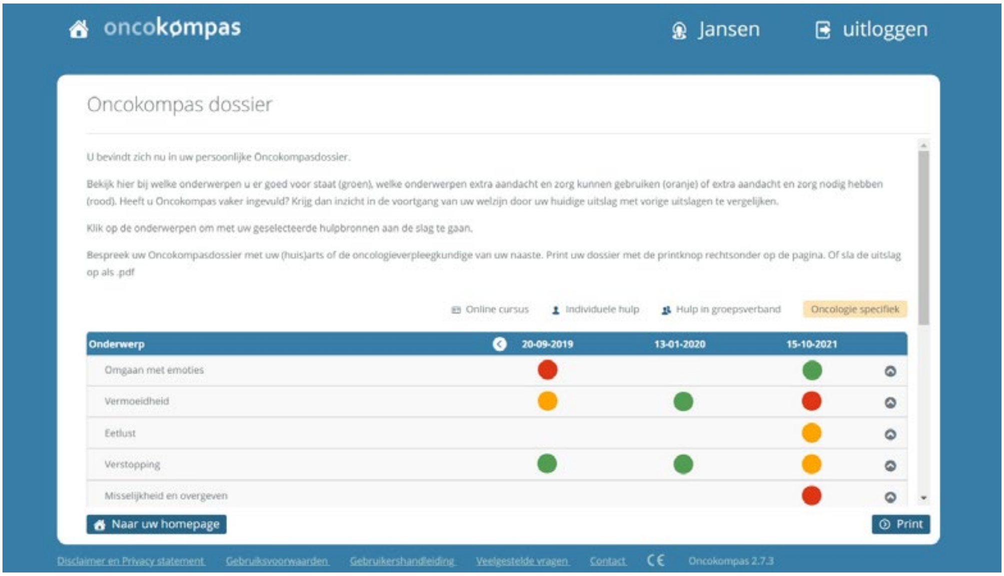
- U heeft op 2 onderwerp(en) groen gescoord
- U heeft op 3 onderwerp(en) oranje gescoord
- U heeft op 6 onderwerp(en) rood gescoord

Doen

Uw Oncokompasdossier

- U heeft 0 hulpbron(nen) geselecteerd.

Figure 14. The homepage of Oncokompas



Oncokompas dossier

U bevindt zich nu in uw persoonlijke Oncokompasdossier.

Bekijk hier bij welke onderwerpen u er goed voor staat (groen), welke onderwerpen extra aandacht en zorg kunnen gebruiken (oranje) of extra aandacht en zorg nodig hebben (rood). Heeft u Oncokompas vaker ingevuld? Krijg dan inzicht in de voortgang van uw welzijn door uw huidige uitslag met vorige uitslagen te vergelijken.

Klik op de onderwerpen om met uw geselecteerde hulpbronnen aan de slag te gaan.

Bespreek uw Oncokompasdossier met uw (huis)arts of de oncologieverpleegkundige van uw naaste. Print uw dossier met de printknop rechtsonder op de pagina. Of sla de uitslag op als .pdf

Onderwerp	20-09-2019	13-01-2020	15-10-2021
Omgaan met emoties	🔴		🟢
Vermoeidheid	🟠	🟢	🔴
Eetlust			🟠
Verstopping	🟢	🟢	🟠
Misselijkheid en overgeven			🔴

Figure 15. The Oncokompas dossier with an overview of scores over time

4

EFFICACY AND COST-UTILITY OF THE EHEALTH APPLICATION ‘ONCOKOMPAS’, SUPPORTING PATIENTS WITH INCURABLE CANCER IN FINDING OPTIMAL PALLIATIVE CARE, TAILORED TO THEIR QUALITY OF LIFE AND PERSONAL PREFERENCES: A STUDY PROTOCOL OF A RANDOMIZED CONTROLLED TRIAL

Anouk S. Schuit
Karen Holtmaat
Nienke Hooghiemstra
Femke Jansen
Birgit I. Lissenberg-Witte
Veerle M.H. Coupé
Myra E. van Linde
Annemarie Becker-Commissaris
Jaap C. Reijneveld
Josée M. Zijlstra
Dirkje W. Sommeijer
Simone E.J. Eerenstein
Irma M. Verdonck-de Leeuw

BMC Palliative Care 2019;18:85

ABSTRACT

Background: Patients with incurable cancer have to deal with a wide range of symptoms due to their disease and treatment, influencing their quality of life. Nowadays, patients are expected to adopt an active role in managing their own health and healthcare. Oncokompas is an eHealth self-management application developed to support patients in finding optimal palliative care, tailored to their quality of life and personal preferences. A randomized controlled trial will be carried out to determine the efficacy and cost-utility of Oncokompas compared to care as usual.

Methods: 136 adult patients with incurable lung, breast, colorectal and head and neck cancer, lymphoma and glioma, will be included. Eligible patients have no curative treatment options and a prognosis of at least three months. Patients will be randomly assigned to the intervention group or the control group. The intervention group directly has access to Oncokompas alongside care as usual, while the waiting list control group receives care as usual and will have access to Oncokompas after three months. The primary outcome measure is patient activation, which can be described as a patient’s knowledge, skills and confidence to manage his or her own health and healthcare. Secondary outcome measures comprise self-efficacy, health-related quality of life and costs. Measures will be assessed at baseline, two weeks after randomization, and three months after the baseline measurement.

Discussion: This study will result in knowledge on the efficacy and cost-utility of Oncokompas among patients with incurable cancer. Also, more knowledge will be generated into the need for and costs of palliative care from a societal and healthcare perspective.

Trial registration: Netherlands Trial Register identifier: NTR 7494. Registered on 24 September 2018.

Keywords: incurable cancer, palliative care, supportive care, eHealth, self-management, patient activation

BACKGROUND

Quality of life is an important aspect of healthcare for patients with incurable cancer. These patients have to deal with physical symptoms due to their disease and treatment, and often suffer from psychological, social and existential concerns, negatively affecting their quality of life[1,2,3]. Palliative care (or supportive care) for patients with incurable cancer focuses on reducing symptoms, improving quality of life and supporting patients and their families[4]. It not only concerns the management of physical symptoms related to the disease and its treatment. It also involves the provision of services to meet emotional, social, psychological, spiritual, informational and practical needs[5,6,7]. Although there is evidence that early palliative care improves patients' quality of life[8], palliative care services are often discussed at a late stage of the advanced cancer trajectory and many patients have unmet needs[9,10].

Nowadays, patients are expected to adopt an active role in the management of their own well-being and healthcare[9,10]. Self-management is defined as "those tasks that individuals undertake to deal with the medical, role, and emotional management of their health condition(s)"[11]. Research has shown that interventions supporting self-management can improve quality of life of patients with chronic disease and can be cost-effective[13,14,15]. They can also be beneficial for patients in terms of self-efficacy and patient activation[11,16]. Evidence suggests that cancer patients with high self-efficacy are less likely to have negative psychological outcomes[17].

Patient activation can be described as a patient's knowledge, skills and confidence to manage his or her own health and healthcare[18]. Research indicated that changes in activation are followed by changes in self-management behaviors[16] and that more activated patients are less likely to have unmet needs[19]. A study among patients with diabetes reported the positive relation between patient activation and self-reported health status across several studies[20]. Furthermore, a higher level of patient activation is associated with lower total costs from a healthcare and societal perspective[21]. Patient outcomes may be influenced by patients' confidence to manage their disease and thereby lead to lower healthcare costs[22].

Self-management can be stimulated through the use of eHealth. A systematic review showed evidence for positive effects of eHealth on cancer patients' knowledge levels and information competence, and possibly also on health status and quality of life[12]. Furthermore, eHealth has the potential to be cost-saving[23]. To the authors' knowledge there is no clear evidence on the efficacy of tailored eHealth interventions supporting self-management in palliative care.

To support cancer patients in managing their well-being by informing them where they can find advice and guidance, the eHealth self-management application Oncokompas has been developed. This application helps patients to monitor their quality of life, using patient-reported outcome measures (PROMs), followed by automatically generated feedback and advice on palliative care services, tailored to their health status and personal preferences. The aim of the current study is to determine the efficacy and cost-utility of Oncokompas as a self-management instrument on patient activation, general self-efficacy, and quality of life among patients with incurable cancer (who are not yet in the terminal phase of their illness) compared to care as usual.

METHODS/DESIGN

Study design

A prospective monocenter randomized controlled trial (RCT) with two parallel groups will be conducted among patients with incurable cancer to determine the efficacy and cost-utility of Oncokompas.

Patients will be randomly assigned to the intervention group or the waiting list control group. Patients in the intervention group will get direct access to Oncokompas alongside care as usual, while patients in the control group will receive care as usual and will be placed on a waiting list. This means that they will be given access to Oncokompas three months after the baseline measurement (i.e., after completion of the last questionnaire (t2)).

This study has been approved by the VUmc Medical Ethical Committee (registration number 2018.224). All respondents are informed that participation is voluntary. Respondents will provide written informed consent before inclusion. The flow diagram of the RCT is shown in figure 1. Figure 2 shows the schedule of enrollment, intervention and assessments (according to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT)).

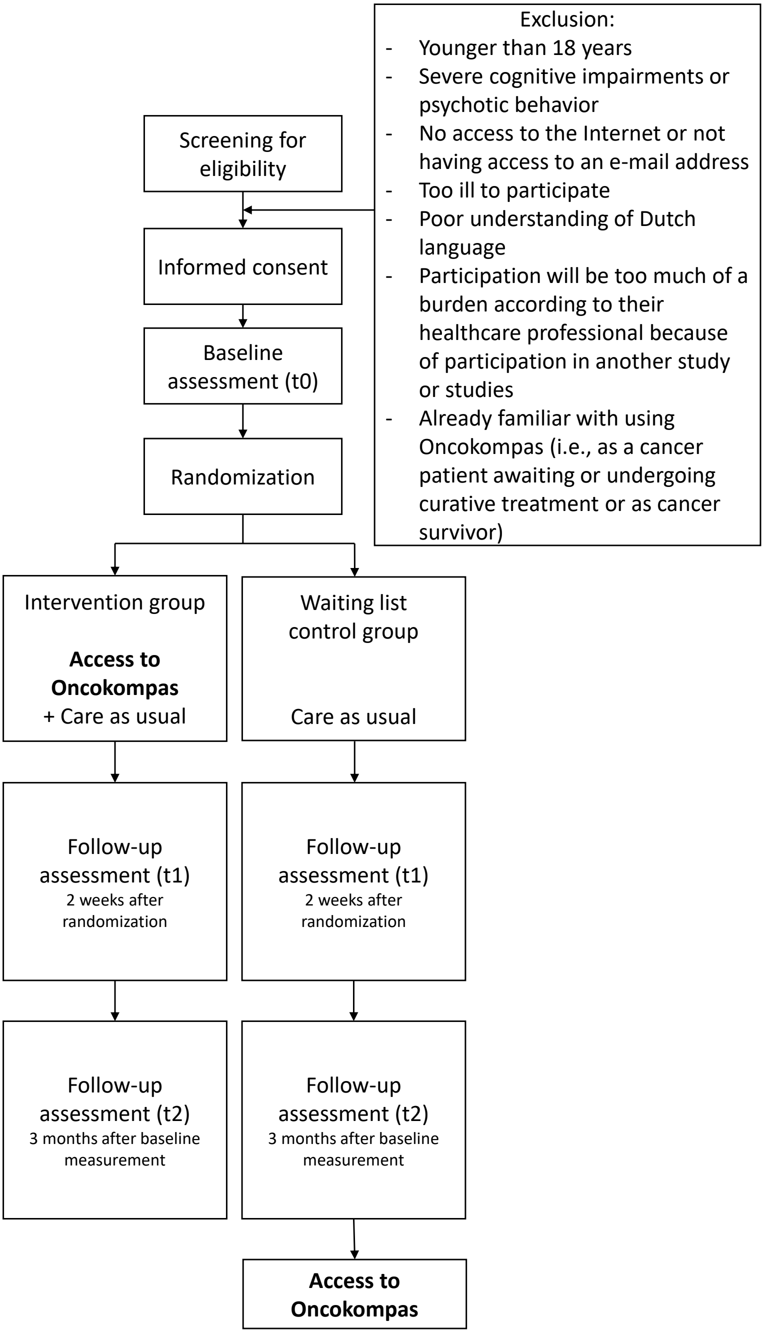


Figure 1. Flow diagram of the RCT

	STUDY PERIOD				
	Enrollment	Allocation	Post-allocation		Close-out
TIMEPOINT	**t0**		**t1**	**t2**	
ENROLLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:		●	—	—	►
Access to Oncokompas (intervention group)		●	—	—	►
Care as usual (intervention and control group)					●—►
Access to Oncokompas (control group)					
ASSESSMENTS:					
Primary outcome measure	X		X	X	
Secondary outcome measures	X		X	X	
Cost-utility measures	X			X	

Figure 2. The schedule of enrollment, intervention and assessments of the RCT (according to SPIRIT)

Study population

Inclusion and exclusion criteria

This study will include adult patients (18 years or older) with incurable cancer (i.e., not having curative treatment options) who have a life expectancy of at least three months. Patients are included when they are diagnosed with lung cancer, breast cancer, colorectal cancer, head and neck cancer, lymphoma, or glioma. Furthermore, patients must be aware of the incurability of their cancer.

Patients are excluded when they have severe cognitive impairments or psychotic behavior (delusions and hallucinations), a poor understanding of the Dutch language (and thereby are not able to complete a Dutch questionnaire), or when they are too ill to participate. Patients are also excluded when they do not have access to the Internet or do not have access to an e-mail address, when their healthcare professional thinks that participation will be too much of a burden because a patient is already participating in other studies, or when they already used Oncokompas before (i.e., as cancer patient awaiting or undergoing curative treatment, or as cancer survivor).

Study procedures

In various hospitals in the Netherlands, patients will be informed about this study by their healthcare professional. Patients eligible to participate will be approached by their medical specialist, (research)nurse or nurse specialist when they visit the outpatient clinic. Apart from informing and referring patients to the research team, no actions regarding the study will take place in the hospitals (therefore this study is marked as a monocenter study).

The coordinating researcher will further inform interested patients by phone or through direct face-to-face contact at the outpatient clinic. Patients also receive a letter with information about the study and Oncokompas. When patients want to participate, they sign the informed consent form. After the researcher has received the informed consent form, patients will receive a link to the online baseline questionnaire by e-mail. Patients who completed the baseline questionnaire (t0) will be randomized into the intervention group or control group. Patients randomized in the intervention group will receive an invitation e-mail for Oncokompas through which they can activate their personal account. Patients randomized in the control group will receive an e-mail to activate their Oncokompas account after completion of the last questionnaire (t2). The other questionnaires will be sent two weeks after randomization (t1) and three months after the baseline measurement (t2).

Randomization

After completion of the baseline questionnaire, patients are randomly assigned to the intervention group or the control group, using block randomization. Blocks will have a length of four up to eight. Randomization takes place in a 1:1 ratio. The randomization scheme is created by a researcher not involved in the study, which also carries out the allocation of participants, using random allocation software (i.e., Sealed Envelope). Subsequently, this researcher notifies the coordinating researcher of the study about the outcome of the allocation after randomizing a participant. Blinding of the coordinating researcher is not possible since this researcher will send out the invitations for Oncokompas to patients and has to support patients during the study, for example when they have questions regarding technical issues.

Intervention

Oncokompas is an eHealth self-management application that supports patients in finding and obtaining optimal palliative care, tailored to their health status, personal characteristics and preferences. Oncokompas comprises three components: 1) Measure, 2) Learn, and 3) Act.

After the log-in procedure is completed, patients enter the first component of Oncokompas, 'Measure'. This component starts with the completion of a general questionnaire. Based on the patient's answers, Oncokompas selects the topics appropriate for this patient (e.g., when someone has no children, there will be no children-related topics). Subsequently, patients can select which topics they want to monitor within Oncokompas. Table 1 gives an overview of all the topics covered in Oncokompas. Patients complete patient-reported outcome measures (PROMs) on the topics they have chosen. Patients can complete PROMs targeting different domains of quality of life; physical, psychological and social functioning, and existential issues. PROMs were selected based on Dutch practical guidelines and literature searches, in collaboration with healthcare professionals and patients. The answers given to the PROMs are processed real-time and algorithms are used to link them to feedback in the 'Learn' component. All algorithms are based on available cut-off scores, Dutch practical guidelines and/or consensus by teams of experts.

In the 'Learn' component, patients get an overview of their overall well-being on topic level, using a three-color system. A green score means that the patient is doing well on a topic, an orange score means that a topic could use attention and support, and a red score means that a topic needs attention and support. Patients get personalized feedback on their outcomes, tailored to their health status, personal characteristics and preferences. In addition, Oncokompas provides information on evidence-based interrelated symptoms (e.g., depression and sleeping problems). The feedback in the 'Learn' component concludes with comprehensive self-care advice, such as tips and tools, tailored to the individual patient.

In the 'Act' component, patients are provided with personalized palliative care options, based on their health status, preferences (e.g., preferences for individual therapy versus group therapy) and their neighborhood (e.g., Oncokompas shows the palliative care options the closest to the patient, based on a patient's ZIP code). When patients have an orange score on a topic, the feedback includes suggestions for self-help interventions. When they have a red score on a topic, the feedback always includes the advice to contact their medical specialist, general practitioner, or a specialized healthcare professional (e.g., a physiotherapist or psychologist)[24].

Initially, Oncokompas was developed targeting cancer survivors[24–26]. From 2016 till 2018 Oncokompas has been extended to make the content of the application suitable for patients with incurable cancer, who are not yet in the terminal phase of their illness. The content of Oncokompas is developed in cooperation with patients, healthcare professionals and representatives of allied health services, using a stepwise, iterative and participatory approach. This method actively involves users and other stakeholders in the design process[27].

Care as usual

In this study, care as usual is defined as the care provided by the oncological team or by other healthcare professionals. This includes all medical and palliative care that patients receive, regardless of their participation in this study.

Outcome assessment

The primary outcome measure to assess the efficacy of Oncokompas is patient activation. Secondary outcome measures are general self-efficacy and health-related quality of life. Also cost-utility outcomes will be evaluated. Outcome measures will be collected through online questionnaires at baseline (t0), two weeks after randomization (t1) and three months after the baseline measurement (t2).

Table 1. Overview of all topics covered in Oncokompas for patients with incurable cancer

Domain	Topics
Physical	Body weight Daily functioning Diarrhea Dysphagia Dyspnea Fatigue Information about treatment options Appetite loss Lymphedema Mouth problems Nausea and vomiting Obstipation Pain Sexuality Skin problems Sleep problems Other side effects of medical treatment
Psychological	Cancer related anxiety (including fear of suffering and fear of dying) Coping with emotions Depression Tenseness
Social	Being single and cancer Choices concerning the end-of-life Loneliness Meaningful daily activities Patient-physician communication Social life Relationship with partner Relationship with (adult) children Work issues
Existential	Meaning of life Saying farewell

An overview of the primary and secondary outcome measures is shown in Table 2.

Table 2. Measurement overview

Aim		**Outcome measures** *Instrument*	**Time point**		
			Baseline (t0)	**Two weeks after randomization (t1)**	**Three months after baseline measurement (t2)**
Efficacy	*Primary outcome measure*	**Patient Activation** *Patient Activation Measure (PAM)*	X	X	X
	Secondary outcome measures	**Self-efficacy** *General Self-Efficacy Scale (GSE)*	X	X	X
		Health-related quality of life *EORTC QLQ-C15 PAL*	X	X	X
Cost-utility		**Quality-Adjusted life years** *EuroQol 5 Dimensions (EQ-5D)*	X		X
		Medical costs *iMTA Medical Consumption Questionnaire (iMCQ)*	X		X
		Productivity costs *iMTA Productivity Cost Questionnaire (iPCQ)*	X		X

Primary outcome measure

Patient activation

Patient activation is measured with the Patient Activation Measure (PAM)[16,26,27,28,29]. This questionnaire measures a patient's self-reported knowledge, skills and confidence for self-management of his or her health or chronic condition[18]. The PAM consists of 13 items with a 4-point Likert scale on which patients can report their level of agreement (i.e., strongly disagree, disagree, agree and strongly agree) or indicate that the item is not applicable. There are four levels of patient activation, ranging from the patients who hardly feel in charge of their own health (level one) to the patients who think they are well capable to manage their own health and healthcare (level four).

The total PAM score is calculated by calculating the mean score of all the applicable items and transforming the mean score to a standardized activation score ranging from 0 to 100[30]. Non-applicable items are not taken into account to calculate the mean score. Higher total PAM scores indicate a higher level of patient activation. The psychometric properties of the PAM 13-Dutch are generally good; the level of internal consistency is good (Chronbach's alpha = 0.88) and item-rest correlations are moderate to strong[30].

Secondary outcome measures

General Self-Efficacy

The General Self-Efficacy Scale (GSE) is a unidimensional questionnaire designed to assess how a person deals with difficult situations in his or her life. The GSE consists of 10 items with 4-point Likert scales ranging from 1 up to 4 (i.e., not at all true, hardly true, moderately true, and exactly true). The total score is calculated by adding up the scores on the 10 items, ranging from 10 to 40. A higher total GSE score indicates higher self-efficacy[31]. The psychometric properties of the GSE have been examined among participants from 25 countries; Cronbach's alphas ranged from 0.76 to 0.90, with the majority in the high 0.80s[32].

Quality of life

Quality of life is measured by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire for cancer patients in palliative care (EORTC QLQ-C15-PAL). The EORTC QLQ-C15-PAL is an abbreviated 15-item version of the EORTC QLQ-C30 questionnaire. The EORTC QLQ-C15-PAL questionnaire is specifically designed for patients with advanced, incurable and symptomatic cancer with a median life expectancy of a few months[33].

The EORTC QLQ-C15-PAL comprises a global quality of life scale, two functional scales (physical and emotional functioning), two symptom scales (fatigue and pain) and five[1] single items (nausea, dyspnea, insomnia, appetite loss and constipation)[33]. All scales range in score from 0 to 100. A high score on the global quality of life scale represents a high quality of life and a high score on a functional scale represents a high or healthy level of functioning. A high score on a symptom scale indicates a high level of symptoms[34].

Cost-evaluation

A cost-utility analysis will be conducted comparing the difference in total three-month costs between the two study arms to the difference in quality-adjusted life years (QALYs) based on the EuroQol 5 Dimensions (EQ-5D).

EuroQol 5 Dimensions

The EuroQol 5 Dimensions (EQ-5D-5L) asks respondents to describe their health state on five dimensions of quality of life (i.e., mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). All those dimensions split into five levels. As a result, there are 3125 possibilities for one's health status. The profile of answers that results after

---

[1] This is a correction in comparison to the published paper.

completing the questionnaire can be transformed to a given answer by the general public: the EQ-5D index using the Dutch index tariff. The EQ-5D also includes a visual analogue scale from 0 (worst health state) to 100 (best health state) on which respondents can represent their own health state. The EQ-5D is a validated instrument to measure health-related quality of life[35].

Medical consumption questionnaire and productivity cost questionnaire

An adapted version of the medical consumption questionnaire (iMCQ) and productivity cost questionnaire (iPCQ) will be used to measure the costs of healthcare (i.e., healthcare use and medication use), the costs for patients and their families (e.g., travelling costs and help received from family or friends), and costs within other sectors (e.g., productivity losses from paid work) in the previous three months. Both questionnaires are developed by the Institute for Medical Technology Assessment of the Erasmus University Rotterdam (IMTA), the Netherlands[36,37].

Sociodemographic and medical data

Sociodemographic and clinical characteristics (i.e., age, gender, education level and work situation) will be assessed at baseline (t0) using a study-specific questionnaire. Other characteristics (i.e., cancer type, treatment modality and time since treatment) will be collected from the hospital information system, using a study-specific case report form.

Sample size

To demonstrate the presence of an effect on the PAM between t0 and t2 of at least 0.5 standard deviations as statistically significant in a one-tailed test at alpha = 0.05 and a power of (1 - beta) = 0.80, at least 51 participants in each condition will be required at three months follow-up. Anticipating a dropout rate of 25% between t0 and t2 (based on earlier research in this population[38]), 68 participants per condition arm need to be included at baseline (t0). In total, 136 cancer patients will be recruited for this study.

Statistical analyses

All analyses will be conducted according to the intention-to-treat principle. Descriptive statistics will be generated to describe all sociodemographic and clinical characteristics, and outcome measures. To analyze whether randomization resulted in a balanced distribution of patient characteristics across the study arms, chi-square tests and independent samples t-tests will be used. When data is not normally distributed, Mann-Whitney U tests will be performed. In addition, independent samples t-tests will be used to test whether there are differences in outcome measures across study arms at baseline.

Linear Mixed Models (LMM) will be used to determine the efficacy of Oncokompas (e.g., changes in patient activation in the intervention group and the control group between t0, t1, and t2) by comparing longitudinal changes between both groups with fixed effects for study arm, time, and their two-way interaction, as well as a random intercept for subjects, and, if necessary, for referring hospitals. In case of baseline differences between study arms in sociodemographic and clinical characteristics, or outcome measures, the LMM analyses will be corrected for these differences. LMM will also be used to determine whether age, gender, socio-economic status (e.g., education level and work situation), cancer type, treatment modality, time since treatment, and baseline quality of life moderate the efficacy of Oncokompas. Fixed effects will be used for study arm, time, the potential moderator and all two-way and three-way interaction effects, as well as a random intercept for subjects, and, if necessary, for referring hospitals.

Post-hoc analysis will be applied when significant results are found in the efficacy and moderation analyses mentioned above. Independent samples t-tests with Bonferroni correction will be used to measure the differences between the intervention group and the control group at follow-up measurements. To measure the effect sizes (ES) of the intervention the (between group) Cohen's d will be calculated. The magnitude of the ES is classified as large (≥ 0.80), moderate (0.50-0.79) or small (< 0.50)[39].
IBM Statistical Package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY USA) will be used to perform all statistical analyses. All tests will be one-tailed. A p-value < 0.05 will be considered significant for all analyses.

Economic outcomes

The cost-utility analysis will be conducted in agreement with the intention-to-treat principle. The incremental cost-utility ratio (ICUR) will be calculated by dividing the differences in total costs (i.e., mean costs in the intervention group minus mean costs in the control group) by the differences in QALYs (i.e., mean QALYs in the intervention group minus mean QALYs in the control group). To calculate total costs from a societal perspective, intervention costs, costs of healthcare (i.e., costs of healthcare use and medication), costs for patients and their families (e.g., travelling costs and help received from family and friends), and costs within other sectors (e.g., productivity losses from paid work) will be included. Also, total costs from a healthcare perspective will be calculated, which includes intervention costs and the costs of healthcare.

By multiplying resource use by integral cost prices as presented in the Dutch Health Care Insurance Board (CVZ) guidelines on cost studies, costs of healthcare and costs for patients and their families will be calculated[40]. The friction cost method will be used to calculate costs within other sectors[41,42].

The time horizon will be set at three months follow-up, and therefore neither costs nor effects will be discounted. QALYs will be calculated by multiplying the EQ-5D utility score by the appropriate time period it accounts for. When data are missing on the costs of healthcare, the costs for patients and their families and the costs within other sectors, measured with the iMCQ and iPCQ cost questionnaires, these will be imputed using multiple imputation. This also accounts for missing data on the utilities measured with the EQ-5D.

Non-parametric bootstrapping with 5000 imputations will be used to obtain 95% confidence intervals around the cost and QALY differences. A cost-utility plane will be plotted for the projection of the resulting pairs of cost and effect differences and a cost-effectiveness acceptability curve will be made to reflect the probability of Oncokompas being cost-effective given different willingness-to-pay ceilings[43]. Sensitivity analyses will be conducted focusing on uncertainty in the main cost factors.

DISCUSSION

This study among patients with incurable cancer will assess the efficacy of the eHealth self-management application Oncokompas on patient activation, general self-efficacy and health-related quality of life and its cost-utility from a healthcare and societal perspective, compared to care as usual.

Patients with incurable cancer often have unmet needs and prefer to stay in charge of their own life as long as possible. Therefore, it is important that these patients know where to go for advice and guidance. Oncokompas is developed to support patients to adopt an active role in managing their own health and healthcare. By improving patient activation and self-efficacy, Oncokompas could be a solution to meet patients' palliative care needs. It provides information and advice to empower patients to take better care of themselves and, when necessary, information on where they can find professional help. By improving the provision of support or facilitating patients to find support, eHealth reduces patients' needs for support[12,44,]. Due to increasing healthcare costs, an essential advantage of eHealth is its cost-saving potential[23]. Oncokompas is based on the stepped care principle, meaning that the application supports patients to undertake actions to control their symptoms, only with professional care if needed. Therefore, it is hypothesized that Oncokompas will improve QALYs at acceptable costs compared to care as usual.

Oncokompas could stimulate patients to discuss symptoms or questions with their healthcare professional that otherwise would remain unmentioned. Previous studies showed that for instance sexuality issues or concerns about the end-of-life are difficult to address for both patients and their healthcare professionals[45,46,47,48]. In addition, consultation time is often short, which hampers addressing all relevant issues that a patient might want to discuss[26]. Oncokompas could also help patients to discuss their symptoms with their healthcare professional in a more structured way (e.g., because they might be more aware of their symptoms and also have the possibility to print their results and take this print to their healthcare professional). Another advantage for patients is that they can use Oncokompas at their own home in their own time.

Since Oncokompas includes topics about decisions at the end-of-life, the application could stimulate patients to think about their wishes regarding the end-of-life (e.g., treatment goals or their preferred place of death) and to talk about this to their family, friends and healthcare professionals. Therefore, Oncokompas has the potential to contribute to the process of advance care planning (ACP). ACP is the process of discussing patients' preferences concerning their healthcare, so that they receive the end-of-life care they desire[49]. Research showed positive effects of ACP on the quality of care at the end-of-life[49,50]. ACP could also have a positive effect on the continuity of care (i.e., the information exchange between healthcare professionals to realize optimal integrated care) during the end-of-life. In its turn this is associated with higher quality of care and lower healthcare costs[51,52].

In three previous studies on Oncokompas among patients diagnosed with glioma, breast cancer and head and neck cancer, patients reported that they expected that Oncokompas would stimulate them in taking control and acting upon their symptoms[26,53,54]. In addition, one of these studies showed that breast cancer survivors' activation level was significantly higher after using Oncokompas than before[54]. In 2016 a large RCT started to determine the efficacy of Oncokompas on patient activation and cost-utility among cancer survivors[55]; this study is still ongoing.

To summarize, there is a growing interest in eHealth to improve self-management among patients with chronic disease to emphasize the central role of patients in the management of their own disease and to reduce healthcare costs. This study could contribute to the evidence about the effectiveness of tailored eHealth interventions supporting self-management used in palliative care. When the results of this study show that Oncokompas is effective for patients with incurable cancer, this means that the application supports self-management among these patients. This might improve sustainable implementation and maintenance of the application in advanced cancer care.

REFERENCES

1. Esther Kim JE, Dodd MJ, Aouizerat BE, Jahan T, Miaskowski C. A Review of the Prevalence and Impact of Multiple Symptoms in Oncology Patients. J Pain Symptom Manage. 2009;37(4):715–736.
2. Teunissen SCCM, Wesker W, Kruitwagen C, de Haes HCJM, Voest EE, de Graeff A. Symptom Prevalence in Patients with Incurable Cancer: A Systematic Review. J Pain Symptom Manage. 2007;34(1):94–104.
3. van Roij J, Brom L, Youssef-El Soud M, van de Poll-Franse L, Raijmakers NJH. Social consequences of advanced cancer in patients and their informal caregivers: a qualitative study. Suppor Care in Cancer. 2018;1–9.
4. WHO | WHO Definition of Palliative Care. World Health Organization; 2012. Available from: http://www.who.int/cancer/palliative/definition/en/. (accessed April 25, 2018)
5. Hui D, De La Cruz M, Mori M, Parsons HA, Kwon JH, Torres-Vigil I, et al. Concepts and definitions for "supportive care," "best supportive care," "palliative care," and "hospice care" in the published literature, dictionaries, and textbooks. Support Care Cancer. 2013;21(3):659–685.
6. Fitch MI. Supportive care framework. Can Oncol Nurs J. 2008;18(1):6–14.
7. Dalal S, Bruera E. End-of-Life Care Matters: Palliative Cancer Care Results in Better Care and Lower Costs. Oncologist. 2017;22(4):361–368.
8. Temel JS, Greer JA, Muzikansky A, Gallagher ER, Admane S, Jackson VA, et al. Early palliative care for patients with metastatic cancer. New Engl J Med Orig. 2010;363(8):733–742.
9. Schenker Y, Park SY, Maciasz R, Arnold RM. Do Patients with Advanced Cancer and Unmet Palliative Care Needs Have an Interest in Receiving Palliative Care Services? J Palliat Med. 2014;17(6):667–672.
10. Moghaddam N, Coxon H, Nabarro S, Hardy B, Cox K. Unmet care needs in people living with advanced cancer: a systematic review. Support Care Cancer. 2016;24(8):3609–3622.
11. McCorkle R, Ercolano E, Lazenby M, Schulman-Green D, Schilling LS, Lorig K, et al. Self-management: Enabling and empowering patients living with cancer as a chronic illness. CA Cancer J Clin. 2011;61(1):50–62.
12. Slev VN, Mistiaen P, Pasman HRW, Verdonck-de Leeuw IM, van Uden-Kraan CF, Francke AL. Effects of eHealth for patients and informal caregivers confronted with cancer: A meta-review. International Journal of Medical Informatics. 2016;87: 54–67.
13. Bakitas M, Lyons KD, Hegel MT, Balan S, Brokaw FC, Seville J, et al. Effects of a Palliative Care Intervention on Clinical Outcomes in Patients With Advanced Cancer. JAMA. 2009;302(7):741–749.
14. Bodenheimer T, Wagner EH. Improving Primary Care for Patients With Chronic Illness. JAMA. 2002;288(14):1775–1779.
15. Trappenburg J, Jonkman N, Jaarsma T, van Os-Medendorp H, Kort H, de Wit N, et al. Self-management: One size does not fit all. Patient Educ Couns. 2013;92(1):134–137.
16. Hibbard JH, Mahoney ER, Stock R, Tusler M. Do increases in patient activation result in improved self-management behaviors? Health Serv Res. 2007;42(4):1443–1463.
17. Lev EL, Daley KM, Conner NE, Reith M, Owen SV. An intervention to increase quality of life and self-care self-efficacy and decrease symptoms in breast cancer patients. Res Theory Nurs Pract. 2001;15(3):277–294.
18. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. Health Serv Res. 2004;39(4p1):1005–1026.
19. Hibbard JH, Cunningham PJ. How engaged are consumers in their health and health care, and why does it matter? Res Brief. 2008;(8):1–9.

20. Hendriks M, Rademakers J. Relationships between patient activation, disease-specific knowledge and health outcomes among people with diabetes; a survey study. BMC Health Serv Res. 2014;14(1):393.
21. Jansen F, Coupé VMH, Eerenstein SEJ, Leemans CR, Verdonck-de Leeuw IM. Costs from a healthcare and societal perspective among cancer patients after total laryngectomy: are they related to patient activation? Support Care Cancer. 2018;26(4):1221–1231.
22. Howell D, Harth T, Brown J, Bennett C, Boyko S. Self-management education interventions for patients with cancer: a systematic review. Support Care Cancer. 2017;25(4):1323–1355.
23. Bergmo TS. How to measure costs and benefits of ehealth interventions: An overview of methods and frameworks. Journal of Medical Internet Research. 2015;17(11):e254.
24. Duman-Lubberding S, van Uden-Kraan CF, Jansen F, Witte BI, van der Velden LA, Lacko M, et al. Feasibility of an eHealth application "OncoKompas" to improve personalized survivorship cancer care. Support Care Cancer. 2016;24(5):2163–2171.
25. Duman-Lubberding S, Van Uden-Kraan CF, Peek N, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. An eHealth application in head and neck cancer survivorship care: Health care professionals' perspectives. Journal of Medical Internet Research. JMIR Publications Inc. 2015;17(10):e235.
26. Lubberding S, van Uden-Kraan CF, Te Velde EA, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. Improving access to supportive cancer care through an eHealth application: A qualitative needs assessment among cancer survivors. J Clin Nurs. 2015;24(9–10):1367–1379.
27. Kelders SM, van Limburg M, Ossebaard HC, van Gemert-Pijnen JEWC, Nijland N, Seydel ER, et al. A Holistic Framework to Improve the Uptake and Impact of eHealth Technologies. J Med Internet Res. 2011;13(4):e111.
28. Greene J, Hibbard JH. Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. J Gen Intern Med. 2012;27(5):520–526.
29. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. Health Serv Res. 2005;40(6p1):1918–1930.
30. Rademakers J, Nijman J, Van Der Hoek L, Heijmans M, Rijken M. Measuring patient activation in the Netherlands: translation and validation of the American short form Patient Activation Measure (PAM13). BMC Public Health. 2012;12:577.
31. Schwarzer R, Jerusalem M, Weinman J, Wright S, Johnston M. Generalised self-efficacy scale. In: Weinman J, Wright S, Johnston M, eds. Causal Control beliefs. Generalised Self-Efficacy Scale, 1st ed. Windsor UK: Nfer-Nelson. 1995.
32. Scholz U, Gutiérrez Doña B, Sud S, Schwarzer R. Is General Self-Efficacy a Universal Construct. Eur J Psychol Assess. 2002;18(3):242–251.
33. Groenvold M, Petersen MA, Aaronson NK, Arraras JI, Blazeby JM, Bottomley A, et al. The development of the EORTC QLQ-C15-PAL: A shortened questionnaire for cancer patients in palliative care. Eur J Cancer. 2006;42(1):55–64.
34. Fayers PM, Bottomley A. EORTC QLQ-C30 Scoring Manual The EORTC QLQ-C30. Eur J Cancer. 2001. Available from: https://www.eortc.be/qol/files/SCManualQLQ-C30.pdf. (accessed November 22, 2018)
35. Versteegh MM, Vermeulen KM, Evers SMAA, Ardine De Wit G, Prenger R, Stolk EA. Dutch Tariff for the Five-Level Version of EQ-5D. Value Heal. 2016;19(4):343–352.
36. Bouwmans C, Hakkaart-van Roijen L, Koopmanschap, Krol H, Severens WB. Handleiding iMTA Medical Cost Questionnaire (iMCQ). Rotterdam; 2013.
37. Bouwmans C, Hakkaart-van Roijen L, Koopmanschap M, Krol H, Severens WB. Handleiding iMTA Productivity Cost Questionnaire (iPCQ). Rotterdam: iMTA, Erasmus Universiteit; 2013.
38. Kleijn G, Lissenberg-Witte BI, Bohlmeijer ET, Steunenberg B, Knipscheer-Kuijpers K, Willemsen V, et al. The efficacy of Life Review Therapy combined with Memory Specificity Training (LRT-MST) targeting cancer patients in palliative care: A randomized controlled trial. PLoS One. 2018;13(5:e0197277).

39. Cohen J. Statistical Power Analysis for the Behavioral Sciences, 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.

40. Tan SS, Bouwmans C, Rutten FFH, Hakkaart-Van Roijen L. Update of the dutch manual for costing in economic evaluations. Int J Technol Assess Health Care. 2012;28(2):152–158.

41. Hakkaart-van Roijen L, van der Linden N, Bouwmans C, Kanters T, Swan TS. Kostenhandleiding: Methodologie van kostenonderzoek en referentieprijzen voor economische evaluaties in de gezondheidszorg. Zorginstituut Ned. 2016;1–73.

42. Koopmanschap MA, Rutten FFH, Van Ineveld BM, Van Roijen L. The friction cost method for measuring indirect costs of disease. J Health Econ. 1995;14(2):171–189.

43. van Hout BA, Al MJ, Gordon GS, Rutten FF. Costs, effects and C/E-ratios alongside a clinical trial. Health Econ. 1994;3(5):309–319.

44. Ventura F, Öhlén J, Koinberg I. An integrative review of supportive e-health programs in cancer care. Eur J Oncol Nurs. 2013;17(4):498–507.

45. Hordern AJ, Street AF. Communicating about patient sexuality and intimacy after cancer: Mismatched expectations and unmet needs. Med J Aust. 2007;186(5):224–227.

46. Kotronoulas G, Papadopoulou C, Patiraki E. Nurses' knowledge, attitudes, and practices regarding provision of sexual health care in patients with cancer: Critical review of the evidence. Supportive Care in Cancer. 2009;17:479–501.

47. Periyakoil VS, Neri E, Kraemer H. No easy talk: A mixed methods study of doctor reported barriers to conducting effective end-of-life conversations with diverse patients. PLoS One. 2015;10(4:e0122321).

48. Barclay S, Maher J. Having the difficult conversations about the end of life. BMJ. 2010;341:c4862.

49. Brinkman-Stoppelenburg A, Rietjens JA, Van Der Heide A. The effects of advance care planning on end-of-life care: A systematic review. Palliat Med. 2014;28(8):1000–1025.

50. Granja C, Janssen W, Johansen MA. Factors determining the success and failure of ehealth interventions: Systematic review of the literature. J Med Internet Res. 2018;20(5):1–21.

51. Ermers DJM, van Bussel KJH, Perry M, Engels Y, Schers HJ. Advance care planning for patients with cancer in the palliative phase in Dutch general practices. Fam Pract. 2018;1–7.

52. Hussey PS, Schneider EC, Rudin RS, Fox DS, Lai J, Pollack CE. Continuity and the costs of care for chronic disease. JAMA Intern Med. 2014;174(5):742–748.

53. Boele FW, van Uden-Kraan CF, Hilverda K, Reijneveld JC, Cleijne W, Klein M, et al. Attitudes and preferences toward monitoring symptoms, distress, and quality of life in glioma patients and their informal caregivers. Support Care Cancer. 2016;24(7):3011–3022.

54. Melissant HC, Verdonck-de Leeuw IM, Lissenberg-Witte BI, Konings IR, Cuijpers P, van Uden-Kraan CF. "Oncokompas", a web-based self-management application to support patient activation and optimal supportive care: a feasibility study among breast cancer survivors. Acta Oncol. 2018;57(7):924–934.

55. van der Hout A, van Uden-Kraan CF, Witte BI, Coupé VMH, Jansen F, Leemans CR, et al. Efficacy, cost-utility and reach of an eHealth self-management application "Oncokompas" that helps cancer survivors to obtain optimal supportive care: Study protocol for a randomised controlled trial. Trials. 2017;18(1):228.

5

EFFICACY OF THE EHEALTH APPLICATION ONCOKOMPAS, FACILITATING INCURABLY ILL CANCER PATIENTS TO SELF-MANAGE THEIR PALLIATIVE CARE NEEDS: A RANDOMIZED CONTROLLED TRIAL

Anouk S. Schuit
Karen Holtmaat
Birgit I. Lissenberg-Witte
Simone E.J. Eerenstein
Josée M. Zijlstra
Corien Eeltink
Annemarie Becker-Commissaris
Lia van Zuylen
Myra E. van Linde
C. Willemien Menke-van der Houven van Oordt
Dirkje W. Sommeijer
Nol Verbeek
Koop Bosscha
Rishi Nandoe Tewarie
Robert-Jan Sedee
Remco de Bree
Alexander de Graeff
Filip de Vos
Pim Cuijpers
Irma M. Verdonck-de Leeuw

The Lancet Regional Health – Europe 2022;18:100390

ABSTRACT

Background: Many patients with incurable cancer have symptoms affecting their health-related quality of life. The eHealth application 'Oncokompas' supports patients to take an active role in managing their palliative care needs, to reduce symptoms and improve health-related quality of life (HRQOL). This randomized controlled trial was conducted to determine the efficacy of Oncokompas compared to care as usual among incurably ill cancer patients with a life expectancy of more than three months.

Methods: Patients were recruited in six hospitals in the Netherlands. Eligible patients were randomly assigned to the intervention (direct access to Oncokompas) or the control group (access to Oncokompas after three months). The primary outcome measure was patient activation (i.e., patients' knowledge, skills and confidence for self-management). Secondary outcomes were general self-efficacy and HRQOL. Measures were assessed at baseline, two weeks after randomization, and three months after the baseline measurement. Linear mixed models were used to compare longitudinal changes between both groups from baseline to the three-month follow-up.

Findings: In total, 219 patients were eligible of which 138 patients completed the baseline questionnaire (response rate 63%), and were randomized to the intervention (69) or control group (69). There were no significant differences between the intervention and control group over time in patient activation (estimated difference in change T0-T2; 1.8 (90% CI: -1.0 to 4.7)), neither in general self-efficacy and HRQOL. Of the patients in the intervention group who activated their account, 74% used Oncokompas as intended. The course of patient activation, general self-efficacy, and HRQOL was not significantly different between patients who used Oncokompas as intended versus those who did not.

Interpretation: Among incurably ill cancer patients with a life expectancy of more than three months and recruited in the hospital setting, Oncokompas did not significantly improve patient activation, self-efficacy, or HRQOL.

Funding: ZonMw, Netherlands Organization for Health Research and Development (844001105)

Keywords: eHealth, palliative care, supportive care, incurable cancer, psychosocial oncology

RESEARCH IN CONTEXT

Evidence before this study

Incurably ill cancer patients have to deal with physical, psychological, social, and existential symptoms related to cancer and its treatment. Palliative care is increasingly recognized as an integral part of cancer care. Also, there is growing interest in self-management and behavioral intervention technologies to improve (access to) palliative care. Evidence on the effects of these interventions in palliative care is promising but limited. The application Oncokompas was developed to monitor physical, psychological, social and existential domains of quality of life, to provide personalized information on quality of life, and to support cancer patients to adopt an active role in managing their disease, adjusted to their personal well-being and preferences. Several studies were conducted to examine the effects of Oncokompas among cancer survivors, showing promising effects on HRQOL but limited effect on patient activation. The current study is conducted to investigate efficacy of Oncokompas among incurably ill cancer patients.

Added value of this study

The findings of this randomized controlled trial show that Oncokompas is not effective to improve patient activation among incurably ill cancer patients with a life expectancy of more than three months and recruited in the hospital setting. Also, no effects were found on self-efficacy and health-related quality of life (HRQOL). This RCT contributes to knowledge on the effects and usage of behavioral intervention technologies in palliative cancer care.

Implications of all the available evidence

To support cancer patients to take an active role in managing their disease and healthcare, it is important to facilitate the uptake of self-management behaviors. Offering patients access to fully automated and self-guided eHealth interventions such as Oncokompas, might help to create a shift in patients’ self-management behavior. The lack of effect of Oncokompas in our study may be due to the relatively good performance of the included patients on the outcome measures at baseline or that Oncokompas in its current form needs more tailoring to incurably ill cancer patients. Research on the possibilities to further personalize behavioral intervention technologies is needed, to create an optimal fit between intervention technologies and patients’ needs. Future research on efficacy of behavioral intervention technologies, such as Oncokompas, that aim to improve HRQOL, should include users who have a need for palliative care.

INTRODUCTION

Incurable cancer challenges patients to deal with physical, psychological and social symptoms, and existential concerns, affecting aspects of their health-related quality of life (HRQOL)[1,2]. Maintaining optimal HRQOL by early identification of symptoms and providing access to palliative care services if needed, is an important aspect of palliative care.

Many cancer patients want to be in charge of their own life as long as possible. Moreover, there is a growing demand on healthcare resources and patients are increasingly expected to adopt an active role in managing their illness and well-being[3]. The tasks that people undertake to deal with managing their health are referred to as *self-management*[4]. Self-management strategies are dependent on individual preferences and characteristics and cover multiple domains[5], including monitoring symptoms and treatment effects, adjusting nutrition and diet, maintaining daily routine by adjusting daily activities, and seeking social support[5].

Interventions to support self-management are becoming an integral component of care and can have positive effects in cancer patients[6]. Furthermore, eHealth interventions are available to detect and manage side effects of cancer and its treatment[7]. These interventions enable patients to be actively engaged in healthcare, improve health outcomes, and lead to positive behavior change[8,9]. Earlier research suggests that if patients' activation level is increased, improved self-management behaviors will follow[10]. Activated patients – with knowledge, skills and confidence for self-management[11] – function as collaborative partners in managing their health[10,11]. Previous studies reported positive effects of eHealth interventions on HRQOL and described the ability of eHealth to track symptoms over time, access web-based information, and provide prompts when to contact healthcare professionals[6].

The eHealth application Oncokompas was developed to support cancer patients to adopt an active role to self-manage their symptoms and improve their well-being. Oncokompas is a behavioral intervention technology (BIT), which is – as described by Mohr et al. – an application which uses features of information and communication technology aimed at changing behavioral and mental health outcomes[12]. Oncokompas is meant as additional support for cancer patients and is based on the stepped care principle, supporting patients to take actions to deal with their symptoms by themselves, and with professional guidance if needed. By using Oncokompas, patients can monitor their symptoms using patient-reported outcome measures (PROMs) and get feedback and advice, supporting them to deal with symptoms by themselves. Patients also get an overview of supportive care options where they can go to when self-care is not sufficient and professional care is needed[13,14]. Patients can use Oncokompas at their own pace, with 24/7 availability. Initially, Oncokompas was developed targeting cancer survivors[13]. Research showed that using Oncokompas improves HRQOL and reduces symptoms among survivors[14], and is as cost-effective as usual care[15].

The content of the application was extended for use among patients with incurable cancer. A pilot study on the feasibility of self-management support delivered by nurses in the home setting, with Oncokompas integrated as eHealth component, showed that incurably ill cancer patients positively assessed Oncokompas as a self-management intervention. However, usage of the intervention was low and Oncokompas had no significant effect on patient activation or HRQOL, which may be explained by the fact that many pilot participants were already very ill (near the end-of-life), and that the self-management support delivered by nurses was superior to the eHealth application[16]. Based on these findings, it was hypothesized that Oncokompas may be more beneficial in patients with longer life expectancy regarding patient activation and HRQOL, and as fully automated behavioral intervention technology.

The aim of this study was to determine the efficacy of the eHealth self-management application Oncokompas as BIT additional to care as usual and compared to care as usual only, on patient activation, general self-efficacy, and HRQOL among incurably ill cancer patients, who have a life expectancy of at least three months. The hypothesis is that Oncokompas supports incurably ill cancer patients to improve their knowledge, skills and confidence to self-manage their symptoms and improve their well-being.

METHODS

Study design

This prospective randomized controlled trial with two parallel groups targeted incurably ill cancer patients. Patients in the intervention group got access to Oncokompas directly after completing the baseline questionnaire and patients in the control group after three months (i.e., after completing the last questionnaire). Outcome measures were collected through an online questionnaire at baseline (t0), two weeks after randomization (t1) and three months after the baseline measurement (t2).

The study protocol was approved by the Medical Ethics Committee of VU University Medical Center (2018.224). All participants provided written informed consent. The study protocol was published previously[17]. This trial was registered in the Netherlands

Trial Register (NTR 7494/NL7285). The CONSORT guidelines (CONsolidated Standards of Reporting Trials) were used to report on the results of this trial[18].

Study population

Inclusion criteria were: (1) being diagnosed with incurable cancer (not having curative treatment options), (2) having a life expectancy of at least three months (not being in the end-of-life phase of cancer), and (3) being aware of the cancer's incurability. Patients were excluded if (1) they had severe cognitive impairments, (2) they had poor understanding of the Dutch language (not able to complete Dutch questionnaires), (3) they were too ill to participate, (4) they did not have access to the Internet or to an e-mail account, (5) their healthcare professional thought that participation would be too burdensome due to the patient's participation in other studies, or (6) they already used Oncokompas before (in previous research).

Study procedures

Eligible patients were informed about the study by their physician, nurse or nurse specialist, at six hospitals in the Netherlands (Amsterdam University Medical Centers, University Medical Center Utrecht, St. Antonius Hospital, Haaglanden Medical Center, and Jeroen Bosch Hospital). When patients were interested, their healthcare provider asked permission to share their contact details with the researchers of the Vrije Universiteit Amsterdam (VU). Interested patients were then contacted by phone by the researcher to receive more information about the study. After signing informed consent, patients received the first questionnaire by e-mail. Thus, patients were informed on the study by their healthcare professional from the hospital and included in the study by the research team of the VU.

Care as usual

All patients received care as usual (CAU) during their study participation. CAU was defined as the care provided by the oncological team or other healthcare professionals, including all medical and supportive care that patients receive, regardless of study participation.

Intervention

Oncokompas is an eHealth self-management application, consisting of three steps: measure, learn and act. Screenshots of Oncokompas and an overview of the topics covered within Oncokompas can be found in the supplementary material. Patients logging in to Oncokompas first enter the step 'Measure', where they complete a general questionnaire used to select the topics appropriate for this patient (e.g., when someone is retired, the topic about 'work' will not be shown). Then patients can select which topics they want to address within Oncokompas. Subsequently, PROMs are used to monitor patients' physical, psychological, social and existential well-being. In the next step, 'Learn', Oncokompas provides information and feedback on patients' outcomes, tailored to their health status, personal characteristics and preferences. Using a traffic-light system (green, orange and red), patients get an overview of their overall well-being on topic level. A green score means that the patient is doing well on this topic, an orange score means that this topic *could* use attention and support, and a red score means that this topic *needs* attention and support. Then, Oncokompas provides comprehensive self-care advice, such as tips and tools. Lastly, within the step 'Act', patients receive a personal overview of supportive care options, with options for professional guidance when needed.

Oncokompas was developed using a stepwise, iterative and participatory approach, actively involving end users and oncological and palliative healthcare health professionals in the design process[19].

More information about Oncokompas is available in the study protocol[17].

Randomization

Patients were randomly assigned to the intervention or control group (1:1 ratio), using block randomization. Stratification was not applied. The randomization scheme was a computer-generated table with random numbers (with a random block length of four, six or eight), created by a researcher not involved in the study, who also performed the allocation of participants. Neither the participants nor the coordinating researcher were blinded after assignment to the intervention, due to the nature of the study intervention.

Study measures

Since Oncokompas primarily aims to stimulate self-management, the primary outcome measure of the study was patient activation, measured with the Patient Activation Measure (PAM), a widely recognized questionnaire to measure self-management abilities[20]. The PAM measures patients' self-reported knowledge, skills and confidence for self-management of their health or chronic condition[11]. It consists of 13 items with a 4-point Likert scale (i.e., strongly disagree, disagree, agree, and strongly agree) and the option "not applicable". Some items are for example: "Taking an active role in my own healthcare is the most important factor in determining my health and ability to function" and "I know what each of my prescribed medications do". The total PAM score ranges from 0 up to 100 and is computed by calculating the mean score of all applicable items, which is transformed to a standardized activation score (non-applicable items are not taken into account). Scores can be divided into four levels, ranging from low activation to high activation. A higher total PAM score indicates a higher level of patient activation. A difference of four points on the PAM is considered to be clinically meaningful[21,22].

Secondary outcome measures were self-efficacy and HRQOL. The General Self-Efficacy Scale (GSE) assesses how a person deals with difficult situations in life[23], consisting of ten items with a 4-point Likert scale (not at all true, hardly true, moderately true, and exactly true). There is no cut-off score available on the GSE; the international average for the GSE sum score is 29.55[24]. Higher GSE scores indicate higher self-efficacy[23]. The total score ranges from 10 to 40, calculated by adding up the scores on all items, as long as no more than three items are missing.

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire for patients in palliative care (EORTC-QLQ-C15-PAL) was used to measure (domains of) HRQOL[25] and consists of 15 items. The questionnaire includes a global quality of life scale, two functional scales (physical and emotional functioning), two symptom scales (fatigue and pain), and five symptom scales based on single items (nausea, dyspnea, insomnia, appetite loss, and constipation). Subscale scores range from 0 up to 100. Higher scores on the global quality of life scale and functional scales represent better HRQOL, while higher scores on symptom scales indicate higher levels of symptoms. Studies regarding the minimal clinically important differences (MCIDs) for the EORTC-QLQ-C15-PAL are limited and inconclusive[26].

Patients' sociodemographic and clinical characteristics were assessed at baseline using a study specific questionnaire. Information on patients' cancer type and treatment modality were retrieved from medical files.

Sample size

To demonstrate an increase of at least 0.5 standard deviations in the intervention group compared to the control group (i.e., between group change of 0.5 SD) on the PAM between t0 and t2 as statistically significant in a one-tailed test using a power of 80% (1-ß = 0.80) and a significance level of 5% (α=0.05), 51 participants were required in each study arm at three-months follow-up. Anticipating a dropout rate of 25% between t0 and t2, the aim was to include 136 patients; 68 participants per study arm at baseline.

Statistical analyses

Descriptive statistics were generated to compare sociodemographic characteristics, clinical characteristics and outcome measures at baseline between the intervention group and control group.

Linear Mixed Models (LMM) were used to compare longitudinal changes in primary and secondary outcome measures in both study arms between t0, t1, and t2. Fixed effects were used for study arm, measurement, and their two-way interaction, and a random intercept for subjects. Missing data was not imputed as LMM accounts for missing data.

This RCT was conducted partly before and partly during the COVID-19 pandemic. Additional analyses were performed to analyze a possible effect of the pandemic, using LMM (measurement * group * (time of participation)). A categorical variable was created representing three groups: patients who participated before COVID-19 pandemic (cut-off date set at 12 March 2020, when the Dutch government advised all citizens to stay at home[27]), patients who were included before the pandemic but completed follow-up measurements during the pandemic, and patients who were included during the pandemic.

Furthermore, to analyze a possible effect of how Oncokompas was used, Oncokompas' logging data of users were used. Usage as intended was defined as completion of the components 'Measure' and 'Learn' for at least one topic. Additional LMM analyses were performed to analyze a possible effect of usage (measurement * usage). Univariable logistic regression models were used to examine whether outcome measures, sociodemographic and clinical characteristics predicted usage as intended.

All analyses were performed using IBM Statistical Package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY USA) and according to the intention-to-treat principle. A p-value of < 0.05 was considered significant for all analyses.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing the report.

RESULTS

Study population

From December 13, 2018 to August 27, 2020, 293 patients were referred to the research team, of whom 219 were eligible for inclusion. In total, 143 patients signed informed consent, of which 5 patients declined participation upon receiving the baseline questionnaire and were not included (response rate 63%). Reasons for declining participation were: participation being too confronting (n=14), lacking computer skills (n=9), not being interested (n=9), privacy concerns (n=3), and other reasons (n=5); 41 patients provided no reason for non-participation (Figure 1). In total, 62 patients were included before the COVID-19 pandemic (of which 25 patients participated partly during the pandemic) and 76 patients during the pandemic.

In total, 138 patients completed the baseline questionnaire, of which 69 patients were allocated to the intervention and 69 to the control group. Gender balance was achieved and the majority had a partner (83%). A large group of participants were highly educated (47%), were diagnosed with brain tumors (28%), and received at least one type of treatment during study participation (91%) (Table 1).

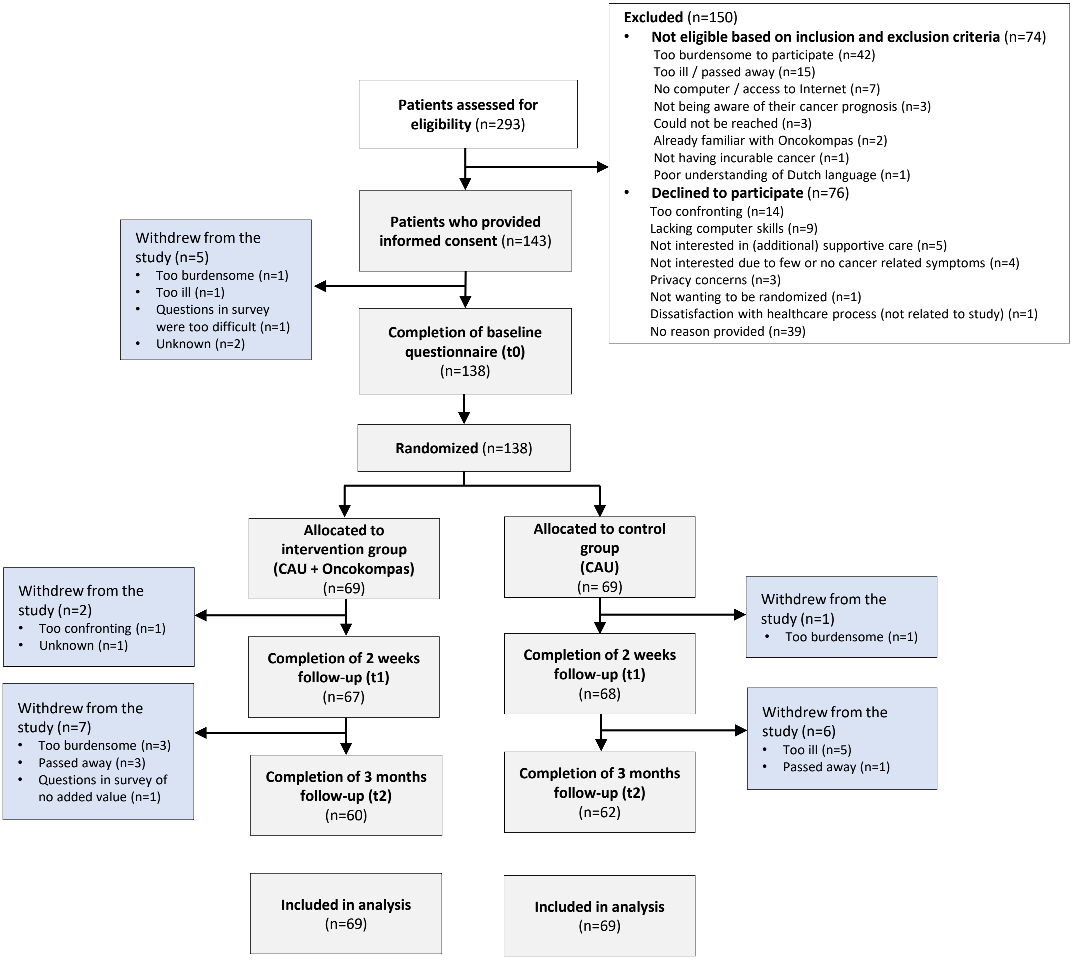


Figure 1. Flow diagram of the study

Table 1. Sociodemographic and clinical characteristics of the study participants at baseline

	Control group (n=69)		**Intervention group (n=69)**		**Total group (n=138)**	
	Number	**%**	**Number**	**%**	**Number**	**%**
Age in years						
Mean (SD)	62.3 (11.9)	-	60.0 (12.7)	-	61.1 (12.3)	-
25th-75th percentile	54.5 – 71.5	-	51 – 68.5	-	53 – 70.3	-
Sex						
Male	37	54	37	54	74	54
Female	32	46	32	46	64	46
Education level[a]						
Low	19	28	19	28	38	28
Medium	18	26	16	23	34	25
High	31	45	34	49	65	47
Other/unknown	1	1	-	-	1	1
Marital status, partner						
Yes	57	83	58	84	115	83
No	12	17	11	16	23	17
Children						
Yes	54	78	52	75	106	77
No	15	22	17	25	32	23
Employed						
Yes	28	41	23	33	51	37
No	41	59.4	46	67	87	63
Tumor type						
Lung cancer	8	12	8	12	16	12
Hematological cancer	8	12	8	12	16	12
Brain tumor	22	32	17	25	39	28
Head and neck cancer	7	10	9	13	16	12
Breast cancer	5	7	10	15	15	11
Gastro-intestinal cancer	10	15	9	13	19	14
Urological cancer	6	9	4	6	10	7
Other	1	1	3	4	4	3
Multiple primaries [b]	2	3	1	1	3	2
Anti-cancer treatment						
None	7	10	5	7	12	9
Single treatment	49	71	49	71	98	71
Combination or multimodal treatment	13	19	15	22	28	20
Comorbidities						
No comorbidities	37	54	28	41	65	47
One comorbidity	17	25	22	32	39	28
Two or more comorbidities	15	22	19	28	34	25

[a] Low = elementary school / preparatory secondary vocational education (VMBO), Middle = secondary vocational education (MBO)/ general secondary education (HAVO)/ pre-university education (VWO), High = higher vocational education (HBO) / university (WO). Dutch abbreviations of the school types are specified between the brackets. [b] Three patients were diagnosed with multiple primary tumors and therefore shown in a separate category.

Table 2. Mean scores per group per assessment and results of the linear mixed model analyses on primary and secondary outcome measures for the total group

	Baseline (t0)		**2 weeks follow-up (t1)**		**3-months follow-up (t2)**			
	N	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**Estimated difference in change between t0 and t2 (90% CI)**	**P-value two-way interaction**
Patient activation (PAM)								**0.56**
Intervention	65	55.6 (11.5)	65	55.1 (12.5)	59	56.4 (11.7)	1.8 (-1.0 to 4.7)	
Control	68	55.1 (11.5)	68	54.7 (9.8)	61	54.7 (11.6)		
General self-efficacy (GSE)								**0.23**
Intervention	69	29.5 (5.5)	67	29.5 (5.4)	60	30.0 (5.7)	1.0 (-0.2 to 2.2)	
Control	69	31.1 (4.5)	68	29.9 (4.6)	62	30.6 (4.3)		
HRQOL (EORTC-QLQ-C15-PAL)								
Global quality of life								0.69
Intervention	69	73.9 (18.8)	67	69.9 (18.2)	60	70.3 (21.3)	-2.6 (-7.5 to 2.4)	
Control	69	73.4 (18.4)	68	70.6 (22.5)	62	72.6 (18.9)		
Physical functioning								0.23
Intervention	69	88.1 (14.4)	67	88.2 (13.4)	60	87.0 (15.2)	-0.8 (-4.3 to 2.6)	
Control	69	90.3 (16.3)	68	87.6 (18.5)	62	88.7 (18.4)		
Emotional functioning								0.32
Intervention	69	71.7 (24.3)	67	74.9 (22.4)	60	71.9 (26.3)	4.6 (-1.0 to 10.1)	
Control	69	81.2 (21.0)	68	81.1 (20.7)	62	77.7 (22.2)		
Fatigue								0.27
Intervention	69	45.4 (28.0)	67	42.0 (24.7)	60	44.4 (28.6)	-3.2 (-9.8 to 3.4)	
Control	69	35.7 (25.6)	68	39.0 (30.1)	62	37.9 (27.7)		

Pain							0.54
Intervention	69	27.5 (28.1)	67	27.9 (24.3)	60	29.4 (27.3)	2.6 (-3.7 to 8.9)	
Control	69	22.9 (25.3)	68	25.2 (26.5)	62	24.2 (27.1)		
Dyspnea								0.32
Intervention	69	19.3 (23.2)	67	22.4 (25.5)	60	21.1 (25.3)	4.7(-1.3 to 10.6)	
Control	69	19.3 (25.8)	68	17.6 (26.7)	62	15.6 (25.4)		
Insomnia								0.91
Intervention	69	33.3 (31.8)	67	31.3 (30.6)	60	32.2 (28.1)	0.4 (-7.1 to 7.9)	
Control	69	29.5 (30.0)	68	28.9 (28.7)	62	25.8 (29.8)		
Appetite loss								0.66
Intervention	69	22.2 (30.6)	67	19.4 (30.2)	60	21.7 (29.3)	-2.3 (-10.2 to 5.6)	
Control	69	18.4 (26.5)	68	20.1 (29.4)	62	22.0 (29.5)		
Nausea								0.68
Intervention	69	18.8 (30.0)	67	13.9 (24.0)	60	20.6 (28.2)	2.8 (-5.6 to 11.2)	
Control	69	18.8 (24.6)	68	15.7 (27.3)	62	18.3 (26.8)		
Constipation								0.48
Intervention	69	24.2 (27.3)	67	20.9 (25.8)	60	22.2 (26.5)	-5.8 (-14.0 to 2.3)	
Control	69	18.8 (21.8)	68	19.1 (27.8)	62	21.5 (29.0)		

Efficacy of Oncokompas on patient activation, general self-efficacy, and HRQOL

The results of the linear mixed model analyses are shown in Table 2. No significant differences were found in the course of patient activation over time in the intervention group compared to the control group (estimated difference in change T0-T2; 1.8 (90% CI -1.0 to 4.7); p-value two-way interaction = 0.56).

Also, the course of general self-efficacy did not differ significantly between patients in the intervention and control group (1.0 (-0.2 to 2.2); p-value two-way interaction = 0.23), nor the course of HRQOL (all domains) (Table 2, p-values of two-way interactions ranging from 0.23 to 0.91).

Usage of Oncokompas

Of the 69 patients in the intervention group, 65 activated their account and 48 of them (74%) used Oncokompas as intended during the three-month follow-up period. The median number of logins among intended users was 3 (interquartile range (IQR) = 2.0-4.0). Topics that were most often chosen were: coping with emotions (n=17), cancer related anxiety (n=12), side-effects of medical treatment (n=12), fatigue (n=10), tenseness (n=9), depression (n=8), and body weight (n=8).

The course of patient activation (-1.2 (90% CI: -5.8 to 3.5); p-value two-way interaction = 0.91), general self-efficacy (1.2 (90% CI: -0.7 to 3.2); p-value two-way interaction = 0.49), and HRQOL (Supplementary material; Table 2, all domains p-values two-way interactions ranging from 0.081 to 0.92) was not significantly different between patients who used Oncokompas as intended versus those who did not (Supplementary material; Table 2).

COVID-19 pandemic

The efficacy of the intervention was not significantly influenced by the COVID-19 pandemic regarding patient activation (p-value three-way interaction = 0.056) and general self-efficacy (p-value three-way interaction = 0.063) (Supplementary material; Table 3). There was an effect on the HRQOL subscale dyspnea (p-value three-way interaction = 0.018). Patients included during the pandemic showed small differences in the course of dyspnea over time (Supplementary material; Figure 2). Among patients who were included before the COVID-19 pandemic and completed their follow-up during the pandemic, the course of dyspnea was better in the intervention group than in the control group at three-months follow-up (Supplementary material; Figure 2). Participation before or during the COVID-19 pandemic did not moderate other HRQOL domains (p-values three-way interactions ranging from 0.14 to 0.94).

DISCUSSION

This RCT investigated the efficacy of the eHealth application Oncokompas and showed no significant improvements on patient activation, self-efficacy, or HRQOL among incurably ill cancer patients with a life expectancy of more than three months.

Previous studies showed that eHealth applications can positively affect patient empowerment in palliative care and contribute to efficient use of palliative care resources[28]. However, effects on HRQOL are inconclusive[29]. In this study, no effects were found on patient activation, similar to another RCT among cancer survivors[14]. Furthermore, Oncokompas did not improve (different domains of) HRQOL among incurably ill cancer patients, similar to a previous RCT on Oncokompas among colon cancer survivors[30]. In contrast, the RCT among cancer survivors (breast-, colorectal-, head and neck cancer, and lymphoma), demonstrated that Oncokompas was beneficial to improve HRQOL (small effect size) and to reduce tumor-specific symptoms (larger effect sizes)[14]. There may have been a ceiling effect of Oncokompas' effects on HRQOL, since HRQOL of participants in all these studies was already high at baseline (mean summary score of the EORTC QLQ-C30 was 87.4 among colon cancer survivors[30] and 85.3 among various cancer survivors[14]). Mean global quality of life score on the EORTC QLQ-C15 PAL among participants in this study was 73.9 (the EORTC QLQ-C15 PAL does not contain a summary score as the QLQ-C30).

A qualitative study was conducted alongside the RCT to obtain insight in patients' self-management strategies to cope with cancer and their experiences with Oncokompas. Interviews among cancer survivors and incurably ill cancer patients showed that objectives of self-management interventions like Oncokompas correspond well with strategies to cope with cancer, i.e. taking a certain responsibility for your well-being, and obtaining information and tailored supportive care options[31]. Due to differences in informational preferences during the cancer trajectory, and varying informational needs, eHealth solutions should be customizable to individual patients' needs[32]. Benefits from Oncokompas among cancer survivors were largely gained because of tumor-specific topics[14]. In the present study, Oncokompas was adapted to the needs of incurably ill patients in general and no tumor-specific topics were included. It may be that the application in its current form is not tailored enough. However, cancer-generic topics that were chosen frequently are similar among cancer survivors and incurably ill patients (fatigue and stress/tenseness)[33].

In the current study, 26% of the patients did not use Oncokompas as intended, which might have affected its efficacy. Reasons for not using Oncokompas were investigated in earlier studies: no symptom burden, a busy daily schedule, concentration problems, or having technical issues[31,33]. To overcome the last two reasons, the interface design may be improved to easily navigate through the application and interactive and user-friendly multimedia formats could be added to present information. To stimulate self-management among patients, patients need to be prepared to actively manage their care and be engaged in a collaborative and empowering relationship with their healthcare professional. It might be helpful to train healthcare providers to support self-management, using techniques like motivational interviewing[34].

A strength of this study is the high follow-up rate. A study limitation is that the study was not powered to examine the efficacy of Oncokompas among patients with different patient activation levels or HRQOL profiles. Analyses were performed to explore differences in the course between patients who used Oncokompas as intended versus those who did not. Those results should be interpreted with caution; these analyses were performed post hoc and it is not possible to interpret these findings in terms of causal relations. Additionally, the sample size of these groups was limited, leading to high uncertainty and imprecision of the findings. Incurably ill patients were included with a life expectancy of at least three months, and no upper limit. This may have resulted in a mixed study population regarding stressors and care needs, and might have affected the results. Oncokompas proved to be more effective among cancer survivors reporting a high burden of tumor-specific symptoms[14], which makes sense. In contrast, among incurably ill patients, cognitive problems may hamper usage and effectiveness of self-management applications. Since evidence on MCIDs was limited, it was not possible explain all results in terms of clinical importance, which may be concerned as a study limitation. Another limitation is that – due to privacy regulations – no information was collected of patients not interested in study participation. Also, no medical information was collected about the time since the start of the palliative phase, which could have been interesting to gain knowledge on how and when to implement behavioral intervention technologies for specific patient groups by examining the efficacy of these interventions among patients being aware of the incurability of their illness for a longer period of time versus patients who just found out. Lastly, the results of the secondary analyses should be interpreted with caution; the significant effects in these analyses could be explained due to multiple testing.

Future research investigating the effect of eHealth self-management interventions on patient activation and HRQOL, should specifically focus on cancer patients and survivors with low activation levels, impaired HRQOL or who express a need for supportive care. Furthermore, a longer follow-up might be necessary to detect changes in patient activation levels; it might take longer than three months' time to develop self-management skills. Future studies should also include outcome measures to assess patients' care needs in order to clarify the relationship between needs and usage on the application's efficacy. Additionally, it might be interesting to further examine usage of Oncokompas through logging data and evaluation forms, generating additional knowledge on topics of interest, informational preferences, and applicability in patients' daily life[33]. It would be interesting to investigate the accuracy of the current definition of usage as intended and to explore whether the relationship between efficacy and usage as intended is properly reflected.

Since Oncokompas is also available for partners of incurably ill patients[35], future research may investigate the effects of Oncokompas when dyads use the application together. Furthermore, 73% of the patients participated in this RCT during the COVID-19 pandemic, which might have influenced routine palliative care[36]. Contacts with cancer patients may have changed from face-to-face contact to video consults, influencing the results. The results regarding dyspnea are puzzling and may be a coincidental finding due to multiple testing.

In conclusion, Oncokompas in its current format does not increase patient activation, general self-efficacy or HRQOL among incurably ill cancer patients with a life expectancy of more than three months. More insight is needed in the associations between care needs, usage and efficacy of behavioral intervention technologies such as Oncokompas, and the added value of further tailoring interventions to individual supportive care needs, to create an optimal fit between intervention technologies and patients' needs.

REFERENCES

1. Teunissen SCCM, Wesker W, Kruitwagen C, de Haes HCJM, Voest EE, de Graeff A. Symptom Prevalence in Patients with Incurable Cancer: A Systematic Review. J Pain Symptom Manage. 2007;34(1):94–104.
2. Vogt J, Beyer F, Sistermanns J, Kuon J, Kahl C, Alt-Epping B, et al. Symptom Burden and Palliative Care Needs of Patients with Incurable Cancer at Diagnosis and During the Disease Course. The Oncologist. 2021;26(6):e1058–e1065.
3. Fitzmaurice C, Allen C, Barber RM, Barregard L, Bhutta ZA, Brenner H, et al. Global, regional, and national cancer incidence, mortality, years of life lost, years lived with disability, and disability-adjusted life-years for 32 cancer groups, 1990 to 2015: a systematic analysis for the global burden of disease study global burden . JAMA Oncol. 2017;3(4):524–548.
4. McCorkle R, Ercolano E, Lazenby M, Schulman-Green D, Schilling LS, Lorig K, et al. Self-management: Enabling and empowering patients living with cancer as a chronic illness. CA Cancer J Clin. 2011;61(1):50–62.
5. van Dongen SI, de Nooijer K, Cramm JM, Francke AL, Oldenmenger WH, Korfage IJ, et al. Self-management of patients with advanced cancer: A systematic review of experiences and attitudes. Palliat Med. 2020;34(2):160–178.
6. Howell D, Harth T, Brown J, Bennett C, Boyko S. Self-management education interventions for patients with cancer: a systematic review. Support Care Cancer. 2017;25(4):1323–1355.
7. Escriva Boulley G, Leroy T, Bernetière C, Paquienseguy F, Desfriches-Doria O, Préau M. Digital health interventions to help living with cancer: A systematic review of participants' engagement and psychosocial effects. Psychooncology. 2018;27(12):2677–2686.
8. Sawesi S, Rashrash M, Phalakornkule K, Carpenter JS, Jones JF. The impact of information technology on patient engagement and health behavior change: a systematic review of the literature. JMIR Med Inform. 2016;4(1):e4514.
9. Kruse CS, Beane A. Health information technology continues to show positive effect on medical outcomes: systematic review. J Med Internet Res. 2018;20(2):e41.
10. Hibbard JH, Mahoney ER, Stock R, Tusler M. Do increases in patient activation result in improved self-management behaviors? Health Serv Res. 2007;42(4):1443–1463.
11. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. Health Serv Res. 2004;39(4p1):1005–1026.
12. Mohr DC, Burns MN, Schueller SM, Clarke G, Klinkman M. Behavioral Intervention technologies: evidence review and recommendations for future research in mental health. Gen Hosp Psychiatry. 2013;35(4):332–338.
13. Duman-Lubberding S, van Uden-Kraan CF, Jansen F, Witte BI, van der Velden LA, Lacko M, et al. Feasibility of an eHealth application "OncoKompas" to improve personalized survivorship cancer care. Support Care Cancer. 2016;24(5):2163–2171.
14. van der Hout A, van Uden-Kraan CF, Holtmaat K, Jansen F, Lissenberg-Witte BI, Nieuwenhuijzen GAP, et al. Role of eHealth application Oncokompas in supporting self-management of symptoms and health-related quality of life in cancer survivors: a randomised, controlled trial. Lancet Oncol. 2020;21(1):80–94.
15. van der Hout A, Jansen F, van Uden-Kraan CF, Coupé VM, Holtmaat K, Nieuwenhuijzen GA, et al. Cost-utility of an eHealth application 'Oncokompas' that supports cancer survivors in self-management: results of a randomised controlled trial. J Cancer Surviv. 2021;15(1):77-86.
16. de Veer AJE, Slev VN, Pasman HR, Verdonck-De Leeuw IM, Francke AL, van Uden-Kraan CF. Assessment of a structured self-management support intervention by nurses for patients with incurable cancer. Oncol Nurs Forum. 2020;47(3):305–317.

17. Schuit AS, Holtmaat K, Hooghiemstra N, Jansen F, Lissenberg-Witte BI, Coupé VMH, et al. Efficacy and cost-utility of the eHealth application “Oncokompas”, supporting patients with incurable cancer in finding optimal palliative care, tailored to their quality of life and personal preferences: A study protocol of a randomized controlled trial. BMC Palliat Care. 2019;18(1):85.
18. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c869.
19. van Gemert-Pijnen JEWC, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res. 2011;13(4):e111.
20. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. Health Serv Res. 2005;40(6 I):1918–1930.
21. Hibbard JH, Greene J, Tusler M. Improving the outcomes of disease management by tailoring care to the patient’s level of activation. Am J Manag Care. 2009;15(6):353–360.
22. Fowles JB, Terry P, Xi M, Hibbard J, Bloom CT, Harvey L. Measuring self-management of patients’ and employees’ health: Further validation of the Patient Activation Measure (PAM) based on its relation to employee characteristics. Patient Educ Couns. 2009;77(1):116–122.
23. Schwarzer R, Jerusalem M, Weinman J, Wright S, Johnston M. Generalised self-efficacy scale. In: Weinman J, Wright S, Johnston M, eds. Causal Control beliefs. Generalised Self-Efficacy Scale, 1st ed. Windsor UK: Nfer-Nelson. 1995.
24. Scholz U, Gutiérrez Doña B, Sud S, Schwarzer R. Is General Self-Efficacy a Universal Construct. Eur J Psychol Assess. 2002;18(3):242–251.
25. Groenvold M, Petersen MA, Aaronson NK, Arraras JI, Blazeby JM, Bottomley A, et al. The development of the EORTC QLQ-C15-PAL: a shortened questionnaire for cancer patients in palliative care. Eur J Cancer. 2006;42(1):55–64.
26. Mouelhi Y, Jouve E, Castelli C, Gentile S. How is the minimal clinically important difference established in health-related quality of life instruments? Review of anchors and methods. Health Qual Life Outcomes. 2020;18(1):136.
27. Rijksoverheid. Maart 2020: Maatregelen tegen verspreiding coronavirus, intelligente lockdown. Available from: https://www.rijksoverheid.nl/onderwerpen/coronavirus-tijdlijn/maart-2020-maatregelen-tegen-verspreiding-coronavirus. (accessed March 19, 2021)
28. Widberg C, Wiklund B, Klarare A. Patients’ experiences of eHealth in palliative care: an integrative review. BMC Palliat Care. 2020;19:158.
29. Finucane AM, O’Donnell H, Lugton J, Gibson-Watt T, Swenson C, Pagliari C. Digital health interventions in palliative care: a systematic meta-review. npj Digit Med. 2021;4:64:1-10.
30. Vos JAM, Duineveld LAM, Wieldraaijer T, Wind J, Busschers WB, Sert E, et al. Effect of general practitioner-led versus surgeon-led colon cancer survivorship care, with or without eHealth support, on quality of life (I CARE): an interim analysis of 1-year results of a randomised, controlled trial. Lancet Oncol. 2021;22(8):1175-1187.
31. Schuit AS, van Zwieten V, Holtmaat K, Cuijpers P, Eerenstein SEJ, Leemans CR, et al. Symptom monitoring in cancer and fully automated advice on supportive care: Patients’ perspectives on self-management strategies and the eHealth self-management application Oncokompas. Eur J Cancer Care (Engl). 2021;30(6):e13497.
32. Hibbard JH. Patient activation and the use of information to support informed health decisions. Patient Educ Couns. 2017;100(1):5–7.
33. van der Hout A, van Uden-Kraan CF, Holtmaat K, Jansen F, Lissenberg-Witte BI, Nieuwenhuijzen GAP, et al. Reasons for not reaching or using web-based self-management applications, and the use and evaluation of Oncokompas among cancer survivors, in the context of a randomised controlled trial. Internet Interv. 2021;25.

34. Howell D, Mayer DK, Fielding R, Eicher M, Verdonck-de Leeuw IM, Johansen C, et al. Management of cancer and health after the clinic visit: a call to action for self-management in cancer care. JNCI J Natl Cancer Inst. 2021;113(5):523–531.
35. Schuit AS, Holtmaat K, Hooghiemstra N, Jansen F, Lissenberg-Witte BI, Coupé VMH, et al. Efficacy and cost-utility of the eHealth self-management application “Oncokompas”, helping partners of patients with incurable cancer to identify their unmet supportive care needs and to take actions to meet their needs: a study protocol of a randomized controlled trial. Trials. 2020;21(1):124.
36. Mehta AK, Smith TJ. Palliative care for patients with cancer in the COVID-19 era. JAMA Oncol. 2020;6(10):1527–1528.

SUPPLEMENTARY MATERIAL

Table 1. Overview of all topics covered in Oncokompas for patients with incurable cancer

Domain	**Topics**
Physical	Body weight Daily functioning Diarrhea Dysphagia Dyspnea Fatigue Information about treatment options Appetite loss Lymphedema Mouth problems Nausea and vomiting Obstipation Pain Sexuality Skin problems Sleep problems Other side effects of medical treatment
Psychological	Cancer related anxiety (including fear of suffering and fear of dying) Coping with emotions Depression Tenseness
Social	Being single and cancer Choices concerning the end-of-life Loneliness Patient-physician communication Social life Relationship with partner Relationship with (adult) children Work issues
Existential	Meaning of life Saying farewell

Table 2. Mean scores per group per assessment and results of the linear mixed model analyses on primary and secondary outcome measures for the intervention group (compliers vs. non-compliers)

	Baseline (t0)		2 weeks follow-up (t1)		3-months follow-up (t2)			
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	Estimated difference in change between t0 and t2 (90% CI)	P-value two-way interaction
Patient activation (PAM)								**0.91**
Compliers	45	56.6 (12.4)	46	55.8 (13.6)	41	56.9 (11.6)	-1.2 (-5.8 to 3.5)	
Non-compliers	19	54.2 (8.7)	19	53.5 (9.4)	18	55.3 (12.2)		
General self-efficacy (GSE)								**0.49**
Compliers	48	29.8 (5.4)	47	29.6 (5.2)	42	30.5 (5.6)	1.2 (-0.7 to 3.2)	
Non-compliers	20	29.4 (5.3)	20	29.3 (6.0)	18	28.8 (5.9)		
HRQOL (EORTC-QLQ-C15-PAL)								
Global quality of life								0.48
Compliers	48	72.2 (18.9)	47	69.9 (18.3)	42	70.6 (22.3)	4.8 (-2.3 to 12.0)	
Non-compliers	20	76.7 (18.3)	20	70.0 (18.4)	18	69.4 (19.2)		
Physical functioning								0.28
Compliers	48	88.0 (13.9)	47	88.9 (13.1)	42	87.0 (15.3)	2.3 (-3.0 to 7.7)	
Non-compliers	20	90.6 (12.6)	20	86.7 (14.2)	18	87.0 (15.4)		
Emotional functioning								0.33
Compliers	48	72.9 (24.9)	47	74.5 (23.3)	42	70.6 (26.2)	-8.2 (-17.4 to 1.0)	
Non-compliers	20	69.2 (23.7)	20	75.8 (20.6)	18	75.0 (27.0)		
Fatigue								0.15
Compliers	48	44.8 (28.0)	47	44.7 (25.6)	42	42.9 (28.3)	-3.7 (-14.3 to 7.0)	
Non-compliers	20	44.2 (26.6)	20	35.8 (21.8)	18	48.1 (29.6)		

Pain							0.85
Compliers	48	24.3 (24.5)	47	25.9 (22.2)	42	27.8 (26.5)	3.5 (-6.8 to 13.7)	
Non-compliers	20	33.3 (34.6)	20	32.5 (28.9)	18	33.3 (29.7)		
Dyspnea								0.87
Compliers	48	20.1 (23.6)	47	23.4 (26.8)	42	20.6 (25.4)	2.6 (-12.2 to 7.0)	
Non-compliers	20	16.7 (22.9)	20	20.0 (22.7)	18	22.2 (25.6)		
Insomnia								0.92
Compliers	48	34.0 (34.0)	47	32.6 (32.2)	42	33.3 (30.4)	0.6 (-10.0 to 11.2)	
Non-compliers	20	31.7 (27.5)	20	28.3 (27.1)	18	29.6 (22.5)		
Appetite loss								0.25
Compliers	48	20.1 (28.1)	47	15.6 (28.5)	42	15.9 (23.6)	-11.6 (-23.5 to 0.2)	
Non-compliers	20	25.0 (35.7)	20	28.3 (32.9)	18	35.2 (37.0)		
Nausea								0.081
Compliers	48	11.8 (20.0)	47	9.2 (15.1)	42	19.8 (27.6)	18.4 (4.7 to 31.6)	
Non-compliers	20	33.3 (41.9)	20	25.0 (35.7)	18	22.2 (30.2)		
Constipation								0.45
Compliers	48	21.5 (25.3)	47	20.6 (24.6)	42	21.4 (29.3)	8.4 (-4.9 to 21.7)	
Non-compliers	20	31.7 (31.5)	20	21.7 (29.2)	18	24.1 (19.2)		

Table 3. Mean scores per group per assessment and results of the linear mixed model analyses on primary and secondary outcome measures for the groups participating before, partly during and during the COVID-19 pandemic

	Baseline (t0)		2 weeks follow-up (t1)		3-months follow-up (t2)			
	N	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**Estimated difference in change between t0 and t2 (90% CI)**	**P-value three-way interaction**
Patient activation (PAM)								0.056
Intervention group								
Participation before pandemic*	18	56.7 (13.3)	19	50.0 (9.6)	18	54.8 (11.7)	0	
Participation partly during pandemic	12	54.5 (13.9)	13	52.3 (16.4)	11	57.2 (15.2)	-1.1 (-9.3 to 7.2)	
Participation during pandemic	35	55.4 (9.9)	33	59.2 (11.0)	30	57.1 (10.6)	6.0 (-0.3 to 12.4)	
Control group								
Participation before pandemic	18	52.5 (11.1)	17	51.9 (9.3)	16	52.6 (12.3)		
Participation partly during pandemic	12	55.5 (11.7)	12	54.7 (8.6)	11	59.7 (8.0)		
Participation during pandemic	38	56.2 (11.8)	39	56.0 (10.3)	34	54.1 (12.1)		
General self-efficacy (GSE)								0.063
Intervention group								
Participation before pandemic	19	29.3 (3.7)	19	29.1 (5.3)	18	28.0 (6.7)	0	
Participation partly during pandemic	13	28.2 (5.2)	13	27.4 (5.9)	11	29.9 (4.2)	1.5 (-2.0 to 4.9)	
Participation during pandemic	37	30.0 (6.4)	35	30.5 (5.2)	31	31.2 (5.4)	2.4 (-0.3 to 5.1)	
Control group								
Participation before pandemic	18	30.7 (4.5)	17	28.8 (5.9)	16	30.2 (5.1)		
Participation partly during pandemic	12	30.3 (4.6)	12	31.5 (3.7)	11	31.2 (1.1)		
Participation during pandemic	39	31.5 (4.6)	39	29.9 (4.3)	35	30.6 (4.5)		

	Baseline (t0)		2 weeks follow-up (t1)		3-months follow-up (t2)			
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	Estimated difference in change between t0 and t2 (90% CI)	P-value three-way interaction
HRQOL (EORTC-QLQ-C15-PAL)								
Global quality of life								0.35
Intervention group								
Participation before pandemic	19	70.2 (18.1)	19	64.9 (19.9)	18	64.8 (24.8)	0	
Participation partly during pandemic	13	66.7 (15.2)	13	66.7 (18.0)	11	65.2 (20.4)	7.9 (-7.1 to 22.9)	
Participation during pandemic	37	78.4 (19.6)	35	73.8 (16.8)	31	75.3 (18.7)	2.8 (-8.8 to 14.4)	
Control group								
Participation before pandemic	18	68.5 (18.0)	17	73.5 (22.9)	16	69.8 (19.5)		
Participation partly during pandemic	12	72.2 (17.9)	12	72.2 (22.8)	11	68.2 (26.3)		
Participation during pandemic	39	76.1 (18.7)	39	68.8 (22.7)	35	75.2 (15.8)		
Physical functioning								**0.25**
Intervention group								
Participation before pandemic	19	85.4 (14.8)	19	86.0 (13.3)	18	80.9 (18.6)	0	
Participation partly during pandemic	13	87.2 (14.2)	13	86.3 (12.1)	11	92.0 (11.2)	11.3 (0.9 to 21.6)	
Participation during pandemic	37	89.8 (14.4)	35	90.2 (13.9)	31	88.9 (13.5)	5.5 (-2.5 to 13.5)	
Control group								
Participation before pandemic	18	91.4 (10.5)	17	87.6 (15.7)	16	91.7 (14.3)		
Participation partly during pandemic	12	90.7 (10.4)	12	86.1 (15.8)	11	86.9 (13.0)		
Participation during pandemic	39	89.7 (19.8)	39	88.0 (20.6)	35	87.9 (21.5)		

	Baseline (t0)		**2 weeks follow-up (t1)**		**3-months follow-up (t2)**			
	N	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**Estimated difference in change between t0 and t2 (90% CI)**	**P-value three-way interaction**
Emotional functioning								**0.41**
Intervention group								
Participation before pandemic	19	66.7 (22.9)	19	69.3 (23.1)	18	65.7 (31.0)	0	
Participation partly during pandemic	13	65.4 (30.0)	13	67.9 (29.2)	11	62.1 (28.0)	1.4 (-15.4 to 18.2)	
Participation during pandemic	37	76.6 (22.4)	35	80.5 (17.8)	31	79.0 (21.1)	9.6 (-3.5 to 22.6)	
Control group								
Participation before pandemic	18	75.9 (23.7)	17	79.4 (22.5)	16	79.2 (24.0)		
Participation partly during pandemic	12	77.8 (25.9)	12	69.4 (24.4)	11	72.7 (29.1)		
Participation during pandemic	39	84.6 (17.7)	39	85.5 (17.6)	35	78.6 (19.2)		
Fatigue								**0.31**
Intervention group								
Participation before pandemic	19	49.1 (30.7)	19	44.7 (23.6)	18	52.8 (28.7)	0	
Participation partly during pandemic	13	52.3 (24.4)	13	47.4 (22.4)	11	43.9 (28.2)	-23.0 (-43.1 to 2.9)	
Participation during pandemic	37	41.0 (27.7)	35	38.6 (26.1)	31	39.8 (28.4)	-12.3 (-27.9 to 3.3)	
Control group								
Participation before pandemic	18	39.8 (30.9)	17	39.2 (35.8)	16	30.2 (27.4)		
Participation partly during pandemic	12	29.2 (28.5)	12	38.9 (32.8)	11	39.4 (35.2)		
Participation during pandemic	39	35.9 (22.1)	39	38.9 (27.4)	35	41.0 (25.4)		

	Baseline (t0)		2 weeks follow-up (t1)		3-months follow-up (t2)			
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	Estimated difference in change between t0 and t2 (90% CI)	P-value three-way interaction
Pain								**0.29**
Intervention group								
Participation before pandemic	19	35.1 (32.8)	19	24.6 (24.4)	18	31.5 (31.8)	0	
Participation partly during pandemic	13	29.5 (20.6)	13	39.7 (22.1)	11	28.8 (23.7)	5.1 (-13.8 to 23.9)	
Participation during pandemic	37	23.0 (27.6)	35	25.2 (24.4)	31	28.5 (26.6)	-1.6 (-16.2 to 13.0)	
Control group								
Participation before pandemic	18	21.3 (26.1)	17	21.6 (24.8)	16	18.8 (24.2)		
Participation partly during pandemic	12	29.2 (25.7)	12	26.4 (30.5)	11	24.2 (20.2)		
Participation during pandemic	39	21.8 (25.1)	39	26.5 (26.4)	35	26.7 (30.3)		
Dyspnea								**0.018**
Intervention group								
Participation before pandemic	19	24.6 (24.4)	19	26.3 (30.6)	18	31.5 (33.3)	0	
Participation partly during pandemic	13	28.2 (26.7)	13	30.8 (25.3)	11	12.1 (16.8)	-36.7 (-54.2 to -19.2)	
Participation during pandemic	37	13.5 (20.0)	35	17.1 (21.9)	31	18.3 (20.8)	-14.0 (-27.5 to -0.5)	
Control group								
Participation before pandemic	18	29.6 (37.7)	17	19.6 (35.5)	16	12.5 (26.9)		
Participation partly during pandemic	12	25.0 (20.7)	12	30.6 (30.0)	11	30.3 (31.5)		
Participation during pandemic	39	12.8 (18.1)	39	12.8 (19.7)	35	12.4 (21.5)		

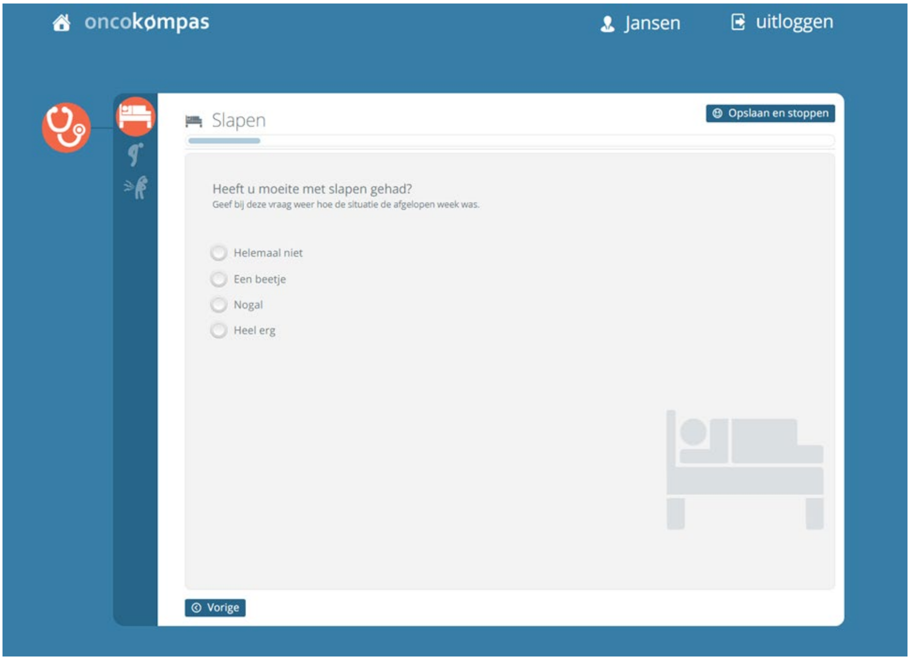
	Baseline (t0)		2 weeks follow-up (t1)		3-months follow-up (t2)			
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	Estimated difference in change between t0 and t2 (90% CI)	P-value three-way interaction
Insomnia								**0.14**
Intervention group								
Participation before pandemic	19	33.3 (27.2)	19	31.6 (28.3)	18	33.3 (25.6)	0	
Participation partly during pandemic	13	46.2 (39.8)	13	46.2 (39.8)	11	30.3 (34.8)	-9.4 (-31.8 to 13.0)	
Participation during pandemic	37	28.8 (30.6)	35	25.7 (26.9)	31	32.3 (27.9)	5.4 (-11.9 to 22.7)	
Control group								
Participation before pandemic	18	37.0 (30.0)	17	27.5 (35.8)	16	33.3 (32.2)		
Participation partly during pandemic	12	36.1 (38.8)	12	30.6 (26.4)	11	27.3 (32.7)		
Participation during pandemic	39	23.9 (26.4)	39	29.1 (26.7)	35	21.9 (27.9)		
Appetite loss								**0.94**
Intervention group								
Participation before pandemic	19	29.8 (38.3)	19	28.1 (37.3)	18	25.9 (35.3)	0	
Participation partly during pandemic	13	17.9 (22.0)	13	20.5 (25.6)	11	15.2 (22.9)	-0.5 (-24.4 to 23.5)	
Participation during pandemic	37	19.8 (28.8)	35	14.3 (27.2)	31	21.5 (28.0)	-6.3 (-24.8 to 12.2)	
Control group								
Participation before pandemic	18	31.5 (31.3)	17	29.4 (37.0)	16	25.0 (31.0)		
Participation before pandemic	12	16.7 (22.5)	12	19.4 (30.0)	11	18.2 (27.3)		
Participation partly during pandemic	39	12.8 (23.7)	39	16.2 (25.2)	35	21.9 (30.2)		

	Baseline (t0)		2 weeks follow-up (t1)		3-months follow-up (t2)			
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	Estimated difference in change between t0 and t2 (90% CI)	P-value three-way interaction
Nausea								**0.55**
Intervention group								
Participation before pandemic	19	29.8 (36.7)	19	17.5 (28.0)	18	25.9 (35.3)	0	
Participation partly during pandemic	13	10.3 (25.0)	13	10.3 (16.0)	11	12.1 (22.5)	20.1 (-5.4 to 45.7)	
Participation during pandemic	37	16.2 (26.8)	35	13.3 (24.5)	31	20.4 (25.4)	13.6 (-6.1 to 33.4)	
Control group								
Participation before pandemic	18	16.7 (23.6)	17	17.6 (35.6)	16	20.8 (29.5)		
Participation partly during pandemic	12	19.4 (33.2)	12	11.1 (21.7)	11	12.1 (22.5)		
Participation during pandemic	39	19.7 (22.6)	39	16.2 (25.2)	35	19.0 (27.2)		
Constipation								**0.87**
Intervention group								
Participation before pandemic	19	31.6 (30.4)	19	21.1 (29.8)	18	27.8 (32.8)	0	
Participation partly during pandemic	13	10.3 (21.0)	13	20.5 (29.0)	11	12.1 (22.5)	2.4 (-22.2 to 27.1)	
Participation during pandemic	37	25.2 (26.5)	35	21.0 (23.0)	31	22.6 (23.4)	-6.6 (-25.6 to 12.5)	
Control group								
Participation before pandemic	18	20.4 (23.3)	17	17.6 (31.4)	11	18.8 (27.1)		
Participation partly during pandemic	12	16.7 (17.4)	12	27.8 (31.2)	16	21.2 (30.8)		
Participation during pandemic	39	18.8 (22.7)	39	17.1 (25.2)	35	22.9 (30.0)		

* Pandemic = COVID-19 pandemic

Figure 1. Overview of the different steps within Oncokompas

Step 1: Measure

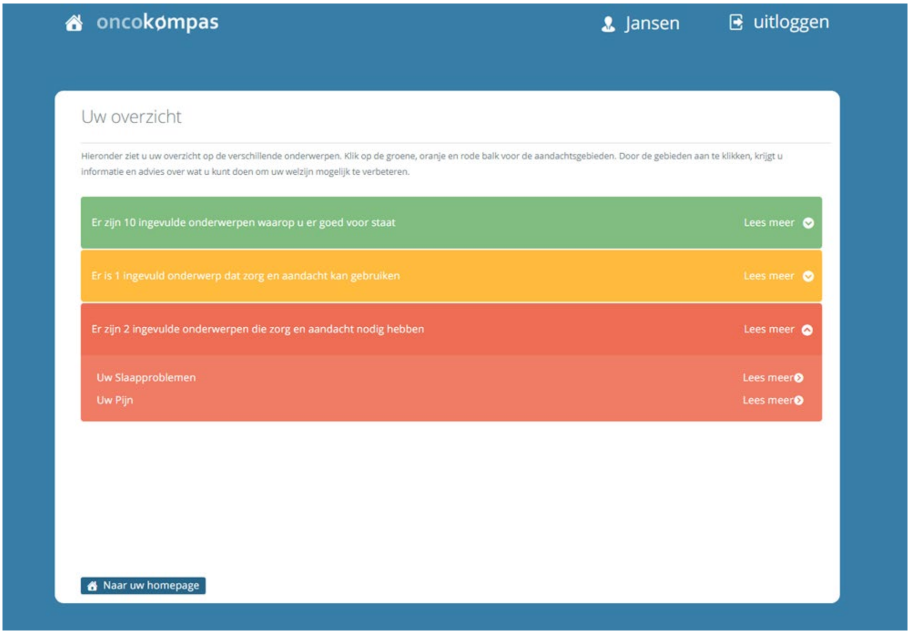


Slapen

Heeft u moeite met slapen gehad?
Geef bij deze vraag weer hoe de situatie de afgelopen week was.

○ Helemaal niet
○ Een beetje
○ Nogal
○ Heel erg

Step 2a: Learn – Overview of well-being on different topics



Uw overzicht

Hieronder ziet u uw overzicht op de verschillende onderwerpen. Klik op de groene, oranje en rode balk voor de aandachtsgebieden. Door de gebieden aan te klikken, krijgt u informatie en advies over wat u kunt doen om uw welzijn mogelijk te verbeteren.

Er zijn 10 ingevulde onderwerpen waarop u er goed voor staat — Lees meer

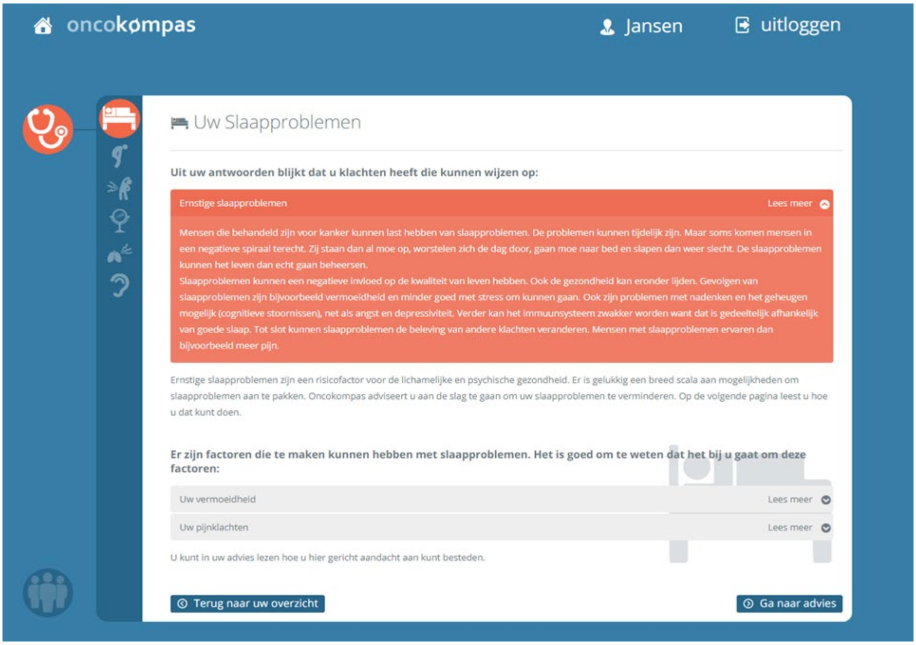
Er is 1 ingevuld onderwerp dat zorg en aandacht kan gebruiken — Lees meer

Er zijn 2 ingevulde onderwerpen die zorg en aandacht nodig hebben — Lees meer

Uw Slaapproblemen — Lees meer

Uw Pijn — Lees meer

Step 2b: Learn – Tailored information and advice



Uw Slaapproblemen

Uit uw antwoorden blijkt dat u klachten heeft die kunnen wijzen op:

Ernstige slaapproblemen

Mensen die behandeld zijn voor kanker kunnen last hebben van slaapproblemen. De problemen kunnen tijdelijk zijn. Maar soms komen mensen in een negatieve spiraal terecht. Zij staan dan al moe op, worstelen zich de dag door, gaan moe naar bed en slapen dan weer slecht. De slaapproblemen kunnen het leven dan echt gaan beheersen.
Slaapproblemen kunnen een negatieve invloed op de kwaliteit van leven hebben. Ook de gezondheid kan eronder lijden. Gevolgen van slaapproblemen zijn bijvoorbeeld vermoeidheid en minder goed met stress om kunnen gaan. Ook zijn problemen met nadenken en het geheugen mogelijk (cognitieve stoornissen), net als angst en depressiviteit. Verder kan het immuunsysteem zwakker worden want dat is gedeeltelijk afhankelijk van goede slaap. Tot slot kunnen slaapproblemen de beleving van andere klachten veranderen. Mensen met slaapproblemen ervaren dan bijvoorbeeld meer pijn.

Ernstige slaapproblemen zijn een risicofactor voor de lichamelijke en psychische gezondheid. Er is gelukkig een breed scala aan mogelijkheden om slaapproblemen aan te pakken. Oncokompas adviseert u aan de slag te gaan om uw slaapproblemen te verminderen. Op de volgende pagina leest u hoe u dat kunt doen.

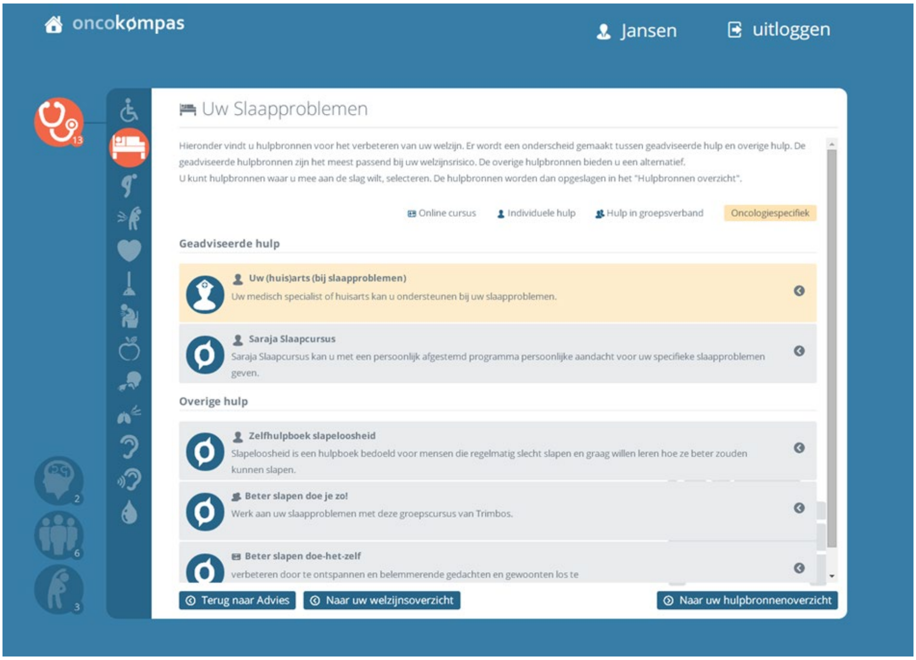
Er zijn factoren die te maken kunnen hebben met slaapproblemen. Het is goed om te weten dat het bij u gaat om deze factoren:

Uw vermoeidheid

Uw pijnklachten

U kunt in uw advies lezen hoe u hier gericht aandacht aan kunt besteden.

Step 3: Act



Uw Slaapproblemen

Hieronder vindt u hulpbronnen voor het verbeteren van uw welzijn. Er wordt een onderscheid gemaakt tussen geadviseerde hulp en overige hulp. De geadviseerde hulpbronnen zijn het meest passend bij uw welzijnsrisico. De overige hulpbronnen bieden u een alternatief.
U kunt hulpbronnen waar u mee aan de slag wilt, selecteren. De hulpbronnen worden dan opgeslagen in het "Hulpbronnen overzicht".

Geadviseerde hulp

Uw (huis)arts (bij slaapproblemen)
Uw medisch specialist of huisarts kan u ondersteunen bij uw slaapproblemen.

Saraja Slaapcursus
Saraja Slaapcursus kan u met een persoonlijk afgestemd programma persoonlijke aandacht voor uw specifieke slaapproblemen geven.

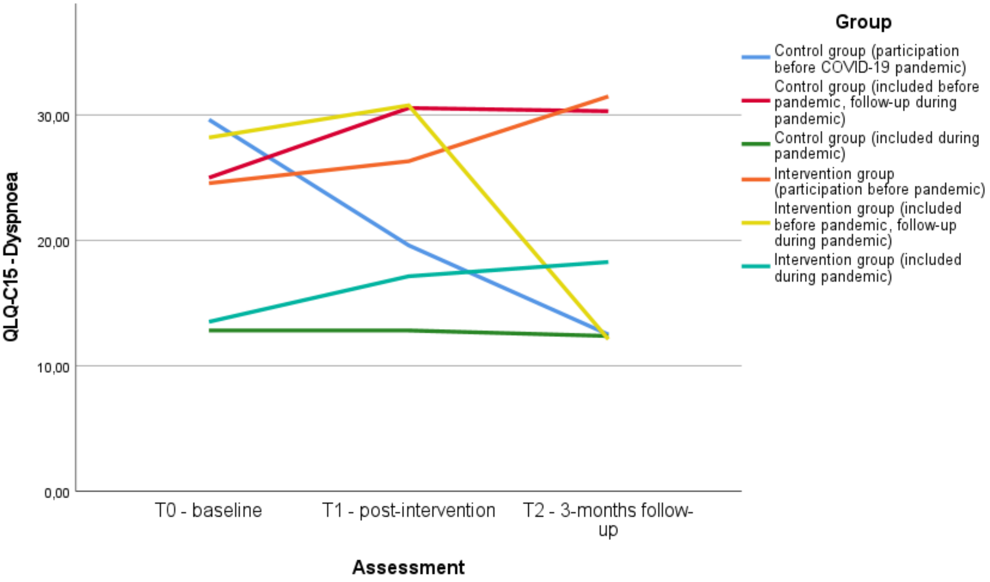
Overige hulp

Zelfhulpboek slapeloosheid
Slapeloosheid is een hulpboek bedoeld voor mensen die regelmatig slecht slapen en graag willen leren hoe ze beter zouden kunnen slapen.

Beter slapen doe je zo!
Werk aan uw slaapproblemen met deze groepscursus van Trimbos.

Beter slapen doe-het-zelf
verbeteren door te ontspannen en belemmerende gedachten en gewoonten los te

Figure 2. Graphics of the course of dyspnea over time for patients participating (partly) before and (partly) during the COVID-19 pandemic



6

COST-UTILITY OF THE EHEALTH APPLICATION 'ONCOKOMPAS', SUPPORTING INCURABLY ILL CANCER PATIENTS TO SELF-MANAGE THEIR CANCER-RELATED SYMPTOMS: RESULTS OF A RANDOMIZED CONTROLLED TRIAL

Anouk S. Schuit
Karen Holtmaat
Veerle M.H. Coupé
Simone E.J. Eerenstein
Josée M. Zijlstra
Corien Eeltink
Annemarie Becker-Commissaris
Lia van Zuylen
Myra E. van Linde
C. Willemien Menke-van der Houven van Oordt
Dirkje W. Sommeijer
Nol Verbeek
Koop Bosscha
Rishi Nandoe Tewarie
Robert-Jan Sedee
Remco de Bree
Alexander de Graeff
Filip de Vos
Pim Cuijpers
Irma M. Verdonck-de Leeuw
Femke Jansen

Current Oncology 2022;29:6186-6202

ABSTRACT

Background: Evidence on the cost-effectiveness of eHealth in palliative care is scarce. Oncokompas, a fully automated behavioral intervention technology, aims to support self-management in cancer patients. This study aimed to assess the cost-utility of the eHealth application Oncokompas among incurably ill cancer patients, compared to care as usual.

Methods: In this randomized controlled trial, patients were randomized into the intervention group (access to Oncokompas) or the waiting-list control group (access to Oncokompas after three months). Healthcare costs (iMCQ), productivity losses (iPCQ), and health status (EQ-5D-5L) were measured at baseline and three months after the baseline measurement. Intervention costs were also taken into account. Non-parametric bootstrapping with 5000 replications was used to obtain 95% confidence intervals around the incremental costs and quality-adjusted life years (QALYs). A probabilistic approach was used because of the skewness of cost data.

Results: Altogether, 138 patients completed the baseline questionnaire and were randomly assigned to the intervention group (69) or the control group (69). In the base case analysis, mean total costs and mean total effects were non-significantly lower in the intervention group (-€806 and -0.01 QALYs). The probability that the intervention was more effective and less costly was 4%, whereas the probability of being less effective and less costly was 74%.

Conclusions: Among patients with incurable cancer, the fully automated behavioral intervention technology Oncokompas does not impact incremental costs and seems slightly less effective in terms of QALYs, compared to care as usual. Future research on the costs of eHealth in palliative cancer care is warranted to assess the generalizability of the findings of this study.

Keywords: palliative care, eHealth, cost-utility analysis, cost evaluation, incurable cancer, quality of life

INTRODUCTION

Incurable cancer challenges patients to deal with physical and psychological symptoms, as well as social and existential concerns[1–3]. eHealth solutions offer an innovative way to support cancer patients in self-managing their cancer-related symptoms. They enable patients to remain in charge of their own quality of life as long as possible by providing information and advice on how to manage side-effects of cancer and its treatment[4,5]. eHealth applications are available at any time and almost any place. Furthermore, they have the potential to improve health outcomes and to reduce healthcare costs by providing resource-efficient, patient-oriented care[6].

Oncokompas was developed as a fully automatic behavioral intervention technology (BIT) to support cancer patients to adopt an active role in self-managing cancer-related symptoms[7,8]. Patients get tailored feedback and advice based on patient-reported outcome measures (PROMs), and a personalized overview of supportive care services. Oncokompas is based on the stepped care principle, supporting patients to take actions to deal with their symptoms by themselves, only with professional guidance if needed. Recently, a randomized controlled trial (RCT) was conducted to determine the efficacy of Oncokompas among patients with incurable cancer, in which no significant improvements were found on patient activation (i.e., patients' skills, knowledge and confidence to manage their disease[9]), general self-efficacy and health-related quality of life (HRQOL)[10].

Previous research indicated that psychosocial care and eHealth interventions for cancer patients is likely to be cost-effective at different, potentially acceptable, willingness-to-pay ceilings[11–13]. Little evidence is available on the cost-effectiveness of eHealth interventions in palliative care and mainly focusing on telemonitoring and video conferencing[14]. To our knowledge, evidence on the cost-effectiveness or cost-utility of fully automated eHealth interventions used in palliative cancer care settings is not yet available. Economic evaluations are needed to enhance evidence-based decision making and to create and facilitate realistic business models and payment of eHealth services[15,16]. With a cost-utility analysis (CUA), the ratio between the costs and effects of an intervention are analyzed. Effects of an intervention are often expressed using the generic measure of health gain, quality-adjusted life years (QALYs)[17,18].

The aim of this study was to assess the cost-utility of the eHealth application Oncokompas among patients with incurable cancer, compared to care as usual, within the context of an RCT.

METHODS

Study design and population

Detailed information on the study design can be found in previous publications[10,19]. Data on the cost-utility of Oncokompas were collected alongside an RCT to determine the efficacy of Oncokompas among adult patients (≥ 18 years) with incurable cancer (i.e., not having curative treatment options)[10].

Patients were recruited through healthcare professionals (e.g., medical oncologists, nurses, or nurse specialists) in six hospitals in the Netherlands (Amsterdam University Medical Centers (locations VUmc and AMC), University Medical Center Utrecht, St. Antonius Hospital, Haaglanden Medical Center, and Jeroen Bosch Hospital). Patients were included when they had a life expectancy of at least three months and when they were aware of the incurability of their cancer. Patients were excluded when they had severe cognitive impairments, poor understanding of the Dutch language, did not have access to the Internet or to an e-mail address, or when they were already familiar with Oncokompas. In addition, patients were excluded when they were too ill to participate or when participation would be too burdensome according to their healthcare professional due to the patient's participation in other studies. All participants provided informed consent before study participation.

The study protocol was approved by the Medical Ethics Committee of VU University Medical Center (2018.224) and has been published previously[19]. This trial was registered in the Netherlands Trial Register (NTR 7494/ NL7285).

Randomization and allocation

Patients who completed the baseline questionnaire were randomly allocated (1:1 ratio) to the intervention group or the control group, getting access to Oncokompas directly or after three months respectively. Randomization was performed by an independent researcher, using a computer-generated randomization scheme with a random block length of four, six or eight. Neither the coordinating researcher nor the participants were blinded after allocation, due to the nature of the intervention.

Care as usual

Patients randomized to the intervention group and the control group received care as usual, which is defined as the care provided by the oncological team or by other healthcare professionals. This includes all medical and supportive care that patients received, regardless of their study participation.

Intervention

Oncokompas is an eHealth application, supporting patients to adopt an active role in managing their disease. Patients navigate through Oncokompas in three steps; measure, learn, and act. First, patients are asked to fill in online patient-reported outcome measures (PROMs) on the topics of their own choice, to measure the severity of their symptoms ('Measure'). Subsequently, patients get an overview of their health status on their chosen topics, after which they get information on their symptoms and advice on how to manage their symptoms on their own ('Learn'). In addition, patients get an overview of healthcare professionals where they can go to when professional help is necessary ('Act'). Oncokompas is meant as an additional form of support, not as a replacement of healthcare professionals.

Outcome assessment

Outcomes measuring the efficacy of Oncokompas (i.e., patient activation, general self-efficacy and HRQOL) were assessed at baseline (t0), after two weeks (t1), and three months after the baseline measurement (t2)[10]. Outcomes measuring the cost-utility of Oncokompas (i.e., costs and utility outcomes) were collected at t0 and t2. Costs were assessed with the Medical Consumption Questionnaire (iMCQ) and the Productivity Cost Questionnaire (iPCQ), developed by the Institute for Medical Technology Assessment (iMTA)[20,21]. The iMCQ and iPCQ measure healthcare use, help received from family and friends, and productivity losses in the previous three months, respectively. Patients' HRQOL was measured using the EuroQol-5 Dimensions (EQ-5D-5L). The Dutch index tariff was used to transform patients' given answers to utility scores[22].

Costs were calculated from a societal perspective and included costs of healthcare, costs for patients and their families (e.g., travelling costs, help received from family and friends), costs within other sectors (e.g., productivity losses), and intervention costs. Costs of healthcare and costs for patients and their families were calculated by multiplying the units of resource use (e.g., general practitioner (GP) visits) by the integral cost price per unit[23,24]. To calculate costs for travelling to healthcare services, the units of resource use were multiplied by the mean distance to the healthcare service times the price per kilometer. Productivity losses included losses as a result of absenteeism (absence from paid work) and presenteeism (reduced quality of the paid work performed). Absenteeism was calculated as the number of days absent from work. The friction cost method, using a friction period of 85 days, was used to calculate losses due to absenteeism[23]. Presenteeism was calculated by multiplying the days of less productivity at work by the estimated amount of lost quality of the work performed on an 11-point scale. One hour of paid work was priced as €38 (regardless of gender and age)[24]. All prices were converted to prices for 2019, using price indexes. Neither costs nor effects were discounted, due to the three months follow-up period.

Intervention costs included the costs for Oncokompas, which are estimated at €450,000 annually. These were calculated using a top-down approach and comprise the costs for ICT, product and data management, content updating, implementation, and marketing. Based on 18.000 users per year (i.e., approximately 15% of all newly diagnosed patients[25]), intervention costs per user were estimated at €25[13].

Statistical analysis

SPSS version 27 (IBM, Armonk, NY, USA) and STATA version 16 (STATA, College Station, TX, USA) were used to perform the analyses. Chi-square tests and independent t-tests were used to analyze whether randomization resulted in comparable groups of patient characteristics across study arms, as well as a Mann-Whitney U test when data were not normally distributed.

A base case intention-to-treat analysis was performed to test the cost-utility of Oncokompas compared to care as usual. In the base case analysis, all participants – who completed the first questionnaire and were allocated to a study arm – were included, imputing any missing data. Due to the differences in baseline total costs and EQ-5D score and the fact that only one follow-up measurement was available (i.e., three months after the baseline measurement), the base case analysis was corrected for baseline EQ-5D and costs.

Depending on level of missing data (i.e., data missing on item level or questionnaire level), different methods were used for imputing missing data. When data were missing on item level (e.g., when a patient reported to have visited the GP, but did not report the number of visits), assumptions were based on means per study arm (intervention or control) and time point. When data was missing on questionnaire level, total costs or EQ-5D utility scores were imputed per time point per study arm, using multiple imputation by chained equations (predictive mean matching). Variables found to be associated with missing data (i.e., living situation), observed costs (i.e., living situation), or EQ-5D utility scores (i.e., treatment, education level, comorbidities, having children, GSE score) were included in the multiple imputation model. Ten imputed datasets were created and analyzed separately. Using Rubin's rules (1987), results of the 10 analyses were pooled.

The cumulative costs and the number of QALYs per patient were calculated to perform incremental cost-utility analyses. The sum of all costs measured with the iMCQ and iPCQ at t2, and the intervention costs (intervention group only), were used to calculate the total cumulative costs per patient from t0 to t2. EQ-5D utility scores measured at t2 were multiplied by the three months' time period (time between t0 and t2) to calculate QALYs.

An incremental cost-utility ratio (ICUR) was calculated by dividing the incremental costs (mean costs in the intervention group minus mean costs in the control group) by the incremental effects (mean QALYs in the intervention group minus mean QALYs in the control group). Non-parametric bootstrapping with 5000 replications was used to obtain 95% confidence intervals around the ICUR, which were projected on a cost-utility plane. A probabilistic approach was used rather than reliance upon significance levels to describe the results due to the skewness of cost data[26].

Sensitivity analyses were performed to assess the robustness of the findings of the base case analysis, namely:

1. not adjusting the base case analysis for baseline EQ5D scores and baseline total costs;
2. performing a complete case analysis among patients with complete data at all time-points;
3. including varying intervention costs of Oncokompas (€15 and €100 per user) in the base case analysis;
4. performing the base-case analysis from a healthcare perspective, including only healthcare costs and intervention costs;
5. imputing data for patients who died during the study (to preclude an effect of higher mortality in the intervention group compared to the control group);
6. excluding patients who died during the study (idem).

RESULTS

Study population

Patients were recruited between December 2018 and August 2020. In total, 293 patients were screened for eligibility to participate in this study, of which 219 patients were eligible. Of these patients, 138 were willing to participate and completed the baseline questionnaire (response rate 63%) (10). Reasons to decline participation were: participation being too (emotionally) confronting (n = 14), lacking computer skills (n = 9), not being interested (n = 9), privacy concerns (n = 3), and other reasons (n = 5); 41 patients provided no reason for non-participation. Subsequently, patients were randomly assigned to the intervention group (n = 69) or the control group (n= 69), of which respectively 60 (87%) and 61 (88%) patients completed the follow-up questionnaire three months after the baseline measurement. No significant differences in sociodemographic and clinical characteristics were found between the intervention and control group at baseline (Table 1). Figure 1 shows a flow diagram of the study and the reasons for drop-out. Table 1 summarizes the characteristics of the 138 patients included in this study.

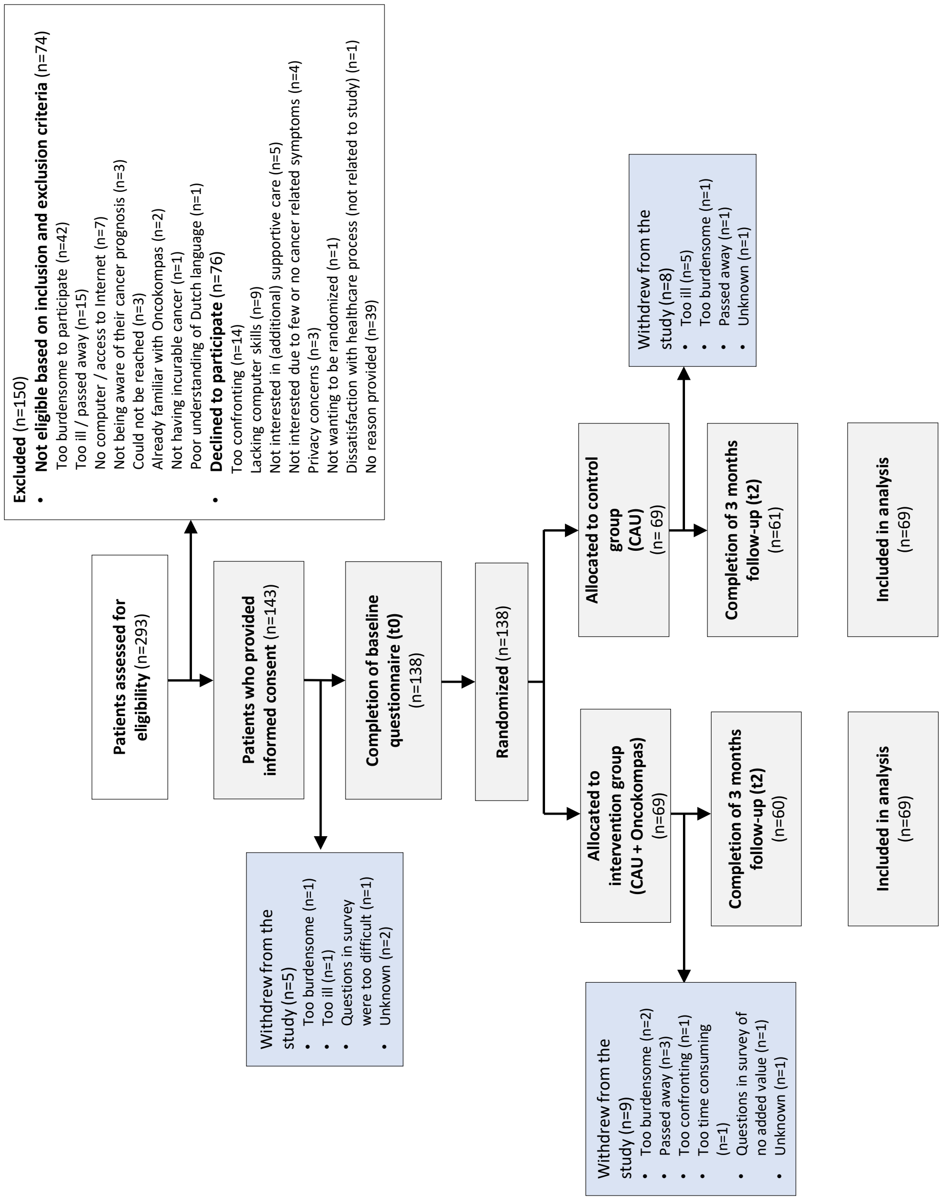


Figure 1. Flow diagram of the study

Table 1. Patients' sociodemographic and clinical characteristics at baseline

	Total group (n=138)		Control group (n=69)		Intervention group (n=69)		p-value
	Number	**%**	**Number**	**%**	**Number**	**%**	
Age in years							0.29
Mean (SD)	61.1 (12.3)	-	62.3 (11.9)	-	60.0 (12.7)	-	
IQR	53 – 70.3	-	54.5 – 71.5	-	51.0 – 68.5	-	
Gender							1.00
Male	74	55%	37	54%	37	54%	
Female	64	45%	32	46%	32	46%	
Education level							0.61
Low/medium/unknown	73	53%	38	55%	35	51%	
High	65	47%	31	45%	34	49%	
Living situation*							0.38
Living alone	28	20%	16	24%	12	17%	
Living with kids/partner	109	80%	52	77%	57	83%	
Marital status							0.82
Partner	115	83%	57	83%	58	84%	
No partner	23	17%	12	17%	11	16%	
Children							0.69
Yes	106	77%	54	79%	52	75%	
No	32	23%	15	22%	17	25%	
Employment							0.38
Yes	51	37%	28	41%	23	33%	
Absent from work > 3 months	*29*	57%	*17*	61%	*12*	52%	
No	87	63%	41	59%	46	67%	
Tumor type							0.83
Brain tumor	39	29%	22	32%	17	25%	
Gastro-intestinal cancer	19	14%	10	15%	9	13%	
Lung cancer	17	12%	8	12%	8	12%	
Hematological cancer	16	12%	8	12%	8	12%	
Head and neck cancer	16	12%	7	10%	9	13%	
Breast cancer	15	11%	5	7%	10	15%	
Urological cancer	10	7%	6	9%	4	6%	
Other	4	3%	1	1%	3	6%	
Multiple primaries[a]	3	2%	2	3%	1	1%	
Treatment							0.55
No treatment[b]	12	9%	7	10%	5	7%	
Single, multiple or multimodal treatment	126	91%	62	90%	64	93%	
Comorbidities							0.43
None or one comorbidity	104	75%	54	78%	50	73%	
Multiple comorbidities	34	25%	15	22%	19	28%	

[a] Three patients were diagnosed with multiple primary tumors (one with head and neck cancer & gastro-intestinal cancer, one with lung cancer & urological cancer, and one with gastro-intestinal cancer & melanoma (other)) and are therefore shown in a separate category. [b] Getting no treatment also includes best supportive care and symptom management. *Missing in one patient.

Table 2. Mean costs per time point at t0 and t2

		Baseline (t0)				3-months follow-up (t2)			
		Intervention (*N* = 69)		Control (*N* = 69)		Intervention (*N* = 60)		Control (*N* = 61)	
	Price[*]	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**
Healthcare costs		**3463**	**(3576)**	**4771**	**(6112)**	**2589**	**(2458)**	**3660**	**(4427)**
General practitioner									
Phone	18	39	(38)	39	(42)	35	(42)	34	(34)
Home visit	53	16	(43)	30	(68)	18	(46)	25	(59)
Consultation at practice	35	53	(64)	40	(58)	40	(60)	40	(55)
Company doctor	73	28	(60)	29	(69)	30	(62)	23	(53)
Social worker	69	19	(64)	24	(72)	17	(62)	7	(24)
Physiotherapist	35	172	(293)	69	(169)	155	(203)	104	(229)
Ergotherapist	35	9	(39)	3	(18)	3	(12)	3	(16)
Dietitian	32	16	(35)	27	(62)	12	(28)	14	(44)
Speech therapist	32	2	(13)	4	(20)	1	(6)	3	(21)
Oral hygienist	27	5	(11)	6	(11)	5	(10)	4	(10)
Psychologist/psychiatrist[**]	100-131	109	(248)	58	(171)	66	(174)	90	(207)
Medical specialist									
General hospital	85	25	(76)	38	(134)	37	(109)	21	(72)
Academic hospital	174	754	(788)	1019	(1249)	696	(735)	796	(773)
Spiritual counsellor	137	20	(95)	24	(97)	14	(65)	22	(101)
Home-care (cleaning)	21	50	(184)	16	(131)	97	(259)	9	(70)
Personal care	53	48	(265)	11	(63)	25	(121)	126	(970)
Nursing care	78	43	(177)	392	(2346)	39	(264)	348	(1743)
Emergency care visit	277	72	(194)	100	(232)	83	(193)	59	(125)
Ambulance to hospital	550	40	(144)	56	(285)	55	(195)	36	(137)

		Baseline (t0)				**3-months follow-up (t2)**			
		Intervention (*N* = 69)		**Control (*N* = 69)**		**Intervention (*N* = 60)**		**Control (*N* = 61)**	
	Price*	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**
Day treatment									
Hospital	324	1226	(2108)	1493	(2482)	718	(1378)	1392	(2403)
*Care centre****	72-327	0	(0)	0	(0)	0	(0)	0	(0)
Admission									
Hospital	508	611	(1757)	1230	(3180)	322	(944)	425	(1296)
*Care center****	179-491	0	(0)	0	(0)	0	(0)	0	(0)
Supportive care****	From 15 - 67	105	(320)	51	(192)	114	(320)	50	(187)
Costs for patients and their families		**657**	**(1504)**	**462**	**(891)**	**780**	**(2866)**	**856**	**(2489)**
Transport and parking costs*****	0-9	71	(62)	82	(80)	57	(45)	71	(69)
Alternative treatment	65	2	(16)	12	(66)	7	(50)	30	(140)
Informal care	15	586	(1499)	379	(882)	723	(2865)	784	(2469)
Other costs (i.e., productivity losses)		**358**	**(1666)**	**273**	**(1143)**	**334**	**(2551)**	**291**	**(1129)**
Absenteeism paid work	38/hour	355	(1666)	272	(1143)	329	(2551)	287	(1113)
Presenteeism paid work	38/hour	4	(20)	1	(11)	5	(37)	4	(25)
TOTAL COSTS		4479	**(4933)**	5506	**(6521)**	3703	**(4495)**	4806	**(5525)**

Abbreviations: SD, standard deviation; n, sample size

* Reference price per unit (€)

** Psychologic or psychiatric help = psychological help at a private practice (€100), mental health service (out-patient) (€105), addiction clinic (€131), and/or psychologic help in hospital (€131)

*** Care centre = residential centre (treatment: €72, admission: €179), rehabilitation centre (treatment: €327, admission: €491) and/or psychiatric institution (treatment: €180, admission: €323);

**** Supportive care interventions = help with coping (€68), support groups (€ calculation based on price of specific support group), sport rehabilitation programs (€68), body image care (€15), self-help books (€ calculation based on answers of individual participants) and/or online self-help programs (calculation based on price of specific self-help program)

***** Transport = transportation and parking costs: €0.19/km + €3 parking costs per visit.

Costs and utility scores at baseline and follow-up

Mean total costs for patients over the last three months at baseline were €4479 (SD = 4933) in the intervention group compared to €5506 (SD = 6521) in the control group. No significant differences in total costs were found between the intervention and usual care group (p-value = 0.30). At baseline, also no statistically significant differences were found in EQ-5D utility scores between the intervention group and control group (p-value = 0.35), which were respectively 0.76 (SD = 0.18) and 0.79 (SD = 0.17).

The mean costs of patients per time point per group are presented in Table 2. Complete data at t0 and t2 were available for 138 patients and 121 patients respectively. Table 3 shows the EQ-5D utility score per time point per group.

Table 3. Mean EQ-5D utility score per time point

Time point	N	Control group Mean (SD)	Intervention group Mean (SD)
EQ-5D			
Baseline	138	0.79 (0.17)	0.76 (0.18)
3 months follow-up	121	0.80 (0.18)	0.74 (0.21)

Abbreviations: SD, standard deviation; n, sample size

Cost-utility analyses

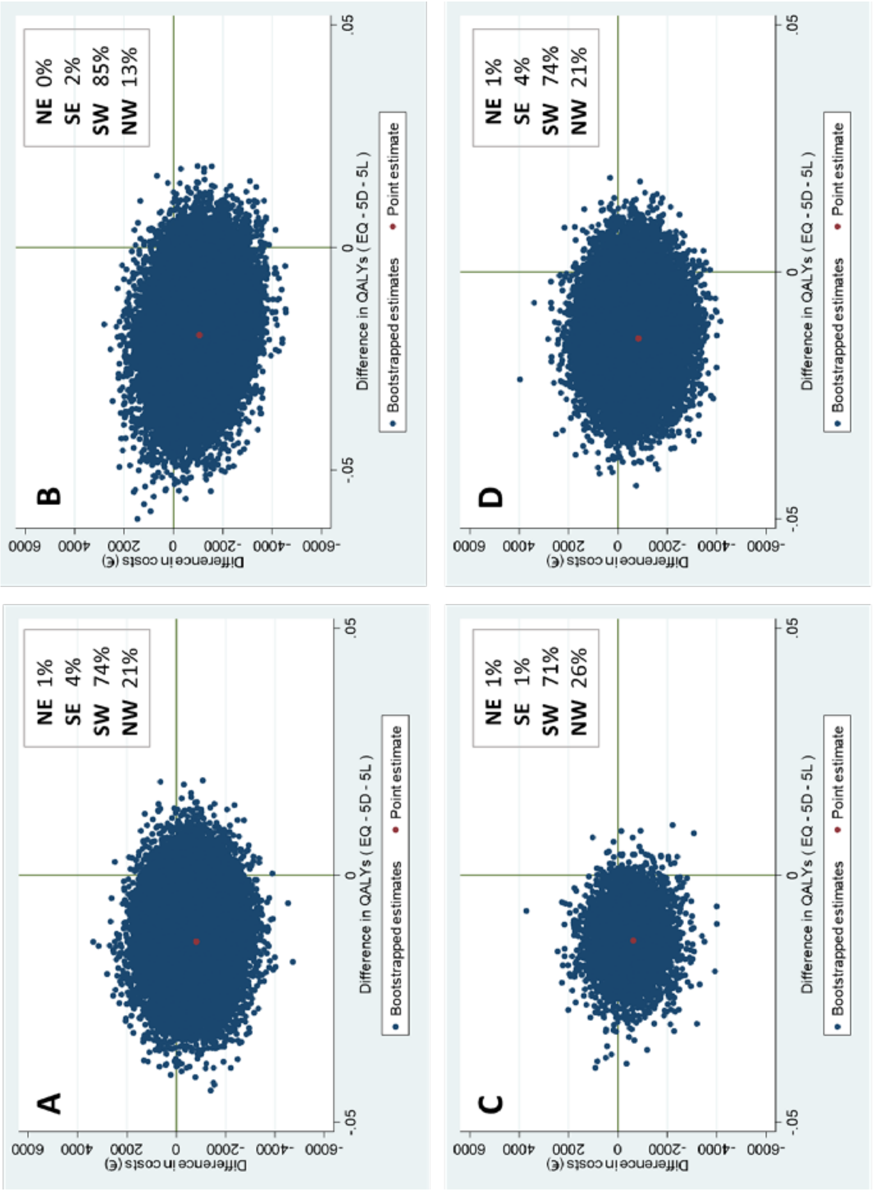
The results of all cost-utility analyses are presented in Table 4. In the base case analysis, mean costs and mean effects were non-significantly lower in the intervention group compared to the control group (incremental costs: −€806, 95% CI −€2453 to €674, and incremental effects: −0.01 QALYs, 95% CI −0.03 to 0.001). Bootstrapping with 5000 replications was performed to assess the uncertainty surrounding the base case analysis. Of the bootstrapped cost-utility pairs, 74% fell into the south-west quadrant, indicating that the intervention was less effective and less costly. In 4% of the simulations, the intervention was more effective and less costly (south-east quadrant).

To assess the robustness of the base case analysis, additional sensitivity analyses were performed (Table 4). All analyses showed non-significantly lower costs in the intervention group compared to the control group (−€990 to −€401) and non-significantly lower QALYs in the intervention group compared to the control group (−0.01 to −0.02), except for the base case analysis with no correction for baseline EQ5D and costs and the complete case analysis (in which only patients with complete data at all time-points (i.e., t0 and t2) were included), which showed significantly lower QALYs in the intervention group compared to the control group (−0.02 and −0.01, respectively). The sensitivity analyses showed that the intervention group had a probability of 71-85% to be less effective and less costly. Figure 2 represents the cost-utility planes of all analyses.

Table 4. Results of the cost-utility analyses (i.e., base case and sensitivity analyses)

		Costs (€)	QALYs	Incremental costs		Incremental effects	
Group	**N**	**Mean (SEM)**	**Mean (SEM)**	**€**	**95% CI**	**QALYs**	**95% CI**
Base case analysis*				-806	[-2453 to 674]	-0.01	[-0.03 to 0.001]
- Control group	69	NA	NA				
- Intervention group	69	NA	NA				
Sensitivity analyses**							
Base case analysis with no correction for baseline EQ 5D and costs				-990	[-2690 to 594]	-0.02	[-0.04 to -0.001]***
- Control group	69	4590 (689)	0.20 (0.01)				
- Intervention group	69	3600 (575)	0.17 (0.01)				
Complete case analysis				-611	[-2384 to 947]	-0.01	[-0.03 to -0.001]***
- Control group	61	NA	NA				
- Intervention group	60	NA	NA				
Analysis with differing intervention costs							
€15				-816	[-2469 to 690]	-0.01	[-0.03 to 0.001]
- Control group	69	NA	NA				
- Intervention group	69	NA	NA				
€100				-731	[-2400 to 798]	-0.01	[-0.03 to 0.001]
- Control group	69	NA	NA				
- Intervention group	69	NA	NA				
Analysis from healthcare perspective				-401	[-1393 to 472]	-0.02	[-0.03 to 0.000]
- Control group	69	NA	NA				
- Intervention group	69	NA	NA				
Analysis with imputed data for patients who died during the study				-871	[-2489 to 565]	-0.01	[-0.03 to 0.003]
- Control group	69	NA	NA				
- Intervention group	69	NA	NA				
Analysis excluding patients who died during the study				-778	[-2430 to 742]	-0.01	[-0.03 to 0.001]
- Control group	68	NA	NA				
- Intervention group	66	NA	NA				

Abbreviations: N = sample size, SEM = standard error of the mean, 95% CI = 95% confidence interval
*The base case analysis is corrected for baseline EQ-5D utility score and costs. **The sensitivity analyses were corrected for baseline EQ-5D utility score and costs (except the base case analysis with no correction for baseline EQ5D and costs). *** Significant difference between the two groups ($p < 0.05$).


A
NE 1%
SE 4%
SW 74%
NW 21%
B
NE 0%
SE 2%
SW 85%
NW 13%
C
NE 1%
SE 1%
SW 71%
NW 26%
D
NE 1%
SE 4%
SW 74%
NW 21%
Difference in costs (€)
6000
4000
2000
0
-2000
-4000
-6000
Difference in QALYs (EQ - 5D - 5L)
-.05
0
.05
Bootstrapped estimates
Point estimate

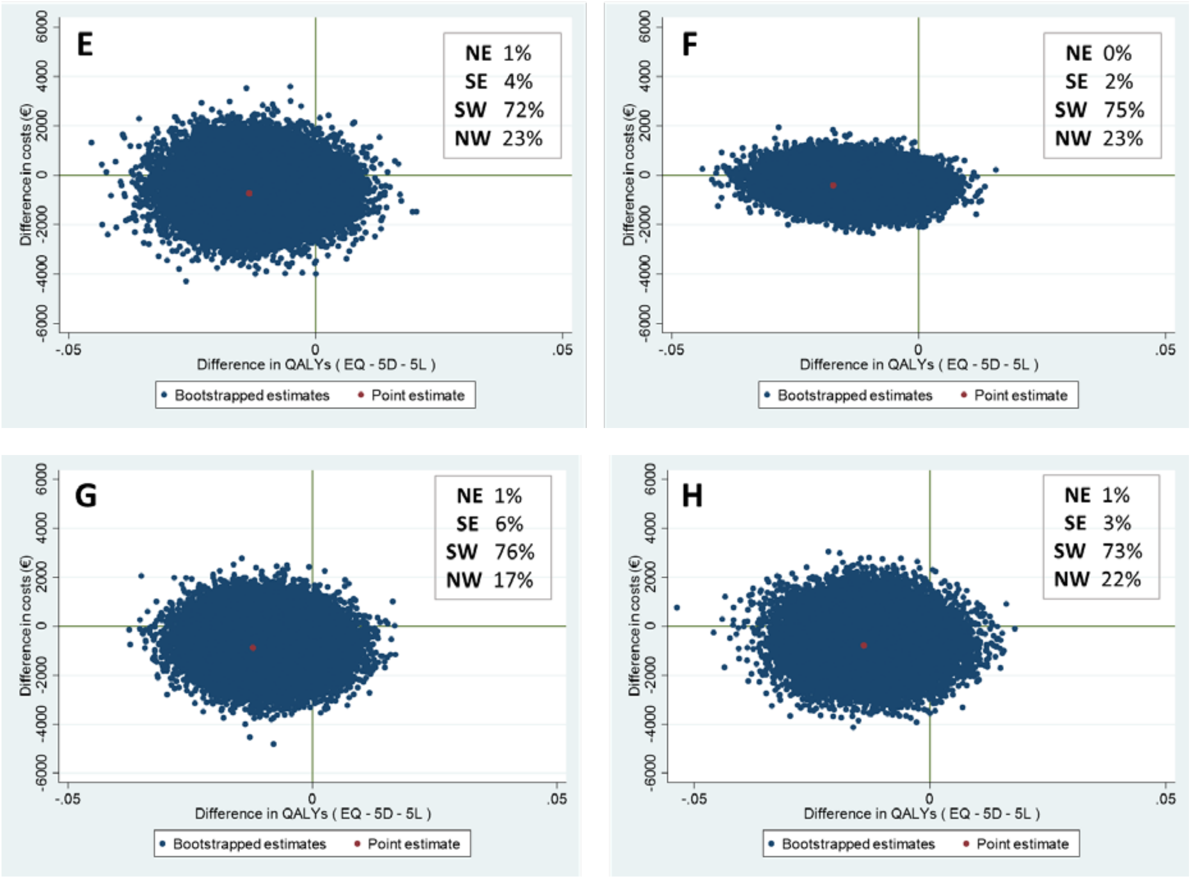


Figure 2. Cost-utility planes of the (A) base case analysis, (B) analysis with no correction for baseline EQ5D score and costs, (C) complete case analysis, (D) analysis with intervention costs of €15, (E) analysis with intervention costs of €100, (F) analysis from healthcare perspective (only healthcare costs and intervention costs were taken into account), (G) analysis with imputed data for patients who died during the study, and (H) analysis excluding patients who died during the study

DISCUSSION

This study investigated the cost-utility of the eHealth self-management application Oncokompas as a behavioral intervention technology to support incurably ill cancer patients to adopt an active role in managing their disease, and to improve their HRQOL. The base case analysis showed that incremental costs and incremental effects were non-significantly lower in the intervention group than in the control group (−€806 and −0.01 QALYs, respectively). These findings indicate that Oncokompas for incurably ill cancer patients does not impact incremental costs and seems slightly less effective than care as usual. The probability that the intervention is less effective and less costly was 74%.

Additional sensitivity analyses – taking into account varying intervention costs, and a healthcare perspective – confirmed the robustness of these findings, showing non-significant lower costs and effects. The sensitivity analyses taking into account only patients with complete data, and the base case analysis with no correction for baseline EQ-5D and costs, showed non-significantly lower incremental costs and significantly lower incremental effects. Two additional analyses were performed to analyze whether patients who died during the study influenced the study results: an analysis in which data was imputed for patients who died during the study (as though they were still alive) and an analysis excluding the patients who died during the study. These sensitivity analyses were performed because mortality in the intervention group was non-significantly higher in the intervention group compared to the control group (3 (5%) versus 1 (2%)). As Oncokompas is not expected to influence mortality, but a difference due to coincidence directly influences mean QALYs, these sensitivity analyses were conducted. Both analyses showed small changes in incremental costs, and the incremental QALYs showed a non-significant difference. The intervention group still had a probability of 73% to 76% that incremental QALYs and costs were lower than in the control group.

The findings of this study are in line with the findings of the parallel study on the efficacy of Oncokompas among incurably ill cancer patients (the cost outcomes were gathered alongside the trial on the efficacy of Oncokompas), which showed no improvements on patient activation, general self-efficacy, and HRQOL[10]. Earlier research indicated that palliative care services among cancer and non-cancer populations are cost-effective compared to care as usual[27,28]. However, these palliative care interventions mainly comprised hospice care, hospital-based palliative care programs and home-based palliative care programs, and did not include eHealth interventions for use in palliative care[27,29]. To the best of our knowledge, this is the first study investigating the cost-utility of a digital health intervention in palliative cancer care. A recent study among cancer survivors treated with curative intent showed that Oncokompas was effective to improve

HRQOL, while costs from a societal perspective were similar to usual cancer survivorship care[13]. In this study, positive effects of Oncokompas on HRQOL could be merely attributed to a decrease of tumor-specific burden (30). The content of Oncokompas for use in cancer survivorship care is developed for survivors of different cancer types specifically[8,30] (e.g., survivors of breast cancer and colorectal cancer get different content within the application). However, Oncokompas for use in palliative care is developed for incurably ill cancer patients in general, which might not be tailored enough for cancer patients to realize improvements on their HRQOL.

There has been a debate whether the use of QALYs in palliative care is appropriate[31,32], due to changing patient values and priorities near the end-of-life and the question whether QALYs are sensitive enough to capture the effects of a complex intervention as palliative care. QALYs enable decision makers to compare between competing demands of resources and to ensure that resources are well distributed[32]. In the Dutch guideline[23], the EQ-5D-5L is the PROM of first choice to calculate QALYs. However, the EQ-5D-5L focuses on generic symptoms and does not measure symptoms relevant for (incurable) cancer or palliative care, such as fatigue, social isolation or spiritual symptoms (e.g., finding meaning and purpose in life)[1–3]. This might affect the results regarding the cost-utility in incurably ill cancer patients. It is notable that EQ-5D-5L scores in this study were relatively high among participants, which adds to the discussion on whether all aspects of HRQOL are properly measured with the EQ-5D-5L within this population. As an alternative measure, it might be interesting for future studies to use a cancer-specific, or even palliative cancer-specific utility instrument alongside the EQ-5D to investigate cost-utility of supportive care interventions among incurably ill cancer patients[33]. In addition, it might be worthwhile to measure HRQOL from a broader perspective than just the ‘health perspective’; for example by using the Adult Social Care Outcomes Toolkit (ASCOT)[34,35].

A strength of this study is that multiple sensitivity analyses were conducted to assess the robustness of the base case analysis. Both an analysis from a societal perspective, as an analysis from a healthcare perspective were performed, including intervention costs and healthcare costs[36]. Another strength is the high follow-up rate, resulting in a more or less comparable percentage of participants with complete data at follow-up in both groups (87% and 88%). A limitation of this study is that the study was not powered to perform cost-utility analyses in specific sub groups, hampering the ability to, for example, conduct analyses among those who used Oncokompas as intended versus those who did not. Additionally, selection bias might have occurred, which may affect generalizability of the study findings. Unfortunately, due to privacy regulations, no data was gathered on non-responders, hampering the possibility to compare characteristics of responders and non-responders. Another potential limitation is that – although the number of missing data was relatively low – missing data was imputed based on assumptions (missing data on item level) or multiple imputation techniques (missing data on questionnaire level), which may not necessarily reflect reality. In addition, the results of this study might not be generalizable to other countries, since cost prices per unit and productivity losses were based on Dutch tariffs[23]. Furthermore, this study was (partly) conducted during the COVID-19 pandemic, which have affected routine palliative care and thereby the results of this study. In addition, the follow-up of this study was three months; this time frame might have been too limited to visualize the cost-saving potential of Oncokompas. Lastly, in this study informal care costs were included to calculate the costs for patients and families. However, in this study only informal costs were included for informal caregivers' time spent on homecare, personal care and nursing care. When caregivers work less in a paid job due to their caregiving tasks, total informal costs made by caregivers in fact could be higher. In addition, caregiving tasks might be demanding which might result in increased costs due to presenteeism[37,38]. Future research might investigate whether usage intensity of eHealth affects cost-utility of eHealth interventions and to what extent total costs of eHealth interventions are affected by costs for informal caregivers.

Study implications

Findings of this economic evaluation of Oncokompas indicate that Oncokompas does not impact incremental costs and seems slightly less effective than care as usual among incurably ill cancer patients. Current evidence on the cost-utility of eHealth interventions is mainly focusing on telemonitoring and video conferencing; to the best of our knowledge this study is among the first studies on cost outcomes regarding a fully automated BIT in palliative cancer care. The results of this study are limited. However, it is still possible that Oncokompas supports patients to be better informed about their symptoms and thereby being of added value to palliative cancer care. More studies in palliative cancer care are needed to put this study on the cost-utility of eHealth among incurably ill cancer patients into perspective. This is warranted, since costs could be a major barrier for the implementation of eHealth interventions.

CONCLUSIONS

The fully automated behavioral intervention technology Oncokompas does not impact costs and seems slightly less effective in terms of QALYs compared to care as usual for patients with incurable cancer. This study contributes to the evidence on cost evaluations of eHealth in palliative care. However, more research on the costs of eHealth in palliative cancer care is warranted to assess the generalizability of the study findings.

REFERENCES

1. van Roij J, Brom L, Youssef-El Soud M, van de Poll-Franse L, Raijmakers NJH. Social consequences of advanced cancer in patients and their informal caregivers: a qualitative study. Support Care in Cancer. 2019:27(4);1187-1195.
2. Teunissen SCCM, Wesker W, Kruitwagen C, de Haes HCJM, Voest EE, de Graeff A. Symptom Prevalence in Patients with Incurable Cancer: A Systematic Review. J Pain Symptom Manage. 2007;34(1):94–104.
3. Mesquita AC, Chaves ÉDCL, Barros GAM De. Spiritual needs of patients with cancer in palliative care: An integrative review. Curr Opin Support Palliat Care. 2017;11(4):334–340.
4. Aapro M, Bossi P, Dasari A, Fallowfield L, Gascón P, Geller M, et al. Digital health for optimal supportive care in oncology: benefits, limits, and future perspectives. Support Care Cancer. 2020;28(10):4589–4612.
5. Widberg C, Wiklund B, Klarare A. Patients' experiences of eHealth in palliative care: an integrative review. BMC Palliat Care. 2020;19(1):1–14.
6. Sanyal C, Stolee P, Juzwishin D, Husereau D. Economic evaluations of eHealth technologies: A systematic review. PLoS One. 2018;13(6):e0198112.
7. Lubberding S, van Uden-Kraan CF, Te Velde EA, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. Improving access to supportive cancer care through an eHealth application: A qualitative needs assessment among cancer survivors. J Clin Nurs. 2015;24(9–10):1367–1379.
8. Duman-Lubberding S, van Uden-Kraan CF, Jansen F, Witte BI, van der Velden LA, Lacko M, et al. Feasibility of an eHealth application "OncoKompas" to improve personalized survivorship cancer care. Support Care Cancer. 2016;24(5):2163–2171.
9. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. Health Serv Res. 2004;39(4p1):1005–1026.
10. Schuit AS, Holtmaat K, Lissenberg-Witte BI, Eerenstein SEJ, Zijlstra JM, Eeltink C, et al. Efficacy of the eHealth application Oncokompas, facilitating incurably ill cancer patients to self-manage their palliative care needs: A randomized controlled trial. Lancet Reg Heal - Eur. 2022;18:100390.
11. Jansen F, van Zwieten V, Coupé VMH, Leemans CR, Verdonck-de Leeuw IM. A Review on Cost-Effectiveness and Cost-Utility of Psychosocial Care in Cancer Patients. Asia-Pacific J Oncol Nurs. 2016;3(2):125–136.
12. Dieng M, Cust AE, Kasparian NA, Mann GJ, Morton RL. Economic evaluations of psychosocial interventions in cancer: a systematic review. Psychooncology. 2016;25(12):1380–1392.
13. van der Hout A, Jansen F, van Uden-Kraan CF, Coupé VMH, Holtmaat K, Nieuwenhuijzen GA, et al. Cost-utility of an eHealth application 'Oncokompas' that supports cancer survivors in self-management: results of a randomised controlled trial. J Cancer Surviv. 2021;15(1):77-86.
14. Finucane AM, O'Donnell H, Lugton J, Gibson-Watt T, Swenson C, Pagliari C. Digital health interventions in palliative care: a systematic meta-review. NPJ Digit Med. 2021;4(1):1-10.
15. Rabarison KM, Bish CL, Massoudi MS, Giles WH. Economic evaluation enhances public health decision making. Front Public Heal. 2015;3:164.
16. Bergmo TS. How to measure costs and benefits of ehealth interventions: An overview of methods and frameworksJournal of Medical Internet Research. 2015;17(11):e4521.
17. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. Methods for the Economic Evaluations of Health Care Programmes. Fourth Edition. Oxford, UK: Oxford University Press; 2015.
18. Whitehead SJ, Ali S. Health outcomes in economic evaluation: The QALY and utilities. Br Med Bull. 2010;96(1):5–21.

19. Schuit AS, Holtmaat K, Hooghiemstra N, Jansen F, Lissenberg-Witte BI, Coupé VMH, et al. Efficacy and cost-utility of the eHealth application “Oncokompas”, supporting patients with incurable cancer in finding optimal palliative care, tailored to their quality of life and personal preferences: A study protocol of a randomized controlled trial. BMC Palliat Care. 2019;18(1):1–11.
20. C. Bouwmans, L. Hakkaart-van Roijen, M. Koopmanschap, M. Krol, H. Severens WB. Handleiding iMTA Productivity Cost Questionnaire (iPCQ); iMTA, Erasmus Universiteit: Rotterdam, The Netherlands 2013.
21. C. Bouwmans, L. Hakkaart-van Roijen, M. Koopmanschap, M. Krol, H. Severens WB. Handleiding iMTA Medical Cost Questionnaire (iMCQ); iMTA, Erasmus Universiteit: Rotterdam, The Netherlands. 2013.
22. Versteegh MM, Vermeulen KM, Evers SMAA, Ardine De Wit G, Prenger R, Stolk EA. Dutch Tariff for the Five-Level Version of EQ-5D. Value Heal. 2016;19(4):343–352.
23. Hakkaart-van Roijen L, van der Linden N, Bouwmans C, Kanters T, Swan Tan S. Kostenhandleiding: Methodologie van kostenonderzoek en referentieprijzen voor economische evaluaties in de gezondheidszorg. Zorginstituut Ned. 2016;1–73. Available from: www.zorginstituutnederland.nl/publicaties/publicatie/2016/02/29/richtlijn-voor-het-uitvoeren-van-economische-evaluaties-in-de-gezondheidszorg. (accessed 1 October, 2021)
24. Kanters TA, Bouwmans CA, Van Der Linden N, Tan SS, Hakkaart-van Roijen L. Update of the Dutch manual for costing studies in health care. PLoS One. 2017;12(11):e0187477.
25. IKNL. Cijfers over kanker. Available from: https://iknl.nl/nkr-cijfers. (accessed March 20, 2022)
26. Elliott R, Payne K. Statistical handling of data in economic analysis Essentials of Economic Evaluation in Healthcare. London, UK: Pharmaceutical Press; 2005.
27. Smith S, Brick A, O’Hara S, Normand C. Evidence on the cost and cost-effectiveness of palliative care: A literature review. Palliat Med. 2014;28(2):130–150.
28. Mathew C, Hsu AT, Prentice M, Lawlor P, Kyeremanteng K, Tanuseputro P, et al. Economic evaluations of palliative care models: A systematic review. Palliat Med. 2020;34(1):69–82.
29. Gardiner C, Ingleton C, Ryan T, Ward S, Gott M. What cost components are relevant for economic evaluations of palliative care, and what approaches are used to measure these costs? A systematic review. Palliat Med. 2017;31(4):323–337.
30. van der Hout A, van Uden-Kraan CF, Holtmaat K, Jansen F, Lissenberg-Witte BI, Nieuwenhuijzen GAP, et al. Role of eHealth application Oncokompas in supporting self-management of symptoms and health-related quality of life in cancer survivors: a randomised, controlled trial. Lancet Oncol. 2020;21(1):80–94.
31. Gomes B, Harding R, Foley KM, Higginson IJ. Optimal Approaches to the Health Economics of Palliative Care: Report of an International Think Tank. J Pain Symptom Manage. 2009;38(1):4–10.
32. Round J. Is a QALY still a QALY at the end of life? J Health Econ. 2012;31(3):521–527.
33. King MT, Costa DS, Aaronson NK, Brazier JE, Cella DF, Fayers PM, et al. QLU-C10D: a health state classification system for a multi-attribute utility measure based on the EORTC QLQ-C30. Qual Life Res. 2016;25(3):625–636.
34. Turnpenny A, Caiels J, Crowther T, Richardson L, Whelton B, Beadle-Brown J, et al. Developing an Easy Read version of the Adult Social Care Outcomes Toolkit (ASCOT). Journal of Applied Research in Intellectual Disabilities. 2018;31(1):e36-e48.
35. van Loon MS, van Leeuwen KM, Ostelo RWJG, Bosmans JE, Widdershoven GAM. Quality of life in a broader perspective: Does ASCOT reflect the capability approach? Qual Life Res. 2018;27(5):1181–1189.
36. Jönsson B. Editorial: Ten arguments for a societal perspective in the economic evaluation of medical innovations. Eur J Heal Econ. 2009;10(4):357–359.
37. Gardiner C, Robinson J, Connolly M, Hulme C, Kang K, Rowland C, et al. Equity and the financial costs of informal caregiving in palliative care: A critical debate. BMC Palliat Care. 2020;19(1):1–7.

38. Coumoundouros C, Ould Brahim L, Lambert SD, McCusker J. The direct and indirect financial costs of informal cancer care: A scoping review. Heal Soc Care Community. 2019;27(5):e622–636.

7

SYMPTOM MONITORING IN CANCER AND FULLY AUTOMATED ADVICE ON SUPPORTIVE CARE: PATIENTS' PERSPECTIVES ON SELF-MANAGEMENT STRATEGIES AND THE EHEALTH SELF-MANAGEMENT APPLICATION ONCOKOMPAS

Anouk S. Schuit
Valesca van Zwieten
Karen Holtmaat
Pim Cuijpers
Simone E.J. Eerenstein
C. René Leemans
Marije R. Vergeer
Jens Voortman
Hakki Karagozoglu
Stijn van Weert
Mira Korte
Ruud Frambach
Margot Fleuren
Jan-Jaap Hendrickx
Irma M. Verdonck-de Leeuw

European Journal of Cancer Care 2021;30(6):e13497

ABSTRACT

Objective: The web-based application Oncokompas was developed to support cancer patients to self-manage their symptoms. This qualitative study was conducted to obtain insight in patients' self-management strategies to cope with cancer and their experiences with Oncokompas as a fully automated behavioral intervention technology.

Methods: Data were collected from semi-structured interviews with 22 participants (10 head and neck cancer survivors and 12 incurably ill patients). Interview questions were about self-management strategies and experiences with Oncokompas. Interviews were audio-recorded, transcribed verbatim, and analyzed using thematic analysis.

Results: Participants applied several self-management strategies, among which trying to stay in control and make the best of their situation. They described Oncokompas' added value; being able to monitor symptoms and having access to a personal online library. Main reasons for not using Oncokompas were concentration problems, lack of time, or having technical issues. Recommendations were made for further development of Oncokompas, relating to its content, technical and functional aspects.

Conclusions: Survivors and incurably ill patients use various self-management strategies to cope with cancer. The objectives of self-management interventions as Oncokompas correspond well with these strategies: taking a certain responsibility for your well-being, and being in charge of your life as long as possible by obtaining automated information (24/7) on symptoms and tailored supportive care options.

Keywords: eHealth, supportive care, self-management, evaluation of care, cancer, head and neck cancer

INTRODUCTION

Digital technologies supporting patients to self-manage cancer-related symptoms are evolving rapidly in cancer care[1–3] and can improve patients' health-related quality of life (HRQOL) and self-management behavior[4–6].

The fully automated behavioral intervention technology (BIT) Oncokompas was developed to support cancer patients to self-manage their cancer-related symptoms in addition to medical care. Self-management is described as "an individual's ability to manage the symptoms, treatment, physical and psychosocial consequences, and lifestyle changes inherent in living with a chronic condition"[7]. Based on three steps in Oncokompas (Measure, Learn and Act), patients are supported to take action to meet their supportive care needs. A participatory design approach was used to develop Oncokompas; end-users, healthcare professionals, researchers, policymakers, and insurance companies were actively involved in the design process[8]. From 2017 until 2020, two randomized controlled trials (RCTs) were conducted to determine the efficacy of Oncokompas among cancer survivors and incurably ill patients[9,10]. Evaluation of the trial among incurably ill patients is still in progress, but the results of the RCT among cancer survivors are available[11]. Oncokompas was (cost)effective to improve HRQOL and to reduce symptom burden among cancer survivors, but did not show significant effects on patients' knowledge, skills and confidence to self-manage their illness (i.e., patient activation)[11]. Most participants were long-term survivors, being more than two years after diagnosis, and already might have obtained sufficient self-management skills, knowledge and confidence.

Oncokompas seems most effective among survivors reporting higher burden of tumor-specific symptoms, survivors with lower self-efficacy, higher personal control (i.e., believing to be able to control life events and circumstances[12]), or higher health literacy[13]. In total, 52% of the survivors used Oncokompas as intended (i.e., completion of the components 'Measure' and 'Learn' for at least one topic). Main reasons for not using Oncokompas were no symptom burden, no supportive care needs, or lack of time[14].

Despite insights in the efficacy of Oncokompas, underlying mechanisms of the efficacy and usage of Oncokompas as a self-management application remain unclear. To create more understanding about ways in which self-management applications could fit into patients' daily life, also patients' self-management strategies to deal with the impact of cancer and its treatment are of interest. To summarize, the aim of this qualitative study was to gain more insight in how cancer survivors and incurably ill cancer patients deal with cancer in their daily lives and how they experience Oncokompas as a fully automated BIT supporting them to cope with cancer-related symptoms. The results can be used to create a better fit between patients' self-management strategies and their wishes regarding BITs.

METHODS

Context and selection of study participants

Since Oncokompas has been developed targeting all cancer patients (all cancer types and all treatment modalities), both cancer survivors and incurably ill cancer patients were included in this study. We recruited participants through two different channels; through routine care (survivors of head and neck cancer (HNC; all subsites, all treatment modalities) (at least three months after cancer treatment with curative intent) and as a follow-up study adjacent to a randomized controlled trial (incurably ill patients (no curative treatment options)). Eligible patients were 18 years or older and able to communicate in Dutch. Patients were excluded if they had severe cognitive impairments or did not have access to a computer or an e-mail address.

Recruitment of HNC survivors was conducted in the context of routine care and therefore ethical approval was not needed. Survivors were asked to participate in this evaluation study by their head and neck surgeon or nurse at the department of Otolaryngology – Head and Neck Surgery, Amsterdam UMC. When patients were interested, they received an information letter about the study and gave their written consent to get contacted by the research team. Subsequently, patients were contacted to schedule the interview. All HNC survivors who participated in the study provided written informed consent at the start of the interview.

Recruitment of incurably ill cancer patients was conducted in the context of an RCT determining the efficacy of Oncokompas[10], and therefore, ethical approval was needed. The study was approved by the Medical Ethical Committee (METc) of Amsterdam UMC, location VUmc (2018.224, A2019.15). Inclusion criteria were being diagnosed with incurable cancer (any cancer type and treatment modality), having a life expectancy of at least three months, and being aware of the incurability of the cancer. Patients were excluded when they were too ill to participate or when participation would be too burdensome. Patients were asked to give their written informed consent for participation in the RCT. Additionally, they were asked to give their consent to be approached for this qualitative follow-up study. Patients who gave their permission to get contacted for the follow-up study received an information letter with an invitation for the interview (per e-mail of per post). When patients were interested to participate, they were asked to return the reply card or to send an e-mail in response. Then, patients were contacted by the research team to schedule the interview. All incurably ill cancer patients who participated in the study provided written informed consent at the start of the interview.

The application 'Oncokompas'

Oncokompas is a web-based eHealth application supporting cancer survivors and patients to self-manage their cancer-generic and tumor-specific symptoms. Oncokompas consists of three steps: Measure, Learn, and Act. Within the first step 'Measure', users are asked to complete patient-reported outcome measures (PROMs) on different topics related to their HRQOL. These PROMs target physical, psychological and social functioning, and existential issues. Users can select which topics they want to monitor in Oncokompas. Answers on PROMs are processed real-time and linked to information and feedback in the step 'Learn', which provides an overview of users' well-being on topic level using a traffic-light system. Green scores mean that users are doing well on topics. Orange scores mean that topics *could use* attention and support. Red scores mean that topics *need* attention and support. Subsequently, Oncokompas provides tailored information and advice, such as tips and tools to deal with symptoms. In the step 'Act', users receive a personalized overview of supportive care options in their neighborhood. When users have orange scores on topics, the overview includes options for self-help interventions. When users have red scores on topics, feedback always includes the advice to contact their (specialized) healthcare professionals[15].

Interview and procedure

From July 2019 till July 2020, 22 semi-structured interviews were performed by two interviewers (VvZ [cancer survivors] and AS [incurably ill cancer patients]), both trained in qualitative research methods. The interviews were scheduled at patients' preferred location; home (n = 11), the outpatient clinic (n = 1), or by phone due to safety measures during the COVID-19 pandemic (n = 9). One participant with speech impairments gave written response to the interview questions. Interviews lasted 39 to 94 minutes (median 66 min).

The interview scheme comprised two main topics with related questions (Table 1), derived from Oncokompas implementation and development experiences of the research team, and the literature. Interviews were recorded digitally and transcribed verbatim. Due to practical reasons, participants did not receive the transcripts for comments or corrections.

Table 1. Interview topics

Topics	Themes
Self-management strategies	– How do you cope with cancer-related symptoms in your daily life?
Experiences using Oncokompas	When patients used Oncokompas: – Why did you use Oncokompas? – How did Oncokompas help you to deal with symptoms? – What actions did you undertake after using Oncokompas? When patients did not use Oncokompas: – Why did you not use Oncokompas?

Data analysis

The software program Atlas.ti (version 8) was used to analyze the transcripts, using reflexive thematic analysis[16,17]. Data analysis ran parallel to data collection. Two coders (AS and VvZ) read the transcripts to get familiar with the data and then analyzed the data individually. Descriptive citations within the transcripts were coded into themes and more refined subthemes derived from the data. Each interview was coded individually, after which the findings were discussed in consensus meetings. In these meetings, the coders discussed their findings, resolved differences, and created a thematic framework based on the consensus of their individual findings. Doubts during these meetings (e.g., coding certain citations into main themes) were consulted with two independent researchers (IVdL and KH). During analysis, themes and subthemes were constantly reviewed critically to review whether a coherent pattern of themes and subthemes was formed[18]. Furthermore, the coders made notes during the consensus meetings to report on the analysis process.

All extracted quotes used in this paper were translated from Dutch into English. To ensure participants' privacy, information that could lead to persons' identification was removed. The guidelines for consolidated criteria for reporting qualitative research (COREQ) were followed to report about the study design, procedures, analysis, and findings[19].

RESULTS

Study population

In total, 71 patients were invited (23 HNC survivors and 48 incurably ill patients) of which 22 patients agreed to be interviewed (10 survivors (43%) and 12 patients (25%); Figure 1). We aimed to get comparable group sizes and had to invite more incurably ill patient to realize this. After 22 interviews no additional valuable information was obtained, and data saturation had been reached (i.e., carefully weighing the adequacy of the data for addressing the research questions, based on all data gathered in both patient groups[20]). Participant characteristics are shown in Table 2.

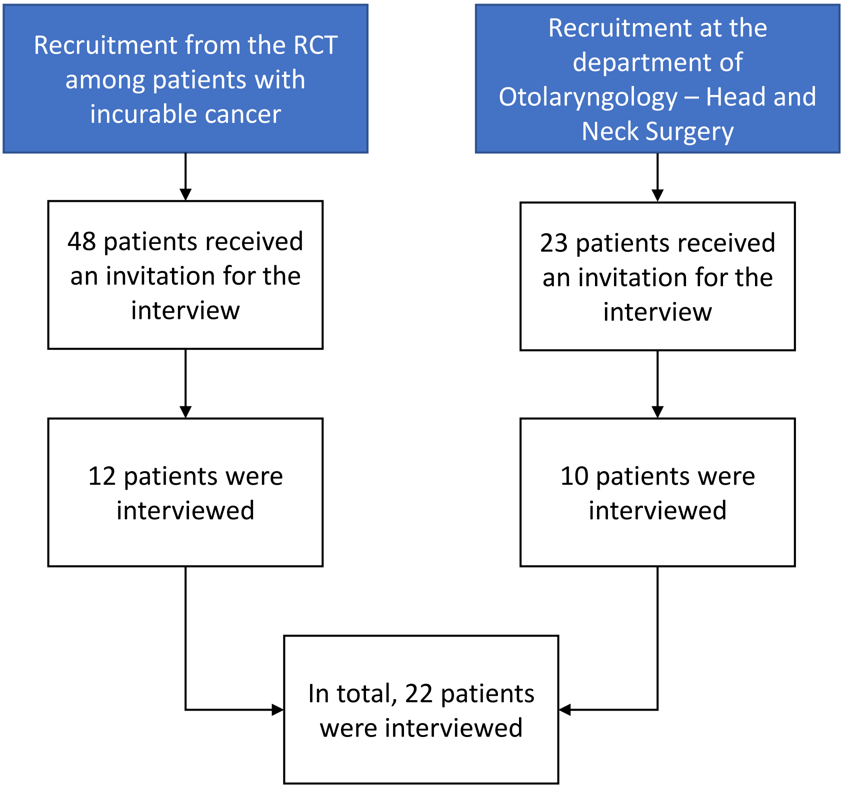


Figure 1. Flow diagram of the study

Table 2. Participant characteristics (n = 22)

	Total n (%)	HNC survivors n (%)	Incurably ill patients n (%)
Sex			
Male	14 (64)	7 (70)	7 (58)
Female	8 (36)	3 (30)	5 (42)
Age at interview (in years)			
Mean (SD)	65.5 (10.2)	64.2 (11.8)	66.6 (8.8)
Minimum	38	38	49
Maximum	81	81	78
Marital status			
Single / divorced	4 (18)	2 (20)	2 (17)
Having a relationship/Living together	2 (9)	1 (10)	1 (8)
Married	15 (68)	6 (60)	9 (75)
Widow(er)	1 (5)	1 (10)	-
Highest level of education completed			
Low	9 (41)	4 (40)	5 (42)
Middle	5 (23)	2 (20)	3 (25)
High	7 (32)	3 (30)	4 (33)
Unknown	1 (5)	1 (10)	-
Current employment			
Paid job	5 (23)	2 (20)	3 (25)
No paid job / Unemployed / Incapacitated	5 (23)	3 (30)	2 (17)
Retired	12 (55)	5 (50)	7 (58)
Type of cancer			
Breast cancer	3 (14)	-	3 (25)
Lung cancer	2 (9)	-	2 (17)
Gastrointestinal cancer	3 (14)	-	3 (25)
Head and neck cancer	11 (50)	10 (100)	1 (8)
Hematological cancer	2 (9)	-	2 (17)
Brain tumor	1 (5)	-	1 (8)
Time since cancer diagnosis			
1 – 3 years	7 (32)	4 (40)	3 (25)
3 – 5 years	8 (36)	5 (50)	3 (25)
> 5 years	6 (27)	-	6 (50)
Unknown	1 (5)	1 (10)	-

The results of the study related to patients' strategies to cope with cancer in their daily lives and their perspectives on Oncokompas. Patients' perspectives on Oncokompas were divided in different categories: the positive aspects of Oncokompas and experiences relating to the content of the application, its technical and functional aspects, and actual usage of the application.

Self-management strategies

Table 3 provides an overview of strategies to cope with cancer in daily life. Self-management strategies described by HNC survivors and incurably ill patients were quite similar. Participants mentioned that self-managing their disease means being able to take care of themselves, not being dependent of others. It means knowing when to ask for help (e.g., from the healthcare provider). They specified that it means to *stay in control of your life*; being able to take care of yourself and being in control. For example, by making a plan for the future, taking care of things that need to be arranged. Some participants made adjustments to their daily lives, such as trying to maintain a daily rhythm, choosing friends more consciously and making adjustments to their living environment (e.g., to make it easier to live at home).

> *"I think it's about making a plan for yourself. [...] Regarding my disease, I made a living will. [...] I also talked to my partner about some things, how I want things to be later on." (P16)*

Many participants – both survivors and incurably ill patients – described that their health behaviors changed after or during their disease. They mentioned being more aware to adopt a healthy life style, (e.g., by having more exercise), paying attention to nutrition and limiting or quitting alcohol consumption and smoking.

> *"You can ensure that your life remains your life as much as possible. That is very important, because often when people get sick they no longer look for solutions. That is understandable, because you have to process many things. Well, after this you try to pick up your life and keep your body in shape, and not just sit and watch the world go by, waiting until it's your time. Because then it will be over in no time." (P20)*

Participants endorsed the importance to *take certain responsibility for their own well-being*; listen to your body, seek help when necessary and remain critical to what their healthcare provider tells. Some participants indicated that they wanted to deal with symptoms on their own first, with additional help if necessary.

Participants endorsed the importance to *stay optimistic*, trying to make the best of the situation. Mainly incurably ill participants mentioned that it is not helpful to feel sorry for yourself, to look forward rather than backward, try to enjoy life and do the things they want to do, and focus on what is still possible rather than what is no longer possible.

Table 3. Participants' self-management strategies to cope with cancer-related symptoms

Themes	Subthemes	Example of a subtheme quotation
Staying in control	– Being able to take care of yourself – Being in control: • Making a plan for the future, arrange things for later • Paying attention to a healthy life style ° Have enough exercise ° Pay attention to diet ° Moderate smoking and alcohol use • Adjustments to daily life ° Adjustments in living environment (house and car) ° Choose consciously with whom you want to stay in contact with – Maintain a daily rhythm	*"It [self-management] means being in control. That I take action when I feel something is wrong. [...] As so many things in life, I'd like to be in control about that [being informed about the disease]. It's not always possible. You are dependent of the doctor's schedule to a certain degree, but I understand that. That's okay. I'm not the director myself, but I'm the assistant director."* (P3)
Taking responsibility	– Listening to your body and its signals – Dealing with symptoms on your own when possible, seek help otherwise – Always continue thinking for yourself	*"In the end I'm the one making the decision about what I eat and which medication I take. So, I think that I have the ultimate responsibility [about my health]"* (P7)
Staying optimistic	– Not feeling sorry for yourself – Trying to make the best of the situation: • Enjoying life and do the things you want to do • Looking at what is still possible instead of what is no longer possible • Looking forward rather than backward	*"My optimism is an instrument to fight the situation. Every day I want to be happy with everything that's surrounding me. Because of the cancer I am much more aware of that, which is also an instrument to feel stronger" (P7)*
Seeking distraction	– Keeping yourself busy and do not think about being ill too much	*"For me, that [seeking distraction] is very important. [...] I've picked up an old stamp collection again, that's a mess now. Well yeah, I'm looking for a purpose and distraction – when it's not possible with others, you also have to keep yourself busy."* (P13)
Acknowledging your symptoms and finding acceptance	– Accepting that the disease has become part of your life – Accepting that you cannot control everything – Adjusting your goals; make less strict demands on yourself – Not being shy to speak about your illness and its limitations to others	*"I dare to speak up for everything – when I'm talking with other people – I do not care what they say. I tell them about my limitations, so that they know about it."* (P1)
Seeking reassurance	– Needing confirmation not to worry from people around you	*"There are so many things that can scare you, because you simply do not know. I need someone who says 'you do not have to worry'. It is normal or it will pass by, or you have to learn how to deal with it in life."* (P9)

> *"Since my health deteriorated last year I said to myself; I just want to do positive things. Anything negative is wasted time. You get angry sometimes, then I take a breath and look at it positively again. I do not want to waste time to negativity anymore. So when things are negative, I take a breath, and then I go on with other, happy things." (P21)*

Participants specified that it helps to *seek distraction*; keep yourself busy and think about the disease as little as possible. It also helped them to *acknowledge their symptoms* and to *find acceptance*; for example, accept that you cannot control everything. Incurably ill patients mentioned their acceptance that cancer is part of their life. Furthermore, participants adjusted their goals and made less strict demands to themselves. Telling people about your disease and limitations and *seeking reassurance* (e.g., needing confirmation from people every now and then not to worry about things) were also mentioned.

> *"There are so many things that can scare you, because you simply don't know. I need someone who says 'you do not have to worry'. It is normal or it will pass by, or you have to learn how to deal with it in life." (P9)*

Participants' perspectives on Oncokompas

Positive aspects of Oncokompas

Many participants mentioned the added value of Oncokompas (Table 4). There were no major differences in experiences between survivors and incurably ill patients. Oncokompas enabled participants to *self-manage their symptoms*. The given advice can be applied immediately and without help of a healthcare provider. Furthermore, Oncokompas allows participants to monitor their symptoms, enables them to compare their well-being over time and helps prioritizing symptoms, based on the traffic light system. Red scores on topics could be a stimulant to take action. It was appreciated when the color system matched a participant's own feelings regarding specific symptoms.

The added value of Oncokompas being *a personal online library* was described, offering a fast and simple way to obtain information and advice, which participants could turn back to 24/7. It was appreciated that Oncokompas covers many topics profoundly and provides an overview of supportive care options. Additionally, the information in Oncokompas on the psychological impact of cancer was appreciated.

"What I really appreciated was that the psychological impact of being ill is discussed extensively [within Oncokompas]. When you talk with the physician in the hospital, that's about the medical -, the physical things. Also, some basic questions when you come in,

like ‘how are you?’. But then it stops. [...] For me that’s more important [the psychological impact] than the physical side of being ill.” (P15)

Participants positively valued being able to print their results in Oncokompas to *discuss their results with their healthcare provider*. Also, the *reliability* of Oncokompas and its *accessibility* were described as valuable. The application is evidence-based and it is pleasant being able to use Oncokompas at home.

> *“I think that it is easier for people to find information established by research among cancer patients themselves. You can find a lot of information on the Internet about what can happen to you, and so many websites tell you different things. So, I think that this [Oncokompas] is very nice to have.” (P20)*

Furthermore, the application being available on your tablet – besides availability on a computer – was appreciated.

The majority mentioned that they would *recommend Oncokompas to fellow patients*. However, participants indicated that it would depend on the specific person. They would recommend Oncokompas, because it could provide solutions that you do not think about yourself immediately, and that it could be especially useful for patients who are less assertive.

> *“Those tips, maybe there are some things that – maybe not when all topics scored green, but if a topic is orange or red, than you can get some nice suggestions [from Oncokompas] that you would not think of yourself.” (P5)*

In addition, it was mentioned that Oncokompas could help patients to reflect on their situation and to take care of symptoms by themselves.

Table 4. Positive aspects of Oncokompas according to participants

Themes	Subthemes	Example of a subtheme quotation
Enabling patients to self-manage	– Advice can be applied immediately (without the support of a healthcare provider) – Compare your well-being over time – Determine priority to manage symptoms based on color-based overview and take action based on orange and red scores – Scores on topics could confirm your own feelings	*"The red scores [on a topic in Oncokompas] – then apparently you suffer from it [the symptoms] and it needs attention. Then I have a look [at the information and advice] and think 'Do I recognize this? What do I do with it? Can I do something about it on my own, or do I need help?' And with the orange scores I just have a look 'What's going on here? And how can I prevent that it [the topic] turns from an orange score into a red score? How do I get it back into green?' That I don't suffer from it anymore."* (P15)
Personal library / resources	– Overview of supportive care options – Attention for the psychological impact of cancer – Possible to get back to the advice in Oncokompas – Fast and simple way to obtain information – Many topics are covered profoundly within Oncokompas	*"[I've learned] that there are many options to get support. And now you know exactly – well, that it is advised to get support or not. Or that the advice is to talk about certain things with people in your environment, that helped me."* (P16)
Discuss symptoms with healthcare provider	– Results can be printed to discuss them with healthcare provider	*"For example, I can print my results. If I can take my results to my general practitioner or whoever, so I can say 'Well, look at this, this is the advice I got [from Oncokompas]. I think that's useful."* (P9)
Reliability	– Evidence-based – Professional lay-out	*"I think that it is easier for people to find information established by research among cancer patients themselves. You can find a lot of information on the Internet about what can happen to you, and so many websites tell you different things. So, I think that this [Oncokompas] is very nice to have."* (P20)
Accessibility	– Availability at home and use Oncokompas at your own pace – Availability on your tablet (besides computer)	*"I thought that it was pleasant to just use it [Oncokompas] by myself, at home."* (P16)
Why recommend Oncokompas to other patients?	– Oncokompas could provide solutions that you do not think about yourself – Oncokompas can be useful for people who are less assertive – Important to analyze yourself and Oncokompas could support this – Specific recommendation to others depends on individual person	*"I think – for people who are not able to – or who do not want to – for whatever reason – search for information by themselves and to be empowered... – because that is necessary when you are in the hospital, to be assertive. I think that this [Oncokompas] can be very useful for those people."* (P3)

Experiences relating to Oncokompas' content, its technical aspects and functional aspects, and actual usage

An overview of patients' experiences with Oncokompas is provided in Table 5. The themes and some underlying subthemes are discussed below. Regarding Oncokompas' content, several downsides were mentioned. Some participants thought the content *was confronting* or *content felt not applicable*. For example, advice could feel judgmental or 'too intense', or the provided information and advice were already known.

> *"You get these supportive care options and in some cases I thought; this is too extreme or too generic. Or I got the advice to contact my GP, well... I thought of that myself already. That's of no use. [...] For me it was too generic." (P9)*

It was mentioned that *certain content in Oncokompas was missing*, such as advice on specific symptoms. Additionally, participants indicated that some content was *difficult to understand*. For example, the complexity of the PROMs to monitor their symptoms. Furthermore, it could be difficult to interpret to which healthcare provider Oncokompas refers:

> *"Then Oncokompas tells me, 'Please contact your healthcare provider'. Well... who is that healthcare provider? I have like three, four physicians..." (P9)*

Regarding technical aspects of Oncokompas, participants mentioned the *structure of the application was not optimal*; for example, flexibility lacks within the application. Several other technical aspects related to the *accessibility of Oncokompas*. It would be appreciated having the possibility to get access to Oncokompas on mobile phones. Furthermore, participants *preferred to set settings in Oncokompas their selves*. For example, how often you want to receive reminders for Oncokompas.

Several functional aspects were mentioned by the participants, related to *user instructions*, *time investment* and *peer-to-peer contact*. Regarding the use of Oncokompas, participants mentioned that it would be helpful to add additional instructions on how to use Oncokompas. Concerning time investment, participants mentioned that filling in questions within Oncokompas is too time-consuming. It would be useful to indicate how much time it takes to complete a topic in the application at the beginning. *Reminders and updates* can motivate to use Oncokompas periodically and notify patients that new content is available in Oncokompas. To facilitate peer-to-peer contact, it was mentioned that it would be helpful to add a functionality making it possible to exchange tips with peers.

Participants also described their *motivation to use Oncokompas* or their *reasons for non-use*. Concentration problems, a busy daily schedule, or having problems with the Oncokompas registration (because of technical problems or because the invitation e-mail ended up in the spam folder) were reasons for not using Oncokompas. Others, who used Oncokompas at least once, indicated that it was hard to get motivated and to follow-up the advice provided in Oncokompas in their daily life (e.g., advice about exercising). Experiencing high symptom burden could stimulate using Oncokompas, compared to experiencing no or few symptoms. Also mentioned was to get more motivated to use the application, when the healthcare provider would have access to the results within Oncokompas.

Participants' expectations regarding future use of Oncokompas varied. Mainly incurably ill patients indicated that it would depend on their disease progression how often they would use Oncokompas in the future. Survivors' expectations varied from using it once per month, or once per quarter, to expecting no further use at all due to having a stable health status.

Participants' opinion about the best moment to provide access to Oncokompas varied. Participants wished they had access to Oncokompas at an earlier timepoint (now they got access months after their treatment or after years of being ill): advices and supportive care options were often already known. Some thought it would be best to get access to Oncokompas at diagnosis. Then people often have many questions and insecurities. Others stated that it would be "too much" when Oncokompas would be offered directly at diagnosis. Some preferred to get access to Oncokompas during treatment, because this would enable them to monitor side-effects of treatment. However, participants mentioned that after treatment they had time to think about all their experiences and be more at ease, which could be helpful for using the application. It was also suggested to offer access to Oncokompas repeatedly during the cancer trajectory. For example, when impactful events happen (e.g., hospital admissions).

Table 5. Experiences during usage of Oncokompas and recommendations for further improvements

Themes		**Subthemes**	**Example of a subtheme quotation**
Content	… is confronting	– Advice feels ‘too intense’ – Advice feels judgmental – Confronting when topics need attention or support (i.e., having orange or red scores on topics) – Confronting to read about having children, when you are not able to become pregnant/have children	*“For example, with the topic ‘Activities of daily living’. I am less fit and then I got the advice to get a personalized rehabilitation plan. Then I just thought like ‘Well, that’s solution is just too ‘heavy’ for my problems. Because I just think ‘I’m less fit, but that applies for many people. I just have to exercise and walk more than I do now, but a personalized rehabilitation plan… […]’ That’s no tailored advice.”* (P9)
	… feels not applicable	– Information and advice within Oncokompas are already known – Referral to healthcare providers is unnecessary, when patient is already treated by that specific healthcare professional – Advice does not match with patients’ preferences – Advice is not specific enough (tailoring)	*“– that topic is about fatigue. Well, then you can read all about that and about what you can do. That you have to exercise more. Well yeah…I know all those things. And my physiotherapist also tells me that. […] To be honest, it does not get me anywhere.”* (P22)
	… is missing	– Missing information and advice about specific symptoms – Topic ‘Sexuality’ in Oncokompas is not sufficient	*“An orange score – your social life [the topic]. It is only about loneliness. Well, I am not lonely. People who have cancer may feel lonely. […] For me it’s too limited. Your social life, when you have always been a member of a sport club and you cannot walk anymore because your leg has been amputated because of cancer, that’s something different than being lonely, right? I think that [the information and advice] is too limited.”* (P3)
	… is difficult to understand	– Referral to healthcare provider is too generic; not clear which healthcare professional is meant – Complexity of PROMs: • Some questions can be interpreted in different ways • Some questions are difficult to answer because some days you feel different than other days	*“Then Oncokompas tells me, ‘Please contact your healthcare provider’. Well… who is that healthcare provider? I have like three, four physicians…”* (P9)

Technical aspects	Structure of the application	Flexibility lacks within the application: – It is not possible to return to the overview with topics (when topics have been chosen) – It is not possible to remove topics after they have been chosen in the topics-overview	*"And then you cannot go back to the overview of all the topics [within Oncokompas]. I tried, but it is not possible. […] And when you start the questions, you cannot go back. But you should be able to go back."* (P2)
	Accessibility	– Facilitate compatibility of the application on your mobile phone – Annoying when you are not able to log in to the application (e.g., when you forgot your password) – It could be a barrier to create an account with a password	*"I was thinking – it should be available for everyone. […] When you first have to create an account – that's the downside – and of course I lost my password… It is accessible, because of course you can create an account. But for me it is a barrier. […] When you just want to have a quick look, you have to create an account."* (P9)

	Preferred settings	– Prefer to set settings yourself, for example:
		  • How often you want to receive a reminder for Oncokompas
		  • Whether or not the page jumps to the next question when answering questions
			"That depends on the stage of the disease you're in [wanting to receive reminders to fill in Oncokompas]. Basically, you're getting better over time. However, not with every type of cancer, but often people get better. So, I think then there is less need. […] I would say, a little more often in the initial phase of the disease." (P3)

Functional aspects	User instructions	Within the application: – Add additional instructions about the possibility to fill in Oncokompas multiple times – Add additional instructions about the possibility to choose (multiple) topics in Oncokompas – It is not clear that Oncokompas remembers your given answers, so that you can fill in Oncokompas at a later moment, right where you left off – The question if you are sure you want to fill in all topics within Oncokompas has to be displayed more prominently Concerning the application: – Not completely clear what Oncokompas is before first use	*"Because initially, I received [the invitation for] Oncokompas by mail, right? For me it was a bit unclear what I could do with it [Oncokompas] exactly. Then I just started to use it anyway."* (P2)
	Time investment	It takes too much time to fill in the PROMs – Add an indication how much time it takes to complete topics – A functionality was missed which gives an indication of the progression regarding completion	*"And just add information on how much time it takes to address that specific topic. That you say something like – normally it takes four minutes, or ten minutes or whatever. So that someone can say 'I'll do that topic next time'."* (P2)

	Peer-to-peer contact	– Add a functionality which makes it possible to exchange tips with peers	*"For example, a small forum – [...] that [tips from other people with cancer] would be nice."* (P6)
	Reminders and updates	– Useful to receive reminders to use Oncokompas periodically – Notify users when new content is available	*"At one point I was using it [Oncokompas] and when I got tired, I thought 'I'll let it rest for a while'. And then I was busy again with 1001 other things and you have to be reminded to use it [Oncokompas] again. [...] It would be useful then [to get a reminder]."* (P7)
Usage	Motivation	– It can be hard to find intrinsic motivation to get started with advice given in Oncokompas – When healthcare provider could see the results within Oncokompas, this would motivate to fill in Oncokompas more seriously – It is more likely that people use Oncokompas when they experience symptoms in their daily life – Curiosity about the advices within Oncokompas could motivate use – Using Oncokompas on recommendation of the healthcare provider	*"When my situation changes and it gets worse – well, I see it [Oncokompas] as a reference book, where I can find information about this and that, about what I can do myself. Or where I can find help. [...] When it's not necessary I think it's nonsense to use it [Oncokompas]. You know, like when I am talking to you on the phone right know – I just feel good. I don't feel the urge to read information [in Oncokompas] about what could happen to me, so to speak."* (P22)
	Reasons for non-use	– Registration was not possible due to technical problems – Not owning a computer – Invitation mail to register for Oncokompas ended up in the spam box – Hard to use a laptop due to concentration problems – Being busy with other things; using Oncokompas had no priority	*"I am sure that it [Oncokompas] will support me in the future, but at the moment it's so busy – and it takes a lot of energy to sit behind a laptop. So that's why it has not happened yet [using Oncokompas]."* (P20)

DISCUSSION

This study provided insight in self-management strategies of survivors and incurably ill patients to cope with cancer and their experiences with the fully automated BIT Oncokompas.

In line with earlier studies[21–26], participants' strategies to cope with cancer varied: taking care of oneself, changing health behaviors and adopting a healthy life style. In addition, participants noted the importance to acknowledge their symptoms and find acceptance. Self-management strategies related to both problem-focused coping (i.e., removing, evading, or diminishing (impact of) stressful situations) and emotion-focused coping (i.e., minimizing emotional distress)[27]. The objectives of self-management applications as Oncokompas correspond well with survivors' and patients' views on how they deal with cancer: these applications enable them to be in charge of their life as long as possible, providing automated information (24/7) on how to take actions to meet their supportive care needs, and encourage them to take a certain responsibility for their own well-being.

Within current healthcare system, it is increasingly acknowledged that not only healthcare professionals are experts regarding patients' diseases; also patients themselves are experts, with most knowledge about their illness experience and their strategies to deal with cancer[28]. Howell et al. (2021) recommended several actions to provide self-management support in routine care[24]. Actively involving patients in their own care and engaging them in self-management at the earliest moment possible, stimulating and guiding them to apply self-management strategies to cope with acute and chronic problems, could maximize the benefits of self-management interventions and stimulate patients to be more engaged in the self-management of their own well-being – with knowledge, skills and confidence to self-manage their illness[24]. Identifying patients' self-management strategies and explaining how interventions such as Oncokompas could contribute to these strategies may increase adoption among patients. Furthermore, techniques like motivational interviewing – creating a constructive conversation about behavior change[29] – and offering self-management support[30] might help patients to get motivated to use BITs in their daily life.

Regarding participants' experiences with Oncokompas, some described Oncokompas' added value on their self-management strategies, while others mentioned that using Oncokompas had no additional value. Our results are in line with previous studies, investigating the feasibility of Oncokompas[15,31]. For example, the usefulness of Oncokompas in general by providing useful information and advice[15,31]. In contrast to previous studies which mentioned that feasibility was positively affected by the user-friendliness of Oncokompas, the present study shows the potential to refine the structure of Oncokompas on its technical level to optimize Oncokompas' ease of use and anticipating on reasons for non-use such as concentration problems or a lack of time. Improving user-friendliness of Oncokompas could stimulate patients to use the application more frequently and thereby positively affect patient activation levels.

This study emphasizes the importance to continuously evaluate interventions in collaboration with end-users, as is stressed by Catwell and Sheikh (2009)[32]. For example, participants specified that information within Oncokompas did not match with their preferences or their personal situation, corresponding to the results of the RCT among cancer survivors[14]. This indicates that further tailoring could improve Oncokompas.

Participants also gave recommendations for further development of Oncokompas regarding its content, and functional and technical aspects. Some of these – for example further tailoring of Oncokompas and adding additional instructions on how to use Oncokompas – may also stimulate patients to use Oncokompas who otherwise would not use the application, for example due to concentration problems or a lack of time, because it could decrease the time patients have to invest to use Oncokompas.

Patients' strategies to cope with cancer vary per individual and can change over time[33]. This suggests that there is no 'perfect' moment to provide patients access to self-management applications such as Oncokompas, which corresponds to our findings that the preferred moment to get access to Oncokompas varied. However, understanding the diversity of patients' preferences regarding access to self-management applications is essential when offering patient-centered care, tailored to the individual. Based on the current evidence, it is recommended to offer patients access to self-management applications at different time points in the cancer trajectory. Using a tailored approach when offering interventions to end-users might be helpful to stimulate patients to use BITs like Oncokompas and increase its benefits.

A strength of this study is that both cancer survivors and incurably ill patients participated. We did not find important differences between these two study populations. However, HNC survivors are a specific patient group, due to their tumor location. The results of the randomized controlled trial among cancer survivors showed most effects of Oncokompas on HRQOL and symptom burden in HNC survivors[11], which might be explained by the large variety of symptoms compared to survivors of other cancer types. This may affect the generalizability of this study among patients with other cancer types.

Another limitation of this study is the elapsed time since the (non)use of Oncokompas, which varied among participants (two weeks to 2,5 months) due to the recruitment procedure of both patient groups. For participants who used Oncokompas more recently, it may have been easier to recall their experiences. In addition, patients' experiences are specific for Oncokompas; it might be difficult to generalize the results to other web-based applications. Furthermore, it is possible that participation bias occurred because patients who experience severe symptom burden or who experience more distress in their daily life, might be less open to study participation which could affect the representativeness of the results. Also, a convenience sampling method was used for data collection, negatively affecting generalizability of the study[34]. Lastly, no background information is available about non-responders and their reasons for non-participation.

In conclusion, cancer survivors and incurably ill cancer patients use various self-management strategies to cope with the impact of cancer in daily life. Objectives of fully automated behavioral intervention technologies as Oncokompas correspond well with these strategies: taking a certain responsibility for their own well-being, and being in charge of their life as long as possible by obtaining automated information (24/7) on symptoms and tailored supportive care options.

REFERENCES

1. Haberlin C, O'Dwyer T, Mockler D, Moran J, O'Donnell DM, Broderick J. The use of eHealth to promote physical activity in cancer survivors: a systematic review. Supportive Care Cancer. 2018;26(10):3323–3336.
2. Seiler A, Klaas V, Tröster G, Fagundes CP. eHealth and mHealth interventions in the treatment of fatigued cancer survivors: A systematic review and meta-analysis. Psychooncology. 2017;26(9):1239–1253.
3. Triberti S, Savioni L, Sebri V, Pravettoni G. eHealth for improving quality of life in breast cancer patients: A systematic review. Cancer Treat Rev. 2019;74:1–14.
4. Slev VN, Mistiaen P, Pasman HRW, Leeuw IMV de, Uden-Kraan CF va., Francke AL. Effects of eHealth for patients and informal caregivers confronted with cancer: A meta-review. International Journal of Medical Informatics. 2016. 87: 54–67.
5. Howell D, Harth T, Brown J, Bennett C, Boyko S. Self-management education interventions for patients with cancer: a systematic review. Supportive Care Cancer. 2017;25(4):1323–1355.
6. Cuthbert CA, Farragher JF, Hemmelgarn BR, Ding Q, McKinnon GP, Cheung WY. Self-management interventions for cancer survivors: A systematic review and evaluation of intervention content and theories. Psychooncology. 2019;28(11):2119–2140.
7. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: A review. Patient Educ Couns. 2002;48(2):177–87.
8. van Gemert-Pijnen JEWC, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res. 2011;13(4):e111.
9. van der Hout A, van Uden-Kraan CF, Witte BI, Coupé VMH, Jansen F, Leemans CR, et al. Efficacy, cost-utility and reach of an eHealth self-management application "Oncokompas" that helps cancer survivors to obtain optimal supportive care: Study protocol for a randomised controlled trial. Trials. 2017;18(1):228.
10. Schuit AS, Holtmaat K, Hooghiemstra N, Jansen F, Lissenberg-Witte BI, Coupé VMH, et al. Efficacy and cost-utility of the eHealth application "Oncokompas", supporting patients with incurable cancer in finding optimal palliative care, tailored to their quality of life and personal preferences: A study protocol of a randomized controlled trial. BMC Palliat Care. 2019;18(1):1–11.
11. van der Hout A, van Uden-Kraan CF, Holtmaat K, Jansen F, Lissenberg-Witte BI, Nieuwenhuijzen GAP, et al. Role of eHealth application Oncokompas in supporting self-management of symptoms and health-related quality of life in cancer survivors: a randomised, controlled trial. Lancet Oncol. 2020;21(1):80–94.
12. Pearlin L, Schooler C. The Structure of Coping. J Health Soc Behav. 1978;19(1):2–21.
13. van der Hout A, Holtmaat K, Jansen F, Lissenberg-Witte BI, van Uden-Kraan CF, Nieuwenhuijzen GAP, et al. The eHealth self-management application 'Oncokompas' that supports cancer survivors to improve health-related quality of life and reduce symptoms: which groups benefit most? Acta Oncol (Madr). 2021; 60(4); 403-411.
14. van der Hout A, van Uden-Kraan C, Holtmaat K, Jansen F, Lissenberg-Witte B, Nieuwenhuijzen G, et al. Reasons for not reaching or using web-based self-management applications , and the use and evaluation of Oncokompas among cancer survivors. Internet Interventions2021; 100429.
15. Duman-Lubberding S, van Uden-Kraan CF, Jansen F, Witte BI, van der Velden LA, Lacko M, et al. Feasibility of an eHealth application "OncoKompas" to improve personalized survivorship cancer care. Supportive Care Cancer. 2016;24(5):2163–2171.
16. Braun V, Clarke V. Thematic analysis. APA Handb Res methods Psychol Vol 2 Res Des Quant Qual Neuropsychol Biol. 2012;2:57–71.
17. Braun V, Clarke V. One size fits all? What counts as quality practice in (reflexive) thematic analysis? Qual Res Psychol. 2020:1–25.

18. Nowell LS, Norris JM, White DE, Moules NJ. Thematic Analysis: Striving to Meet the Trustworthiness Criteria. Int J Qual Methods. 2017;16(1):1–13.

19. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. Int J Qual Heal Care. 2007;19(6):349–357.

20. Braun V, Clarke V. To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales. Qual Res Sport Exerc Heal. 2021;13(2):201–216.

21. Heijmans M, Waverijn G, Van Houtum L. Zelfmanagement, wat betekent het voor de patiënt? NIVEL. 2014.

22. Dunne S, Mooney O, Coffey L, Sharp L, Timmons A, Desmond D, et al. Self-management strategies used by head and neck cancer survivors following completion of primary treatment: A directed content analysis. Psychooncology. 2017;26(12):2194–2200.

23. van Dongen SI, de Nooijer K, Cramm JM, Francke AL, Oldenmenger WH, Korfage IJ, et al. Self-management of patients with advanced cancer: A systematic review of experiences and attitudes. Palliat Med. 2020;34(2):160–178.

24. Howell D, Mayer DK, Fielding R, Eicher M, Verdonck-de Leeuw IM, Johansen C, et al. Management of Cancer and Health After the Clinic Visit: A Call to Action for Self-Management in Cancer Care. JNCI J Natl Cancer Inst. 2021;113(5): 523-531.

25. Budhwani S, Wodchis WP, Zimmermann C, Moineddin R, Howell D. Self-management, self-management support needs and interventions in advanced cancer: A scoping review. BMJ Support Palliat Care. 2019;9(1):12–25.

26. Thomsen TG, Rydahl-Hansen S, Wagner L. A review of potential factors relevant to coping in patients with advanced cancer. J Clin Nurs. 2010;19(23–24):3410–3426.

27. Carroll L. Encyclopedia of Behavioral Medicine. In Gellman MD, Turner JR (editors). Encyclopedia of Behavioral Medicine. Springer. 2013.

28. Karazivan P, Dumez V, Flora L, Pomey MP, Del Grande C, Ghadiri DP, et al. The patient-as-partner approach in health care: A conceptual framework for a necessary transition. Acad Med. 2015;90(4):437–441.

29. Rollnick S, Miller W, Butler C. Motivational interviewing in health care. Helping patients change behavior. New York: The Guilford Press. 2008. 1-224.

30. Slev VN, Pasman HRW, Eeltink CM, Van Uden-Kraan CF, Verdonck-De Leeuw IM, Francke AL. Self-management support and eHealth for patients and informal caregivers confronted with advanced cancer: An online focus group study among nurses. BMC Palliat Care. 2017;16(1):55.

31. Melissant HC, Verdonck-de Leeuw IM, Lissenberg-Witte BI, Konings IR, Cuijpers P, Van Uden-Kraan CF. 'Oncokompas', a web-based self-management application to support patient activation and optimal supportive care: a feasibility study among breast cancer survivors. Acta Oncol . 2018;57(7):924–934.

32. Catwell L, Sheikh A. Evaluating eHealth interventions: The need for continuous systemic evaluation. PLoS Med. 2009;6(8):1–6.

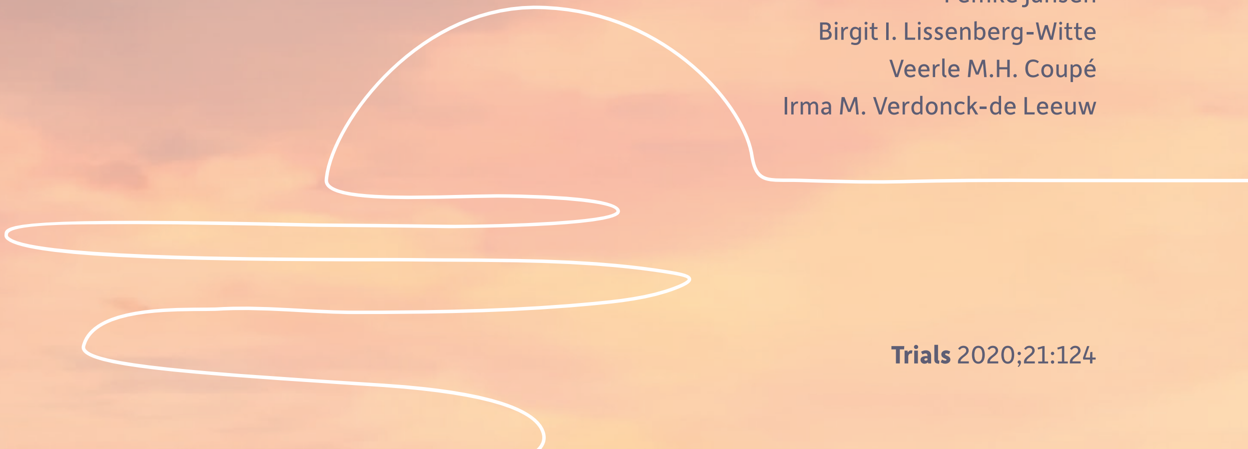
33. Lashbrook MP, Valery PC, Knott V, Kirshbaum MN, Bernardes CM. Coping Strategies used by Breast, Prostate, and Colorectal Cancer Survivors: A Literature Review. Cancer Nurs. 2018;41(5):E23–E39.

34. Etikan I. Comparison of Convenience Sampling and Purposive Sampling. Am J Theor Appl Stat. 2016;5(1):1.

8

EFFICACY AND COST-UTILITY OF THE EHEALTH SELF-MANAGEMENT APPLICATION ‘ONCOKOMPAS’, HELPING PARTNERS OF PATIENTS WITH INCURABLE CANCER TO IDENTIFY THEIR UNMET SUPPORTIVE CARE NEEDS AND TO TAKE ACTIONS TO MEET THEIR NEEDS: A STUDY PROTOCOL OF A RANDOMIZED CONTROLLED TRIAL

Anouk S. Schuit
Karen Holtmaat
Nienke Hooghiemstra
Femke Jansen
Birgit I. Lissenberg-Witte
Veerle M.H. Coupé
Irma M. Verdonck-de Leeuw



Trials 2020;21:124

ABSTRACT

Background: Incurable cancer does not only affect patients, it also affects the lives of their partners. Many partners take on caregiving responsibilities. The burden of these caregiving tasks are often associated with physical, psychological and social difficulties and many partners have unmet supportive care needs. Oncokompas is an eHealth self-management application to support partners in finding and obtaining optimal supportive care, tailored to their quality of life and personal preferences. A randomized controlled trial will be carried out to determine the efficacy and cost-utility of Oncokompas.

Methods: A total of 136 adult partners of patients with incurable cancer will be included. Partners will be randomly assigned to the intervention group, which directly gets access to Oncokompas, or the waiting-list control group, which gets access to Oncokompas after three months. The primary outcome measure is caregiver burden. Secondary outcome measures comprise self-efficacy, health-related quality of life and costs. Measures will be assessed at baseline, two weeks after randomization and three months after the baseline measurement.

Discussion: This study will result in evidence on the efficacy and cost-utility of Oncokompas among partners of patients with incurable cancer, which might lead to implementation of Oncokompas as a health service for partners of patients with incurable cancer.

Trial registration: Netherlands Trial Register identifier: NTR 7636. Registered on 23rd November 2018 (https://www.trialregister.nl/).

Keywords: incurable cancer, caregiving, partners, eHealth, self-management, caregiver burden

BACKGROUND

It is well known that cancer does not only affect patients; the disease also has a considerable impact on the lives of their partners[1,2]. Partners of patients with incurable cancer often help with personal care and provide practical and emotional support to patients[3,4]. It is not uncommon that they perform caregiving tasks they are not trained for (e.g., the management of medication and symptoms). Partners may feel overwhelmed by these tasks. They often also consider their own problems as less important than those of the patient[5,6]. Since cancer increasingly becomes a chronic illness, partners of cancer patients are challenged to be involved in the management of the patient's care and quality of life for an increasing extent of time, while they also have to maintain their own well-being[7].

Although caring for a loved one can be rewarding[8], informal caregiving responsibilities are also associated with physical, psychological and social difficulties[1,4,9–11]. Frequently reported symptoms among caregivers are sleeping problems, fatigue, and psychological distress[12-14]. Many partners have to give up (part of) their normal daily activities due to their caregiving tasks, for example their work or social activities[1,15]. Partners may experience high burden levels related to their responsibilities and the impact of the caregiving on their daily lives[1,5,16]. Caregiver burden is defined as "the extent to which caregivers perceive that caregiving has an adverse effect on their emotional, social, financial, physical, and spiritual functioning"[17]. Studies have shown that these adverse effects negatively influence the quality of life of partners[1,2, 9-14,18-20].

Many partners do not know where to go for advice and guidance or do not have time to seek help [13,21-23]. Therefore, there is a growing interest in self-management interventions and eHealth applications as ways to improve (the early access to) supportive care targeting partners of patients with incurable cancer[7,24,25].

The eHealth self-management application Oncokompas has been developed to support patients and partners of patients with incurable cancer in finding and obtaining optimal supportive care. Oncokompas helps them to monitor their quality of life using patient-reported outcome measures (PROMs), followed by automatically generated tailored feedback, self-care advice, and advice on supportive care services. The content of the version of Oncokompas for partners is focused on self-care of the partner and targets the partner alone instead of the couple (i.e., patient and partner together), for example to inform and advise partners about their shifting roles and responsibilities, their relationship, financial resources, and their work situation. The application is tailored to the partner's health status and personal preferences. There is a dedicated version of Oncokompas available for patients treated with curative intent[26-28] and for patients with incurable cancer[29]. The aim of this randomized controlled trial is to determine the efficacy of Oncokompas as a self-management instrument on caregiver burden, general self-efficacy and health-related quality of life among partners of patients with incurable cancer and to assess its cost-utility.

METHODS/DESIGN

Study design

A prospective randomized controlled trial (RCT) with two parallel groups will be conducted to determine the efficacy and cost-utility of Oncokompas among partners of patients with incurable cancer.

Partners will be randomly assigned to the intervention group or the waiting-list control group. Partners in the intervention group will get direct access to Oncokompas, while partners in the control group will get access to the intervention three months after the baseline measurement (i.e., after completion of the last questionnaire). Partners will receive three questionnaires; at the time of inclusion (t0), two weeks after randomization (t1), and three months after the baseline measurement (t2). Figure 1 shows the flow diagram of the RCT. Figure 2 shows the schedule of enrollment, intervention and assessments (according to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT)).

This study is approved by the VUmc Medical Ethical Committee (registration number 2018.517). All respondents will provide written informed consent before inclusion and will be informed that participation is voluntary. Partners can withdraw from the study at any time without any consequences.

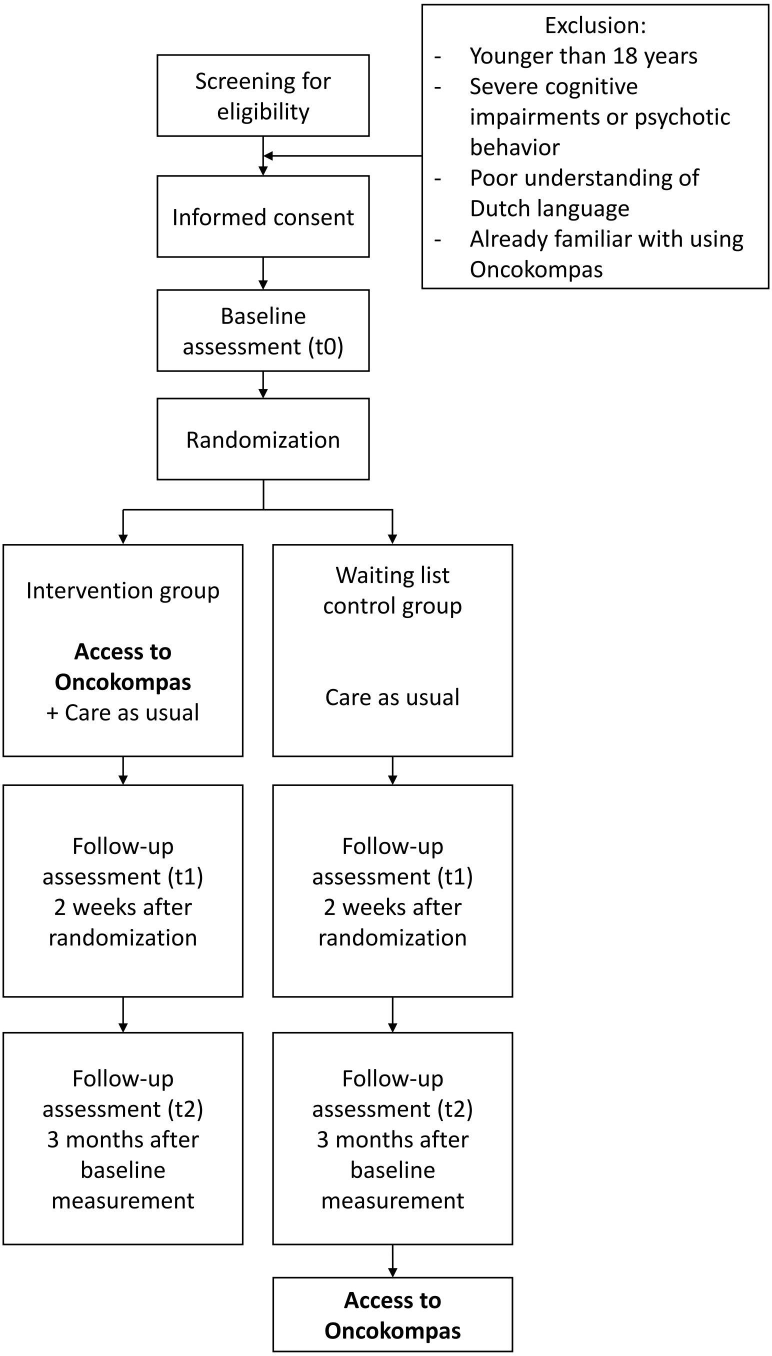


Figure 1. Flow diagram of the RCT

	STUDY PERIOD				
	Enrollment	Allocation	Post-allocation		Close-out
TIMEPOINT	t0		t1	t2	
ENROLLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
Access to Oncokompas (intervention group)		●	—	—	→
Care as usual (intervention and control group)		●	—	—	→
Access to Oncokompas (control group)					●→
ASSESSMENTS:					
Primary outcome measure	X		X	X	
Secondary outcome measures	X		X	X	
Cost-utility measures	X			X	

Figure 2. The schedule of enrollment, intervention and assessments of the RCT (according to SPIRIT)

Study population

Inclusion and exclusion criteria

In this study, partners of patients with incurable cancer will be included. Partners are included when they are aged ≥ 18 years, and have access to an e-mail address. Partners are excluded when they have severe cognitive impairments or psychotic behavior, or when they have a poor understanding of the Dutch language (and thereby are not able to complete a questionnaire in Dutch). They will also be excluded when they already used Oncokompas earlier in life (e.g., if they have had cancer themselves) or when their partner with cancer participates in the Oncokompas RCT which is currently conducted among patients with incurable cancer[29].

Study procedures

In this study, a multi-component recruitment strategy is followed. Partners will be recruited through: 1) (online) recruitment materials, 2) healthcare professionals and 3) direct contact with the researcher. Table 1 gives an overview of the different recruitment strategies used within this study.

Table 1. Overview of the different recruitment strategies

Recruitment strategy	Recruitment channel
Recruitment through (online) recruitment materials	Online: – Online advertising on websites and online newsletters – Social media Printed: – Advertisements in newspapers and magazines – Leaflets and posters in offices of healthcare professionals Recruitment through: – Relevant organizations targeting informal caregivers or relatives of (cancer) patients – Cancer patient organizations – Walk-in consultation services – Hospitals – Psycho-oncological care centers
Recruitment through a healthcare professional	– Healthcare professionals (e.g., psychologists, rehabilitation centers, general practitioners, physiotherapists, nurse practitioners)
Recruitment through face-to-face contact with the researcher	– Events targeting partners of patients with incurable cancer

Recruitment through (online) recruitment materials

Several recruitment materials have been developed to recruit partners through online channels. The contact details of the researcher and URL of the website of Oncokompas (www.oncokompas.nl) are mentioned in all recruitment materials. On the Oncokompas website, partners can find more information about Oncokompas and the study, such as how they can apply to participate. When partners are interested to participate in the study, they can fill in an online contact form on the website.

Recruitment through a healthcare professional

Partners eligible to participate will also be approached through healthcare professionals. When a partner is interested to participate in the study, the researcher will contact the partner by phone to further inform him or her about the study.

Recruitment through direct contact with the researcher

Partners will also be informed about the study on events targeting relatives of patients with incurable cancer. If interested, they will receive an information letter about the study.

To summarize, many organizations throughout the Netherlands will be involved in the study by informing and referring partners of patients to the website of Oncokompas (or directly to the research team); all other actions regarding the study are carried out by the research team of the Vrije Universiteit Amsterdam, the Netherlands. Therefore, this study is marked as a monocenter study.

Partners who want to participate

Partners meeting the inclusion and exclusion criteria will receive an information package by post (consisting of an information letter, an informed consent form and a reply envelope). If partners want to participate in the study, they are asked to return the signed informed consent form using the reply envelope. After the coordinating researcher has received the signed informed consent form, this researcher will send partners a link to the online baseline questionnaire by e-mail. After completion of the first questionnaire, partners will be randomized into the intervention group or the control group. Partners randomized in the intervention group will receive an invitation e-mail for Oncokompas to activate their personal account. Partners randomized in the control group will receive an e-mail to activate their account after completion of the last questionnaire (t2).

Randomization

Randomization takes place in a 1:1 ratio. Block randomization will be used to randomly assign partners to the intervention group or the control group. Block size varies between four up to eight. Random allocation software (i.e., Sealed Envelope) is used by a researcher not involved in the study to create the randomization scheme. This researcher also carries out the allocation process during the study and notifies the coordinating researcher of the study of the outcome of the allocation. The coordinating researcher will send partners the invitations to activate their Oncokompas account, which means that blinding of the researcher is not possible. Trial participants themselves are also aware of the outcome of the allocation; they receive an e-mail with the outcome of the allocation after they filled in the first questionnaire.

Neither the outcome assessors, nor data analysts are blinded regarding the outcome of the allocation. The design of the study is open label; therefore, unblinding will not occur. There will be no special criteria for discontinuing or modifying allocated interventions.

Intervention

Oncokompas is an eHealth self-management application that supports people with cancer and their partners to adopt an active role in the management of their own well-being. It supports them in finding and obtaining optimal supportive care, tailored to their own health status, personal characteristics, and preferences. The content of Oncokompas is developed following a stepwise, iterative and participatory approach, actively involving users and other stakeholders in the design process[30]. In the present study, the version of Oncokompas tailored to partners of patients with incurable cancer is used.

Oncokompas consists of three components: 1) Measure, 2) Learn, and 3) Act. After the log-in procedure, a user enters the first component of Oncokompas which starts with a general questionnaire. Based on this general questionnaire, Oncokompas makes a selection of the topics suitable for this particular user (e.g., when someone has no children, the topic about the relationship with children will not be shown). After this, the user can select which topics he or she wants to address in Oncokompas. The topics target different domains of quality of life; physical, psychological and social functioning, and existential issues. An overview of the topics covered in Oncokompas for partners is shown in Table 2. Subsequently, in the first component 'Measure', a user can complete patient-reported outcome measures (PROMs) on the chosen topics. The PROMs were selected based on Dutch practical guidelines and literature searches, in collaboration with a team of healthcare professionals, partners of patients with cancer, and patients with cancer. Algorithms were developed to link the scores on the PROMs to tailored feedback in the 'Learn' component. The algorithms are based on available cut-off scores, Dutch practical guidelines, and/or consensus by teams of experts (i.e., healthcare professionals, partners, and patients).

Then the user enters the 'Learn' component, in which feedback on his or her outcomes is provided, tailored to his or her health status, characteristics and preferences. First, a user gets an overview of his or her overall well-being on topic level. A three-color system is used to express the level of well-being. When a user is doing well on a topic, he or she gets a green score. An orange score means that a user could use attention and support on that topic. A red score indicates that a user may need professional care. Oncokompas also provides feedback on interrelated symptoms (e.g., caregiver burden and fatigue). The 'Learn' component concludes with comprehensive self-care advice, such as tips and tools, tailored to the individual user.

The third step within Oncokompas is the 'Act' component, in which users are provided with personalized supportive care options, tailored to their health status and preferences (e.g., preferences for individual therapy versus group therapy). When a user has a red score on a topic, the feedback always includes the advice to contact a healthcare professional, such as a general practitioner or a specialized healthcare professional (e.g., a psychologist)[26]. When a user has an orange score on a topic, the feedback includes suggestions for self-help interventions.

Oncokompas is meant as an additional form of support for partners of patients with incurable cancer. It is not meant as a replacement of a healthcare professional.

Table 2. Overview of all topics covered in Oncokompas for partners of incurably ill cancer patients

Domain	Topics
Physical	Fatigue Sexuality Sleep problems Shoulder and back pain Changed role of nutrition in the late palliative phase (topic to inform partners)
Psychological	Anxiety (as a result of the patient's cancer) Coping with emotions Depression Nervousness
Social	Caregiver burden Choices concerning the end-of-life of the patient Loneliness Communication with the physician of the patient Social life Relationship with patient Relationship with children Work issues
Existential	Saying farewell

Care as usual

In this study, care as usual is defined as the care provided by any healthcare professional and includes all medical and supportive care that partners of patients with incurable cancer would receive, regardless of their participation in this study.

Outcome assessment

Caregiver burden is the primary outcome measure used to assess the efficacy of Oncokompas among partners of patients with incurable cancer. Secondary outcome measures are general self-efficacy and health-related quality of life. In addition, outcomes on cost-utility will be measured.

Measurements will be collected at baseline (t0), two weeks after randomization (t1), and three months after the baseline measurement (t2). Measurements will be assessed through online questionnaires. An overview of the primary and secondary outcome measures is shown in Table 3.

Table 3. Measurement overview

Aim		Outcome measures	Instrument
Efficacy	Primary outcome measure	Caregiver Burden	Caregiver Strain Index + (CSI+)
	Secondary outcome measures	Self-efficacy	General Self-Efficacy Scale (GSE)
Cost-utility		Health-related quality of life	EuroQol 5 Dimensions (EQ-5D-5L)
		Medical costs	iMTA Medical Consumption Questionnaire (iMCQ)
		Productivity costs	iMTA Productivity Cost Questionnaire (iPCQ)
		Costs of Informal Care	iMTA Valuation of Informal Care Questionnaire (iVICQ)

Primary outcome measure

Caregiver Strain Index +

Caregiver burden is assessed with the Caregiver Strain Index + (CSI+). The CSI+ is an extended version of the Caregiver Strain Index, developed in 1983[31]. The original 13-item CSI measures the burden that informal caregivers experience as a result of caring for their loved ones. In the CSI+ questionnaire, five positive items were added to the original CSI. These positive items fall into two categories; 'coping' factors and 'attitudinal' factors. All items of the CSI+ are completed with 'yes' or 'no' and are equally weighted to calculate a carer's total CSI+ score. Research showed that the internal consistency (Cronbach's alpha) for the 13-item CSI was 0.86[31]. Furthermore, a study testing the feasibility and validity of the CSI+ reported that by including positive aspects of care, resulting in the CSI+, an improved convergent validity of the Caregiver Strain Index is realized[32].

Secondary outcome measures

General Self-Efficacy Scale

The General Self-Efficacy Scale (GSE) is a 10-item questionnaire, assessing how a person deals with difficult situations in his or her life. The items have a 4-point Likert scale, ranging from 1 up to 4 (i.e., not at all true, hardly true, moderately true, and exactly true). The total score ranges from 10 to 40 and is calculated by adding up the scores on the 10 items. A higher score indicates a greater generalized sense of self-efficacy[33]. A study examining the psychometric properties of the GSE showed that the GSE scale is reliable, homogeneous, and unidimensional[34].

Cost-utility evaluation

To evaluate the cost-effectiveness of Oncokompas compared to current care, a cost-utility analysis will be conducted in which the difference in total three-months costs between the two study arms is compared to the difference in quality-adjusted life years (QALYs) based on the EuroQol 5 Dimensions.

Health-related quality of life

The EuroQol 5 Dimensions (EQ-5D-5L) will be used to measure health-related quality of life on five dimensions of health (i.e., mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), presented to the respondent by five items which all have five answer categories (i.e., no problems, some problems, moderate problems, severe problems, and extreme problems/unable to). As a result, the EQ-5D-5L can describe 3125 unique health states. After completion of the questionnaire, the profile of answers can be transformed to a value given by the general public using the Dutch index tariff of the EQ-5D index[35]. The EQ-5D is a validated questionnaire to measure health-related quality of life[36,37].

Medical consumption questionnaire, productivity cost questionnaire, and valuation of informal care questionnaire

To measure the costs of healthcare, the costs for patients and their families (e.g., travelling costs and help received from family and friends), and costs within other sectors (i.e., productivity losses from paid and unpaid work) in the previous three months, an adapted version of the medical consumption questionnaire (iMCQ) and productivity cost questionnaire (iPCQ) will be used. An adapted version of the valuation of informal care questionnaire (iVICQ) will be used for the valuation of informal care by monetary and non-monetary methods. All these questionnaires are developed by the Institute for Medical Technology Assessment of the Erasmus University Rotterdam (IMTA), the Netherlands[38–40].

Sociodemographic characteristics and health-related characteristics

A study-specific questionnaire will be used at baseline (t0) to assess the sociodemographic characteristics (e.g., age, education level, and work situation) and health-related characteristics of the partner as well as the health situation of the patient with cancer.

Sample size

To demonstrate the presence of an effect on the CSI+ of at least 0.5 standard deviations as statistically significant in a one-tailed test at alpha = 0.05 and a power of (1 - beta) = 0.80, a minimum of 51 participants in each condition of the RCT will be required at follow-up. Anticipating a drop-out rate of 25% between t0 and t2, 68 participants per condition need to be included at t0. Therefore, the total study cohort comprises 136 partners of patients with incurable cancer.

Statistical analyses

All analyses will be conducted in agreement with the intention-to-treat principle. Descriptive statistics will be used to describe the sociodemographic characteristics, health-related characteristics of the partner, the health situation of the patient with cancer, and the outcome measures. Chi-square tests and independent samples t-tests will be used to analyze whether randomization resulted in a balanced distribution of sociodemographic and health-related characteristics across the study arms. Mann-Whitney U tests will be performed in case of non-normality of the data. To test whether there are differences in the outcomes across the study arms at baseline, independent samples t-tests will be used.

Linear Mixed Models (LMM) will be used to determine the efficacy of Oncokompas by comparing longitudinal changes between the intervention group and control group with fixed effects for study arm, time, and their two-way interaction, as well as a random intercept for subjects.

LMM will also be used to determine whether age, gender, socio-economic status (e.g., education level and work situation), the health situation of the patient, and baseline quality of life moderate the efficacy of Oncokompas with fixed effects for study arm, time, the potential moderator, and all two-way and three-way interaction effects, as well as a random intercept for subjects.

Post-hoc analyses will be applied when significant results are found in the efficacy and moderation analyses. To measure the differences in change between the intervention group and control group at follow-up measurements, independent samples t-tests with Bonferroni correction will be used. These tests will also be used to assess whether change scores between the intervention group and control group differed significantly within each category of the significant moderator variables.

The effect sizes (ES) of the intervention will be measured by calculating the (between group) Cohen’s d. The magnitude of the ES is classified as large (≥ 0.80), moderate (0.50-0.79) or small (< 0.50)[41].

A p-value of < 0.05 will be considered significant for all analyses. All tests will be one-tailed. IBM Statistical Package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY USA) will be used to perform all statistical analyses.

Economic outcomes

The analysis of economic outcomes will also be conducted in agreement with the intention-to-treat principle. An incremental cost-utility ratio (ICUR) will be calculated by dividing the incremental costs (i.e., mean costs in the intervention group minus mean costs in the control group) by the incremental QALYs (i.e., mean QALYs in the intervention group minus mean QALYs in the control group).

Total costs from a societal perspective will be calculated using intervention costs, costs of healthcare (i.e., costs of healthcare and medication), costs for patients and their families (e.g., travelling costs and help received from family and friends), and costs within other sectors (i.e., productivity losses from paid and unpaid work). Intervention costs and costs of healthcare will be used to calculate total costs from a healthcare perspective.
Costs of healthcare and costs for patients and their families will be calculated by multiplying resource use by integral costs prices as presented in the Dutch Health Care Insurance Board (CVZ) guidelines on cost studies[42]. The friction cost method will be used to calculate the costs within other sectors [43,44].
The time horizon will be set at three months follow-up; therefore, neither costs nor effects will be discounted. The EQ-5D utility score will be used to calculate QALYs by linking the scores to the various health states of the EQ-5D. Multiple imputation will be used when data are missing on the costs of healthcare, the costs of patients and their families, and the costs within other sectors. This also accounts for missing data on the utilities measured with the EQ-5D.

To obtain 95% confidence intervals around the costs and QALY differences, non-parametric bootstrapping with 5000 imputations will be used. A cost-utility plane will be plotted for the projection of the resulting pairs of cost and effect differences. A cost-effectiveness acceptability curve will be made to reflect the probability of Oncokompas being cost-effective given different willingness-to-pay ceilings[45]. Sensitivity analyses will be conducted focusing on uncertainty in the main cost factors.

Monitoring

Since this trial concerns a low-risk intervention (i.e., access to an online application), no independent Data Monitoring Committee is required for this study. The research team will meet monthly to discuss all study activities (i.e., the daily management and organization of the study, such as the recruitment of participants and participant monitoring) and feasibility of the study (i.e., time management of the trial).

DISCUSSION

This study, targeting partners of patients with incurable cancer, will assess the efficacy of Oncokompas as an eHealth self-management application on caregiver burden, self-efficacy and quality of life, and its cost-utility from a healthcare and societal perspective, compared to care as usual.

Partners of patients with incurable cancer often face challenges due to the patient's diagnosis and cancer treatment. These challenges, such as emotional and financial difficulties, influence their daily lives and health. Partners are often involved in the illness trajectory by providing physical, emotional and practical assistance to the patient[1,46]. Although there are positive aspects related to informal caregiving (e.g., feeling rewarded or experiencing a sense of personal growth)[8], partners often also feel distressed and burdened due to their caregiving responsibilities[10].

A meta-analysis, investigating different types of interventions offered to family caregivers of cancer patients, showed that interventions targeting caregivers alone have better outcomes regarding caregivers' perceptions of their caregiving experiences than interventions provided to cancer patients and their caregivers jointly[47]; these targeted interventions are better able to focus on the needs of the caregivers.

Given et al. (2001) reported that informal caregivers often are gatekeepers to themselves; they may hesitate to seek help for their own needs[10], for example because they protect the patient from their own complaints or because they do not want to shift the attention from the patient to themselves[16]. It might be hard for partners to discuss certain issues with healthcare professionals (e.g., their fears about losing the patient, the strain they experience because their partner has cancer, or their sexual needs), especially in presence of the patient. By informing partners and providing self-care advice on a wide variety of symptoms which could possibly affect their quality of life, Oncokompas could be a solution to meet unmet needs of partners of patients with incurable cancer. Furthermore, Oncokompas could stimulate partners and patients to talk about the patient's and partner's wishes regarding the end-of-life phase of cancer. Oncokompas can be used by partners at their own time in their own home. This is an advantage, because partners often are already burdened due to the patient's cancer. To use Oncokompas partners do not have to take time off from work or find respite care for the patient.

In a study investigating the preferences and attitudes regarding Oncokompas as a system monitoring symptoms, it was reported that caregivers of glioma patients expected that Oncokompas could decrease the barriers to contact healthcare professionals for their own needs[48]. Köhle et al. (2018) found that partners of cancer patients are interested in using web-based supportive interventions and would be interested in obtaining online information when they know the patient has an incurable disease. Other topics of interest identified in that study were how partners could take care of themselves and how they could cope with emotions[49]. Previous studies indicated that palliative care interventions may improve quality of life among caregivers of patients with advanced cancer[19,47,50]. It has also been suggested that interventions targeting caregivers may also have a positive impact on a patient's symptoms[50]. This is worth noting, since research has shown that the level of informal caregiver distress is also related to the well-being of the patient, for example the severity of their symptoms and their level of functional autonomy[51,52].

Since caregiver burden could lead to a deterioration in quality of life, reductions in work productivity and an increase in the use of healthcare resources[53], it is important to investigate the costs and effects related to caregiving, while investigating the effects of interventions[54]. In this study, medical costs, productivity costs, and costs of informal caregiving will be taken into account in the cost-utility analysis. It is expected that Oncokompas will improve QALYs at acceptable costs, compared to care as usual. This study will create knowledge on the impact of informal cancer care, which in its turn could serve as valuable information for policy makers to take into account while developing healthcare arrangements regarding the facilitation and support of informal caregiving.

This study will also contribute to the knowledge about the effectiveness of eHealth interventions used by partners of patients with incurable cancer. When Oncokompas is proven to be effective for partners, this may stimulate the implementation of the intervention as a health service for partners of cancer patients.

REFERENCES

1. Stenberg U, Ruland C, Miaskowski C. Review of the literature on the effects of caring for a patient with cancer. Psycho-Oncology. 2010;19(10):1013–1025.
2. Pitceathly C, Maguire P. The psychological impact of cancer on patients' partners and other key relatives: A review. Eur J Cancer. 2003;39(11):1517–1524.
3. Ugur O, Elcigil A, Arslan D, Sonmez A. Responsibilities and difficulties of caregivers of cancer patients in home care. Asian Pacific J Cancer Prev. 2014;15(2):725–729.
4. Lund L, Ross L, Petersen MA, Groenvold M. Cancer caregiving tasks and consequences and their associations with caregiver status and the caregiver's relationship to the patient: A survey. BMC Cancer. 2014;14:541.
5. Blum K, Sherman DW. Understanding the Experience of Caregivers: A Focus on Transitions. Semin Oncol Nurs. 2010;26(4):243–258.
6. Ussher JM, Perz J, Hawkins Y, Brack M. Evaluating the efficacy of psycho-social interventions for informal carers of cancer patients: A systematic review of the research literature. Health Psychol Rev. 2009;3(1):85–107.
7. McCorkle R, Ercolano E, Lazenby M, Schulman-Green D, Schilling LS, Lorig K, et al. Self-management: Enabling and empowering patients living with cancer as a chronic illness. CA Cancer J Clin . 2011;61(1):50–62.
8. Li Q. B, Loke AY. The positive aspects of caregiving for cancer patients: A critical review of the literature and directions for future research. Psycho-oncology. 2013;22(11):2399–2407.
9. Given BA, Given CW, Sherwood P. The challenge of quality cancer care for family caregivers. Semin Oncol Nurs. 2012;28(4):205–212.
10. Given BA, Given CW, Kozachik S. Family support in advanced cancer. CA Cancer J Clin. 2001;51(4):213–231.
11. Shaffer KM, Jacobs JM, Nipp RD, Carr A, Jackson VA, Park ER, et al. Mental and physical health correlates among family caregivers of patients with newly-diagnosed incurable cancer: a hierarchical linear regression analysis. Support Care Cancer. 2017;25(3):965-971.
12. Peters MEWJ, Goedendorp MM, Verhagen SAHHVM, Smilde TJ, Bleijenberg G, van der Graaf WTA. &, et al. A prospective analysis on fatigue and experienced burden in informal caregivers of cancer patients during cancer treatment in the palliative phase. Acta Oncol. 2015;54(4):500-506.
13. Sklenarova H, Krümpelmann A, Haun MW, Friederich HC, Huber J, Thomas M, et al. When do we need to care about the caregiver? Supportive care needs, anxiety, and depression among informal caregivers of patients with cancer and cancer survivors. Cancer. 2015;121(9):1513–1519.
14. Braun M, Mikulincer M, Rydall A, Walsh A, Rodin G. Hidden morbidity in cancer: Spouse caregivers. J Clin Oncol. 2007;25(30):4829–4834.
15. Lambert SD, Harrison JD, Smith E, Bonevski B, Carey M, Lawsin C, et al. The unmet needs of partners and caregivers of adults diagnosed with cancer: a systematic review. BMJ Support Palliat Care. 2012;2(3):224–230.
16. Bevans M, Sternberg EM. Caregiving burden, stress, and health effects among family caregivers of adult cancer patients. JAMA. 2012;307(4):398–403.
17. Zarit SH, Todd PA, Zarit JM. Subjective burden of husbands and wives as caregivers: a longitudinal study. Gerontologist. 1986;26(3):260–266.
18. Weitzner MA, McMillan SC, Jacobsen PB. Family caregiver quality of life: Differences between curative and palliative cancer treatment settings. J Pain Symptom Manage. 1999;17(6):418–428.
19. Wadhwa D, Burman D, Swami N, Rodin G, Lo C, Zimmermann C. Quality of life and mental health in caregivers of outpatients with advanced cancer. Psycho-Oncology. 2013;22(2):403–410.

20. van Roij J, Brom L, Youssef-El Soud M, van de Poll-Franse L, Raijmakers NJH. Social consequences of advanced cancer in patients and their informal caregivers: a qualitative study. Support Care in Cancer. 2019;27(4):1187-1195.
21. Girgis A, Lambert SD, McElduff P, Bonevski B, Lecathelinais C, Boyes A, et al. Some things change, some things stay the same: A longitudinal analysis of cancer caregivers' unmet supportive care needs. Psycho-Oncology. 2013;22(7):1557–1564.
22. Wang T, Molassiotis A, Chung BPM, Tan JY. Unmet care needs of advanced cancer patients and their informal caregivers: a systematic review. BMC Palliat Care. 2018;17:96.
23. Mazanec SR, Daly BJ, Douglas SL, Lipson AR. Work productivity and health of informal caregivers of persons with advanced cancer. Res Nurs Heal. 2011;34(6):483–495.
24. Kinnane NA, Milne DJ. The role of the Internet in supporting and informing carers of people with cancer: A literature review. Support Care Cancer. 2010;18(9):1123–1136.
25. Slev VN, Mistiaen P, Pasman HRW, Verdonck-de Leeuw IM, van Uden-Kraan CF, Francke AL. Effects of eHealth for patients and informal caregivers confronted with cancer: A meta-review. International Journal of Medical Informatics. 2016;87:54–67.
26. Duman-Lubberding S, van Uden-Kraan CF, Jansen F, Witte BI, van der Velden LA, Lacko M, et al. Feasibility of an eHealth application "OncoKompas" to improve personalized survivorship cancer care. Support Care Cancer. 2016;24(5):2163–2171.
27. Duman-Lubberding S, van Uden-Kraan CF, Peek N, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. An eHealth application in head and neck cancer survivorship care: Health care professionals' perspectives. Journal of Medical Internet Research. 2015;17(10):e235.
28. Lubberding S, van Uden-Kraan CF, Te Velde EA, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. Improving access to supportive cancer care through an eHealth application: A qualitative needs assessment among cancer survivors. J Clin Nurs. 2015;24(9–10):1367–1379.
29. Schuit AS, Holtmaat CJM, Hooghiemstra N, Jansen F, Lissenberg-Witte BI, Coupé VMH, et al. Efficacy and cost-utility of the eHealth application 'Oncokompas', supporting patients with incurable cancer in finding optimal palliative care, tailored to their quality of life and personal preferences: a study protocol of a randomized controlled trial. BMC palliative care. 2019;18:85.
30. van Gemert-Pijnen JEWC, Nijland N, van Limburg M, Ossebaard HC, , Kelders SMEysenbach G, Seydel ER, et al. A Holistic Framework to Improve the Uptake and Impact of eHealth Technologies. J Med Internet Res. 2011;13(4):e111.
31. Robinson BC. Validation of a caregiver strain index. Journals Gerontol. 1983;38(3):344–348.
32. Al-Janabi H, Frew E, Brouwer W, Rappange D, Van Exel J. The inclusion of positive aspects of caring in the Caregiver Strain Index: Tests of feasibility and validity. Int J Nurs Stud. 2010;47(8):984–993.
33. Schwarzer R, Jerusalem M, Weinman J, Wright S, Johnston M. Generalised self-efficacy scale. In: Weinman J, Wright S, Johnston M, eds. Causal Control beliefs. Generalised Self-Efficacy Scale, 1st ed. Windsor UK: Nfer-Nelson. 1995.
34. Scholz U, Gutiérrez Doña B, Sud S, Schwarzer R. Is General Self-Efficacy a Universal Construct. Eur J Psychol Assess. 2002;18(3):242–251.
35. Versteegh MM, Vermeulen KM, Evers SMAA, Ardine De Wit G, Prenger R, Stolk EA. Dutch Tariff for the Five-Level Version of EQ-5D. Value Heal. 2016;19(4):343-352.
36. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of life research. 2011;20(10):1727-1736.
37. Janssen MF, Pickard AS, Simon, Golicki D, Gudex C, Niewada M, Scalone L, et al. Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study. Qual Life Res. 2013;22:1717–1727.
38. Bouwmans C, Hakkaart-van Roijen L, Koopmanschap M, Krol M, Severens H, Brouwer W. Handleiding iMTA Medical Cost Questionnaire (iMCQ). Rotterdam: iMTA, Erasmus Universiteit, 2013.

39. Bouwmans C, Hakkaart-van Roijen L, Koopmanschap M, Krol M, Severens H, Brouwer W. Handleiding iMTA Productivity Cost Questionnaire (iPCQ). Rotterdam: iMTA, Erasmus Universiteit; 2013.
40. Hoefman RJ, Van Exel NJA, Brouwer WBF. iVICQ. iMTA Valuation of Informal Care Questionnaire Version 1.1; 2011.
41. Cohen J. Statistical Power Analysis for the Behavioral Sciences, 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.
42. Tan S, Bouwmans-Frijters CAM, Hakkaart-van Roijen L. Handleiding voor kostenonderzoek: methoden en referentieprijzen voor economische evaluaties in de gezondheidszorg - Manual for cost research: methods and reference prices for economic evaluations in health care. Tijdschr voor gezondheidswetenschappen. 2012;90(6):367–372.
43. Hakkaart-van Roijen L, van der Linden N, Bouwmans C, Kanters T, Tan SS. Kostenhandleiding: Methodologie van kostenonderzoek en referentieprijzen voor economische evaluaties in de gezondheidszorg - Costing manual: Methodology of costing research and reference prices for economic evaluations in healthcare. Zorginstituut Ned. 2016;1–73.
44. Koopmanschap MA, Rutten FFH, Van Ineveld BM, Van Roijen L. The friction cost method for measuring indirect costs of disease. J Health Econ. 1995;14:171–189.
45. van Hout BA, Al MJ, Gordon GS, Rutten FF. Costs, effects and C/E-ratios alongside a clinical trial. Health Econ. 1994;3(5):309–319.
46. Applebaum AJ, Breitbart W. Care for the cancer caregiver: A systematic review. Palliat Support Care. 2013;11(3):231–252.
47. Northouse LL, Katapodi MC, Song L, Zhang L, Mood DW. Interventions with Family Caregivers of Cancer Patients: Meta-Analysis of Randomized Trials. CA Cancer J Clin. 2010;60(5):317-339.
48. Boele FW, van Uden-Kraan CF, Hilverda K, Reijneveld JC, Cleijne W, Klein M, et al. Attitudes and preferences toward monitoring symptoms, distress, and quality of life in glioma patients and their informal caregivers. Support Care Cancer. 2016;24(7):3011–3022.
49. Köhle N, Drossaert CHC, Van Uden-Kraan CF, Schreurs KMG, Hagedoorn M, Verdonck-de Leeuw IM, et al. Intent to use a web-based psychological intervention for partners of cancer patients: Associated factors and preferences. J Psychosoc Oncol. 2018;36(2):203–221.
50. Osse BHP, Vernooij-Dassen MJFJ, Schade E, Grol RPTM. Problems experienced by the informal caregivers of cancer patients and their needs for support. Cancer Nurs. 2006;29(5):378–388.
51. Dumont S, Turgeon J, Allard P, Gagnon P, Charbonneau C, Vézina L. Caring for a Loved One with Advanced Cancer: Determinants of Psychological Distress in Family Caregivers. J Palliat Med. 2006;9(4):912–921.
52. Kershaw T, Ellis KR, Yoon H, Schafenacker A, Katapodi M, Northouse L. The Interdependence of Advanced Cancer Patients' and Their Family Caregivers' Mental Health, Physical Health, and Self-Efficacy Over Time. Ann Behav Med. 2015;49(6):901–911.
53. Goren A, Gilloteau I, Lees M, Dacosta Dibonaventura M. Quantifying the burden of informal caregiving for patients with cancer in Europe. Support Care in Cancer. 2014;22(6):1637-1646.
54. Krol M, Papenburg J, Van Exel J. Does Including Informal Care in Economic Evaluations Matter? A Systematic Review of Inclusion and Impact of Informal Care in Cost-Effectiveness Studies. Pharmacoeconomics. 2015;33:123–135.

9

REACH AND EFFICACY OF THE EHEALTH APPLICATION ONCOKOMPAS, FACILITATING PARTNERS OF INCURABLY ILL CANCER PATIENTS TO SELF-MANAGE THEIR CAREGIVER NEEDS: A RANDOMIZED CONTROLLED TRIAL

Anouk S. Schuit
Michelle M. Rienks
Nienke Hooghiemstra
Femke Jansen
Birgit I. Lissenberg-Witte
Pim Cuijpers
Irma M. Verdonck-de Leeuw
Karen Holtmaat

Submitted

ABSTRACT

Purpose: Many partners of incurably ill cancer patients experience caregiver burden. The eHealth application ‘Oncokompas’ supports these partners to manage their caregiver needs and to find optimal supportive care for themselves. The aim of this randomized controlled trial (RCT) was to investigate the reach of Oncokompas and its efficacy on caregiver burden, self-efficacy and health-related quality of life (HRQOL).

Methods: The reach was estimated based on eligibility, participation rate, and evaluation of the recruitment process. Efficacy on caregiver burden was measured using the Caregiver Strain Index+ (CSI+). Secondary outcomes were self-efficacy (General Self-Efficacy Scale (GSE)) and HRQOL (EQ-5D VAS). Assessments were scheduled at baseline, two weeks after randomization and three months after baseline. Linear mixed models were used to compare longitudinal changes between the experimental and control group from baseline to the three-month follow-up.

Results: The reach was estimated at 83-91%. Partners were most likely reached via palliative care consultants, patient organizations and palliative care networks and less likely via home care organizations, general practitioners, and hospitals. In the one-and-a-half-year recruitment period and via the 101 organizations involved, 58 partners were included in the RCT. There were no significant effects of Oncokompas on caregiver burden, self-efficacy or HRQOL.

Conclusion: The reach of Oncokompas among interested individuals was high, but the difficulties that were encountered to include partners suggest that the reach in real life may be lower. This study showed no effect of Oncokompas on caregiver burden, self-efficacy or HRQOL among partners of incurably ill cancer patients.

Relevance: The results of this study may be used in the process of developing, efficacy testing and implementing eHealth applications for caregivers of incurably ill cancer patients.

Funding: ZonMw, Netherlands Organization for Health Research and Development (844001105)

Trial registration: Netherlands Trial Register identifier: NTR7636/NL7411. Registered on 23rd November 2018 (https://www.trialregister.nl/)

Keywords: eHealth, palliative care, caregiving, partners, incurable cancer, caregiver burden

INTRODUCTION

There is convincing evidence that informal caregiving for an incurably ill cancer patient is associated with physical, psychological and social problems and that these problems negatively impact aspects of health-related quality of life (HRQOL) of informal caregivers[1–14]. Caregiver burden can be defined as "*a multidimensional biopsychosocial reaction resulting from an imbalance of care demands relative to caregivers' personal time, social roles, physical and emotional states, financial resources, and formal care resources given the other multiple roles they fulfill*"[15]. There is a growing interest in healthcare resources to support informal caregivers of incurably ill patients. Many informal caregivers do not use these healthcare options. For instance, because they are unaware or unconcerned that their own HRQOL is being compromised, they are unaware of the available healthcare resources, or they may feel that focusing at their own needs is at the expense of the patients' needs[16–21]. Delivering interventions through the Internet may help to reach a greater number of informal caregivers[17,22–24].

The eHealth self-management application Oncokompas was developed to support partners of incurably ill cancer patients to adopt an active role in improving their own HRQOL and to find optimal supportive care if needed. Oncokompas helps partners to monitor their own HRQOL using patient-reported outcome measures (PROMs), followed by automatically generated tailored feedback, self-care advice, and advice on supportive care services. The application is tailored to the partner's personal characteristics and preferences[25].

The aim of this randomized controlled trial was to investigate the reach and efficacy of Oncokompas as a digital self-management instrument on caregiver burden, self-efficacy, and HRQOL among partners of patients with incurable cancer. It is expected that using Oncokompas helps partners to reduce caregiver burden and to increase self-efficacy and HRQOL.

METHODS

Study design

A prospective RCT with two parallel groups was conducted to investigate the reach and efficacy of Oncokompas among partners of patients with incurable cancer. Partners in the intervention group got access to Oncokompas directly after completing the baseline questionnaire and partners in the control group got access after three months (i.e., after completing the last questionnaire). Outcome measures were collected at baseline (t0), two weeks after randomization (t1), and three months after the baseline measurement (t2).

The study protocol was approved by the Medical Ethics Committee of VU University Medical Center (2018.517). This trial was registered in the Netherlands Trial Register (NTR7636/NL7411) and the study protocol was published previously[25]. All participants provided written informed consent. The CONSORT guidelines (CONsolidated Standards of Reporting Trials) were used to report on this trial[26].

Study population

Inclusion criteria were: being an adult partner of an incurably ill cancer patient and having access to an e-mail address. Partners were excluded when they had severe cognitive impairments or when they had a poor understanding of the Dutch language. They were also excluded when their partner with cancer already used Oncokompas for patients with incurable cancer.

Recruitment

A multi-component recruitment strategy was followed in which healthcare professionals in various settings were asked to place and spread recruitment materials and to inform partners of incurably ill cancer patients on the study (Table 1). Partners could also contact the researchers directly by using the reply form at the Oncokompas website or by e-mailing the researcher. Recruitment materials consisted of leaflets in waiting rooms and offices of healthcare providers, and online advertising on websites, newsletters and social media. The contact details of the researcher and URL of the Oncokompas website (www.oncokompas.nl) were mentioned in all materials.

Study procedures

Individuals who expressed interest in participating in this study were contacted by a researcher to be further informed about the study. Eligible partners received an information letter and informed consent form. After signing informed consent, partners received the baseline questionnaire by e-mail. After completion of the baseline questionnaire, partners were randomly assigned to a study arm. Partners randomized to the intervention group received an invitation e-mail for Oncokompas to activate their personal account. Partners randomized to the control group received this e-mail after completion of the third questionnaire (t2).

Randomization

Partners were randomized in a 1:1 ratio. Block randomization was used with a random block length of four, six or eight. Stratification was not applied. The randomization

Table 1. Overview of parties involved in recruiting participants

Type of organization	Approached	Agreed to participate		Declined		No response		Main reasons to decline
	n	n	%	n	%	n	%	
General practitioner	288	11	4	13	5	264	92	No time and interest.
Hospital	28	3	11	8	29	17	61	No time or already involved in other studies.
Home care organization	42	1	2	6	14	35	83	Not in contact with (many) partners of incurably ill cancer patients.
Center for supportive cancer care	68	26	38	0	0	42	62	
Patient organization	23	11	48	7	30	5	22	Not in contact with partners of incurably ill cancer patients.
Informal care organization	51	7	14	10	20	34	67	Already involved in other studies.
Informal care consultant	86	16	19	18	21	52	60	Not in contact with partners of incurably ill cancer patients.
Palliative care network	41	17	41	3	7	21	51	Already involved in other studies.
Palliative care consultant	5	5	100	0	0	0	0	
Elderly association	24	4	17	2	8	18	75	
Total	656	101	15	67	10	488	74	

scheme was computer-generated, created by a researcher not involved in the study, who also performed the allocation of participants. Neither the researcher, and, because of the nature of the intervention, participants could not be blinded.

Wait list control group

All partners received care as usual during their participation in the wait list control group. Care as usual was defined as all care provided by healthcare professionals regardless of study participation.

Intervention

Oncokompas is an eHealth self-management application, consisting of three steps: Measure, Learn, and Act. Previously, a version of Oncokompas has been developed for cancer patients during or after curative treatment[27] and for incurably ill cancer patients[28]. All versions were developed using a stepwise, iterative and participatory approach, actively involving end users and healthcare professionals in the design process[29]. In the first step ‘Measure’, partners complete a questionnaire on their personal characteristics used to select the topics appropriate for this individual (e.g., when someone is retired, the topic about ‘work’ will not be shown). Then partners can select which topics they want to address within Oncokompas (e.g., fatigue, loneliness, or financial problems). The topics target four domains of quality of life: physical, psychological and social functioning, and existential issues. Subsequently, PROMs are used to measure partners’ functioning on the selected topics[25]. In the step, ‘Learn’, Oncokompas provides information and feedback on partners’ outcomes, tailored to their personal characteristics and preferences. Using a traffic-light system (green, orange and red), partners get an overview of their well-being per topic. A green score means that the partner is doing well on this topic, an orange score means that this topic could use attention and support, and a red score means that this topic needs attention and support. Then, Oncokompas provides comprehensive self-care advice. Lastly, within the step ‘Act’, partners receive a personal overview of supportive care options for themselves, with options for professional guidance when needed.

Study measures

Caregiver burden was assessed using the Caregiver Strain Index + (CSI+). The CSI+ measures the self-reported burden that informal caregivers experience as a result of caring for their loved ones (13 items), as well as positive and rewarding experiences as a result of informal caregiving (5 items). Response options are ‘yes’ (coded as 1 for the negative items and -1 for the positive items) and ‘no’ (always coded as 0). The total score range is -5 to 13. A higher score indicates more caregiver burden. The CSI+ does not have a cut-off score. The total CSI+ score was analyzed, as well as the negative and positive items separately. In the separate analyses, a higher score indicates more caregiver burden. In contrary to the way positive items of the CSI+ were coded (as -1), in the separate analyses positive items were coded as 1, so that a higher score indicates a more positive caregiver experience[30,31].

Self-efficacy was assessed using the General Self-Efficacy Scale (GSE). The GSE is a 10-item self-report questionnaire, assessing how a person deals with difficult situations in life. The items have a 4-point Likert scale, ranging from 1 (not at all true) up to 4 (exactly true). The total score is calculated by adding up the scores on the 10 items and ranges from 10 to 40. A higher score indicates a greater sense of self-efficacy. The GSE does not have a cut-off score. The international average GSE score in the general population is 29.55[32,33].

HRQOL was measured using the visual analogue scale (VAS) of the self-report questionnaire EuroQol-5D (EQ-5D). The VAS ranges from 0 to 100, in which 100 indicates the best imaginable health state. The norm score of general Dutch citizens from 55 to 64 years is 80.7[34,35].

Partners' and patients' sociodemographic and health-related characteristics were assessed at baseline using a study specific questionnaire.

Sample size

To demonstrate an increase on the CSI+ of at least 0.5 standard deviations in the intervention group compared to the control group (i.e., between group change of 0.5 SD) between t0 and t2 as statistically significant in a one-tailed test using a significance level of 5% (alpha = 0.05) and a power of 80% ($1 - \beta = 0.80$), 51 participants were required at t2 in each study arm. Anticipating a drop-out rate of 25% between t0 and t2, 68 participants per study arm needed to be included at t0 (in total 136 participants).

Statistical analyses

Reach was estimated based on eligibility and participation rate. Eligibility rate was calculated as the number of eligible partners divided by the number of partners who were informed on the study after they expressed interest in Oncokompas. Participation rate was calculated by dividing the number of included partners by the number of eligible partners.

Descriptive statistics were used to describe the recruitment process, sociodemographic and health-related characteristics of the partner and the patient, and the outcome measures at baseline.

Linear Mixed Models (LMM) were used to compare longitudinal changes in primary and secondary outcome measures in both study arms between t0, t1, and t2. Fixed effects were used for study arm, measurement, and their two-way interaction, and a random intercept for subjects. All analyses were conducted according to the intention-to-treat principle. Missing data was not imputed as LMM accounts for missing data.

All analyses were performed using IBM Statistical Package for the Social Sciences (SPSS) version 27 (IBM Corp., Armonk, NY USA). A p-value of < 0.05 was considered significant for all analyses.

RESULTS

Reach

Between March 2019 and August 2020, 93 individuals expressed interest in Oncokompas. Sixteen of them could not be contacted. The other 77 were informed about the study, of which 64 were eligible (eligibility rate 83%). Reasons for ineligibility were: patient (the partner's partner) passed away (n=6), patient was in the terminal phase of the disease (n=2), patient still had options for curative treatment (n=2), applicant was not the partner but another informal caregiver (n=2), and having no computer (n=1). Of the 64 eligible partners, 58 agreed to participate in the study (participation rate 91%). Reasons for not agreeing to participate were: not being interested (n=3), participation being too confronting (n=2), and having privacy concerns (n=1). The flow diagram of the study is shown in figure 1.

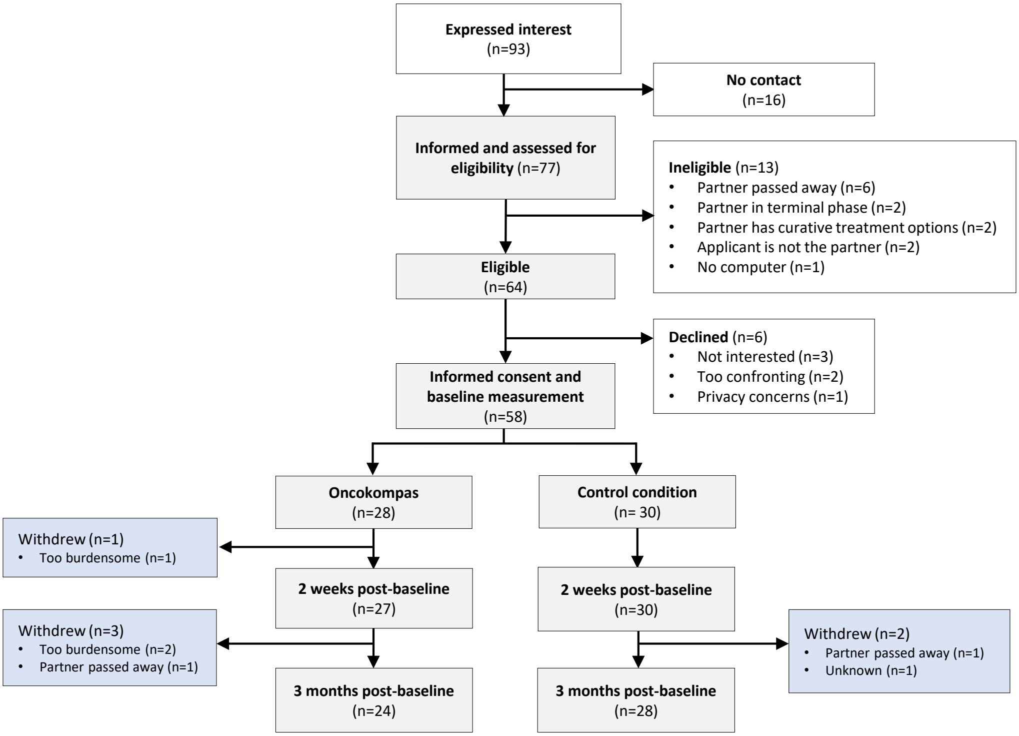


Figure 1. Flow diagram

During the recruitment process 656 persons from various organizations involved in palliative care were asked to participate in recruiting partners (Table 1). In total, 101 agreed to participate (15%), 67 declined (10%), and the majority did not respond (n=488, 74%). Main reasons for organizations that declined were: having no time, already being involved in other studies, or not having partners of incurably ill cancer patients in their care. The types of organization that most often agreed to participate, in terms of percentages, were palliative care consultants (100%), patient organizations (48%), palliative care networks (41%), and centers for supportive cancer care (38%). The types of organizations that were least likely to participate were home care organizations (2%), general practitioners (4%) and hospitals (11%). Despite all efforts, after recruiting for almost one and a half year, the inclusion of partners lagged behind considerably. Part of the study (March-August 2020) took place during the COVID-19 pandemic. Due to the national lockdown in the Netherlands, many organizations were not able to continue their services as they were used to. Reaching the target of 136 included partners was judged not to be feasible anymore and therefore the study stopped in September 2020. The 101 parties involved in the recruitment process led to 93 individuals expressing interest in Oncokompas and 58 inclusions.

Efficacy

From the 58 included partners, 28 were allocated to the intervention group and 30 to the control group (Figure 1). Mean age was 57 years and two third (67%) was female. The majority had children (86%), was highly educated (55%), and employed (60%). Almost half of the partners (45%) reported no comorbidities (Table 2a). The patients that the partners were caring for were on average 59 years old and their health (as perceived by the partner) was on average 4.7 on a scale of 0 to 10. Most of the patients had lung cancer (19%) or a brain tumor (17%), and received treatment mainly directed at the disease (as opposed to treatment mainly directed at reducing symptoms) (72%). Fifty-one percent was diagnosed with cancer more than two years ago and six (10%) patients passed away during the follow-up period (Table 2b).

Table 2a. Sociodemographic characteristics of the study participants

	Total group (n=58)		Control group (n=30)		Intervention group (n=28)	
	n	**%**	**n**	**%**	**n**	**%**
Age in years						
Mean (SD)	57 (11)	-	58 (13)	-	57 (10)	-
Gender						
Male	19	33	10	33	9	32
Female	39	67	20	67	19	68
Education level						
Low	7	12	2	7	5	18
Medium	19	33	11	37	8	29
High	32	55	17	57	15	54
Children						
Yes	50	86	27	90	23	82
No	8	14	3	10	5	18
Employed						
Yes	35	60	17	57	18	64
No	23	40	13	43	10	36
Comorbidities						
None	26	45	13	43	13	46
One comorbidity	18	31	11	37	7	25
Multiple comorbidities	14	24	6	20	8	29

Table 2b. Sociodemographic and clinical characteristics of the patients

	Total group (n=58)		Control group (n=30)		Intervention group (n=28)	
	n	%	n	%	n	%
Age in years						
Mean (SD)	59 (12)	-	61 (14)	-	57 (10)	-
Gender						
Male	40	69	21	70	19	68
Female	18	31	9	30	9	32
Health as perceived by partner (0-10)	4.7 (1.9)		4.9 (1.9)		4.5 (2.0)	
Tumor site						
Lung	11	19	5	17	6	21
Brain	10	17	5	17	5	18
Prostate	6	10	4	13	2	7
Colon	6	10	2	7	4	15
Breast	5	9	3	10	2	7
Hematological	4	7	1	3	3	11
Other	14	24	9	30	5	18
Multiple	2	3	1	3	1	4
Time since diagnosis						
<1 month	4	7	3	10	1	4
<6 months	7	12	3	10	4	14
<2 years	17	29	8	27	9	32
>2 years	30	51	16	53	14	50
Treatment target						
Cancer	42	72	22	73	20	71
Symptoms	7	12	5	17	2	7
No treatment	9	16	3	10	6	21
Passed away						
2 weeks follow-up	1	2	0	0	1	4
3 months follow-up	5	9	3	10	2	7

Results of the linear mixed model analyses are shown in Table 3. No significant difference was found in the course of caregiver burden (CSI+) in the intervention group, compared to the control group. The estimated difference in change from t0 to t2 was 0.3 points (90% CI -0.8 – 1.5). This means that the estimated change in the intervention group (t0 – t2) was 0.3 points higher than in the control group. The p-value of the interaction between the study arm and the time of assessment was 0.64.

Table 3. Mean scores per group per assessment and results of the linear mixed model analyses on the primary and secondary outcome measures

	Baseline (t0)		2 weeks follow-up (t1)		3 months follow-up (t2)			
	n	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**Estimated difference in change between t0 and t2 (90% CI)**	**P-value two-way interaction**
Caregiver Strain Index (CSI+)								0.64
Intervention	28	2.8 (3.4)	25	2.5 (3.2)	22	2.5 (2.6)	0.3 (-0.8 – 1.5)	
Control	30	4.2 (3.2)	30	4.6 (3.0)	24	4.3 (3.0)		
Caregiver Strain Index (CSI+ negative items)								0.53
Intervention	28	7.1 (3.0)	25	6.8 (2.7)	22	7.0 (2.4)	0.2 (-0.7 – 1.1)	
Control	30	8.3 (2.7)	30	8.5 (2.5)	24	8.3 (2.4)		
Caregiver Strain Index (CSI+ positive items)								0.79
Intervention	28	4.4 (0.8)	25	4.2 (0.7)	22	4.5 (0.6)	-0.2 (-0.6 – 0.2)	
Control	30	4.0 (0.9)	30	3.9 (1.0)	24	4.0 (1.0)		
General self-efficacy (GSE)								0.77
Intervention	28	30.8 (6.2)	26	30.8 (6.0)	24	30.7 (5.7)	-0.1 (-1.6 – 1.3)	
Control	30	31.2 (3.5)	30	31.7 (4.1)	28	31.0 (3.3)		
HRQOL[a] (EQ-5D VAS)								0.24
Intervention	28	72.8 (16.7)	26	77.0 (13.2)	24	74.0 (19.2)	1.0 (-6.2 – 8.2)	
Control	30	72.8 (14.3)	30	71.2 (15.0)	24	75.0 (12.1)		

[a] HRQOL: Health-related quality of life

Also, the course of caregiver burden (negative items of the CSI+), positive caregiving experience (positive items of the CSI+), self-efficacy (GSE) and HRQOL (EQ-5D VAS) did not differ significantly between partners randomized into the intervention or wait list control group.

DISCUSSION

This study assessed the reach and efficacy of the eHealth self-management application Oncokompas, among partners of patients with incurable cancer. The reach was estimated at 83-91%. There was no significant effect on caregiver burden, self-efficacy, or HRQOL of the partners.

In this study, reach was defined as a combination of the eligibility and participation rate among individuals with an expressed interest in Oncokompas, complemented by an evaluation of the recruitment process. While the eligibility and participation rate were high, the difficulties that were encountered to include partners suggest that in real life the reach may be lower. In previous studies, the reach of Oncokompas was estimated at 45-68% in cancer survivors[27,36] and 63% in patients with advanced cancer[28]. Main reasons for not reaching cancer survivors were: wanting to leave the period of being ill behind, no symptom burden, or lacking computer skills[36]. Main reasons for not reaching patients with incurable cancer were: participation being too confronting, lacking computer skills, or not being interested[28]. In the present study, various online channels were used to recruit partners, which may explain that a lack of computer skills was not a main reason for not reaching the target population, and which may have overestimated the reach. In contrast to the studies among cancer survivors and patients, where recruitment took place in hospitals solely, partners were most likely reached via palliative care consultants, palliative care networks, and patient organizations and less via hospitals. A hospital-based recruitment strategy might have been more successful, but was not feasible for the present study, because in parallel incurably ill cancer patients were recruited in the hospital for the study on the efficacy of Oncokompas for patients[28]. Unfortunately, during the present study, all recruitment channels were affected by the national lock-down due to the COVID-19 pandemic. Most affected were probably the palliative care consultants and palliative care networks.

Based on the results of this study, it cannot be concluded that Oncokompas decreases caregiver burden, and increases self-efficacy or HRQOL among partners of incurably ill cancer patients. It might be that palliative care for the partner of the patient is already very effective, and Oncokompas does not add much to this care. The absence of significant effects of Oncokompas is in line with a recent study on the efficacy of the version of Oncokompas for incurably ill cancer patients[28], but not with a large study on the efficacy of the version of Oncokompas for cancer survivors[27]. Oncokompas for cancer survivors differs from the other two versions of Oncokompas, in that it has several tumor-specific modules and its effects were mainly found among tumor-specific symptoms. Oncokompas for partners is tailored to the characteristics and preferences of the partner, but may need to be further tailored to the specific demands of caring for a patient with a specific tumor type (e.g., coping with a poor prognosis for partners of patients with lung cancer, or dealing with cognitive impairment for partners of patients with a brain tumor).

There are also some limitations that may explain these results. First, the sample size was smaller than intended and therefore the power to detect changes in the outcome measures was insufficient. Second, Oncokompas was developed before the COVID-19 pandemic, but the RCT was largely conducted during the pandemic. There might have been an effect on the personalized supportive care options as provided in the third step within Oncokompas (the ‘Act’ component). When a user has a red score on a topic, the feedback always included the advice to contact a healthcare professional, such as a general practitioner or a specialized healthcare professional (e.g., a psychologist). These contacts may have changed from face-to-face contact to contact through telehealth during the COVID-19 pandemic. This may have influenced the results. Third, the follow-up period of three months might have been too short to measure effects that take more than three months (e.g., psychotherapy or physiotherapy). A fourth explanation could be that 51% of the participants were caring for a patient diagnosed more than two years ago. These partners may have already learned to cope with the situation and did not need Oncokompas at that moment anymore. Informal caregivers tend to develop self-management strategies over time. On the other hand, 10% of the participants had a partner (patient) who passed away during the study, which may also have influenced the effect of using Oncokompas. In any case, it may be better to provide access to Oncokompas at an early stage, for instance, shortly after a diagnosis of incurable cancer. Such an approach would also fit well into advanced cancer care planning[37].

Alongside this RCT, a cost-utility analysis was planned, including medical costs, productivity costs, and costs of informal caregiving. It was expected that Oncokompas would improve quality-adjusted life years at acceptable costs, compared to the wait list control group[25]. Because the sample size was smaller than expected, this cost-utility analysis was deemed not to be feasible and was not carried out. Nonetheless, this project generated new knowledge on the reach and efficacy of an eHealth self-management intervention among partners of incurably ill cancer patients. This project may serve as a model for developing and testing eHealth self-management applications targeting partners of incurably ill cancer patients.

In conclusion, the reach of Oncokompas among interested individuals was high, but the difficulties that were encountered to include partners suggest that the reach in real life may be lower. This study showed no effect of Oncokompas on caregiver burden, self-efficacy or HRQOL among partners of incurably ill cancer patients.

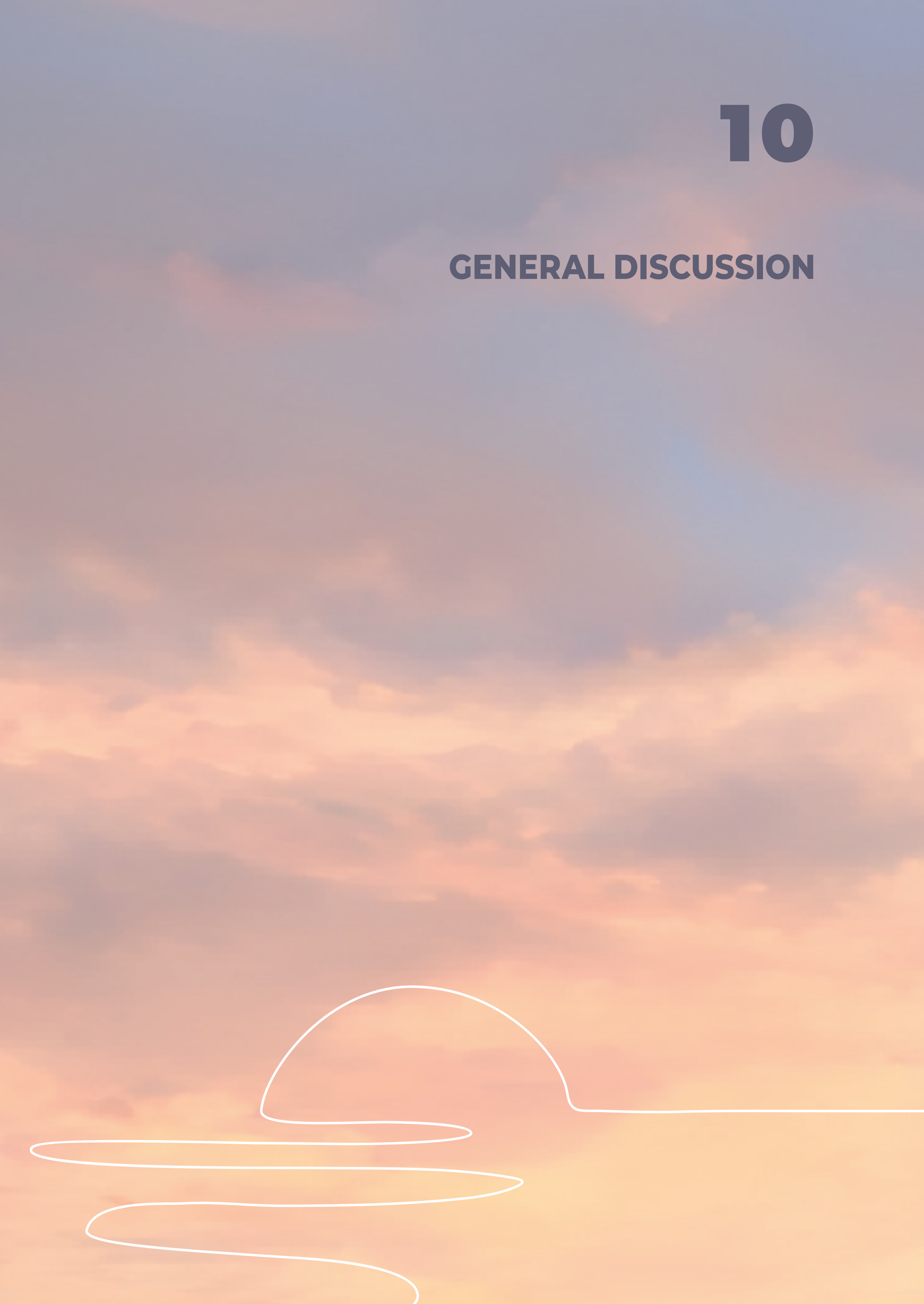
REFERENCES

1. Given BA, Given CW, Kozachik S.Family Support in Advanced Cancer. CA Cancer J Clin 2001;51(4):213–231.
2. Geng H, Chuang D, Yang F, Yang Y, Liu W, Liu L, et al. Prevalence and determinants of depression in caregivers of cancer patients: A systematic review and meta-analysis. Medicine. 2018;97(39):e11863.
3. Shaffer KM, Jacobs JM, Nipp RD, Carr A, Jackson VA, Park ER, et al. Mental and physical health correlates among family caregivers of patients with newly-diagnosed incurable cancer: a hierarchical linear regression analysis. Support Care Cancer. 2017;25(3):965–71.
4. van Roij J, Brom L, Youssef-El Soud M, van de Poll-Franse L, Raijmakers NJH. Social consequences of advanced cancer in patients and their informal caregivers: a qualitative study. Support Care Cancer. 2019;27(4):1187–1195.
5. van Roij J, Brom L, Sommeijer D, van de Poll-Franse L, Raijmakers N. Self-care, resilience, and caregiver burden in relatives of patients with advanced cancer: results from the eQuiPe study. Support Care Cancer. 2021;29:7975–7984.
6. Weaver R, O'Connor M, Golding RM, Gibson C, White R, Jackson M, et al. "My life's not my own": A qualitative study into the expectations of head and neck cancer carers. Support Care Cancer. 2022;30(5):4073–4080.
7. Young J, Snowden A. A systematic review on the factors associated with positive experiences in carers of someone with cancer. Eur J Cancer Care. 2017;26(3):e12544.
8. Pitceathly C, Maguire P. The psychological impact of cancer on patients' partners and other key relatives. Eur J Cancer. 2003;39(11):1517–1524.
9. Braun M, Mikulincer M, Rydall A, Walsh A, Rodin G. Hidden Morbidity in Cancer: Spouse Caregivers. J Clin Oncol. 2007;25(30):4829–4834.
10. Stenberg U, Ruland CM, Miaskowski C. Review of the literature on the effects of caring for a patient with cancer. Psychooncology. 2010;19(10):1013–1025.
11. Mazanec SR, Daly BJ, Douglas SL, Lipson AR. Work productivity and health of informal caregivers of persons with advanced cancer. Res Nurs Heal. 2011;34(6):483–495.
12. Bevans M, Sternberg EM. Caregiving Burden, Stress, and Health Effects. JAMA. 2012;307(4):398–403.
13. Wadhwa D, Burman D, Swami N, Rodin G, Lo C, Zimmermann C. Quality of life and mental health in caregivers of outpatients with advanced cancer. Psychooncology. 2013;22(2):403–410.
14. Peters MEWJ, Goedendorp MM, Verhagen SAHHVM, Smilde TJ, Bleijenberg G, Van Der Graaf WTA. A prospective analysis on fatigue and experienced burden in informal caregivers of cancer patients during cancer treatment in the palliative phase. Acta Oncol. 2015;54(4):500–506.
15. Given B, Kozachik S, Collins C. Caregiver role strain. In: Given B, Kozachik S, Collins C, (eds). St. Louis, MO: Mosby; 2001.
16. Lambert SD, Harrison JD, Smith E, Bonevski B, Carey M, Lawsin C, et al. The unmet needs of partners and caregivers of adults diagnosed with cancer: A systematic review. BMJ Support Palliat Care. 2012;2(3):224–230.
17. Applebaum AJ, Breitbart W. Care for the cancer caregiver: A systematic review. Palliat Support Care. 2013;11(3):231–252.
18. Sklenarova H, Krümpelmann A, Haun MW, Friederich HC, Huber J, Thomas M, et al. When do we need to care about the caregiver? Supportive care needs, anxiety, and depression among informal caregivers of patients with cancer and cancer survivors. Cancer. 2015;121(9):1513–1519.
19. Zavagli V, Raccichini M, Ostan R, Ercolani G, Franchini L, Varani S, et al. Identifying the prevalence of unmet supportive care needs among family caregivers of cancer patients: an Italian investigation on home palliative care setting. Support Care Cancer. 2022;30(4):3451–3461.

20. Wang T, Molassiotis A, Chung BPM, Tan JY. Unmet care needs of advanced cancer patients and their informal caregivers: a systematic review. BMC Palliat Care. 2018;17(1):96.
21. Dionne-Odom JN, Applebaum AJ, Ornstein KA, Azuero A, Warren PP, Taylor RA, et al. Participation and interest in support services among family caregivers of older adults with cancer. Psychooncology. 2018;27(3):969–976.
22. Slev VN, Mistiaen P, Pasman HRW, Leeuw IMV de, Uden-Kraan CF va., Francke AL. Effects of eHealth for patients and informal caregivers confronted with cancer: A meta-review. Int J Med Inform. 2016;87:54–67.
23. Köhle N, Drossaert CHC, Van Uden-Kraan CF, Schreurs KMG, Hagedoorn M, Verdonck-de Leeuw IM, et al. Intent to use a web-based psychological intervention for partners of cancer patients: Associated factors and preferences. J Psychosoc Oncol. 2018;36(2):203–221.
24. Su Z, Li X, McDonnell D, Fernandez AA, Flores BE, Wang J. Technology-Based Interventions for Cancer Caregivers: Concept Analysis. JMIR Cancer. 2021;7(4):e22140.
25. Schuit AS, Holtmaat K, Hooghiemstra N, Jansen F, Lissenberg-Witte BI, Coupé VMH, et al. Efficacy and cost-utility of the eHealth self-management application “Oncokompas”, helping partners of patients with incurable cancer to identify their unmet supportive care needs and to take actions to meet their needs: a study protocol of a randomized controlled trial. Trials. 2020;21(1):124.
26. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. (2010) CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. BMJ.2010;340: c869.
27. van der Hout A, van Uden-Kraan CF, Holtmaat K, Jansen F, Lissenberg-Witte BI, Nieuwenhuijzen GAP, et al. Role of eHealth application Oncokompas in supporting self-management of symptoms and health-related quality of life in cancer survivors: a randomised, controlled trial. Lancet Oncol. 2020;21(1):80–94.
28. Schuit AS, Holtmaat K, Lissenberg-Witte BI, Eerenstein SEJ, Zijlstra JM, Eeltink C, et al. Efficacy of the eHealth application Oncokompas, facilitating incurably ill cancer patients to self-manage their palliative care needs: A randomized controlled trial. Lancet Reg Heal – Eur. 2022;18:100390.
29. Van Gemert-Pijnen JEWC, Nijland N, Van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of ehealth technologies. J Med Internet Res. 2011;13(4):e111. 1
30. Robinson BC. Validation of a Caregiver Strain Index. J Gerontol. 1983;38(3):344–348.
31. Al-Janabi H, Frew E, Brouwer W, Rappange D, Van Exel J. The inclusion of positive aspects of caring in the Caregiver Strain Index: Tests of feasibility and validity. Int J Nurs Stud. 2010;47(8):984–993.
32. Schwarzer R, Jerusalem M, Weinman J, Wright S, Johnston M. Generalised self-efficacy scale. Causal and control beliefs. In: Weinman J, Wright S, Johnston M (eds). Measures in health psychology: A user’s portfolio. Windsor UK: Nfer-Nelson. 1995.
33. Scholz U, Gutiérrez Doña B, Sud S, Schwarzer R. Is General Self-Efficacy a Universal Construct? Psychometric findings from 25 countries. Eur J Psychol Assess. 2002;18(3):242–251.
34. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. (2011) Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 20(10):1727–36.
35. Janssen B, Szende, A. Population norms for the EQ-5D. In: Szende A, Janssen B, Cabases J (eds). Self-reported population health: An international perspective based on EQ-5D. Dordrecht: Springer Netherlands; 2014.
36. van der Hout A, van Uden-Kraan CF, Holtmaat K, Jansen F, Lissenberg-Witte BI, Nieuwenhuijzen GAP, et al. Reasons for not reaching or using web-based self-management applications, and the use and evaluation of Oncokompas among cancer survivors, in the context of a randomised controlled trial. Internet Interv. 2021;25:100429.
37. Brinkman-Stoppelenburg A, Rietjens JAC, Van Der Heide A. The effects of advance care planning on end-of-life care: A systematic review. Palliat Med. 2014;28(8):1000–1025.

10

GENERAL DISCUSSION



This thesis focused on the role of the web-based self-management intervention Oncokompas in palliative cancer care, targeting incurably ill cancer patients and their partners. In addition, the perspective of patients on the organization of psycho-oncological care was investigated. This chapter contains a summary of the main findings and a reflection on these findings. Strengths and limitations are discussed, as well as implications for clinical practice. Lastly, recommendations for further research are provided.

MAIN FINDINGS OF THIS THESIS

This thesis started with a study on the organization of psycho-oncological care for cancer patients (**chapter 2**). Knowledge on patients' preferences regarding the organization of psycho-oncological care and insight into the barriers and facilitators for receiving psycho-oncological care, enable patient-centered care. From patients' perspectives, organization of psycho-oncological care should focus on easy accessibility and availabiliy, delivered by specialized psychologists and integrated in the cancer care trajectory. Online therapy and group therapy are acceptable, but individual face-to-face therapy is preferred.

Chapter 3 provided background information on the eHealth application Oncokompas, a behavioral intervention technology (BIT) supporting incurably ill cancer patients and their partners to self-manage their symptoms related to cancer and its treatment, or the caregiving experience. Oncokompas is based on the stepped-care principle, supporting patients to take actions to deal with symptoms by themselves, and with professional guidance if needed.

The next part of this thesis (**chapter 4, 5, 6 and 7**) concerned the efficacy and cost-utility of Oncokompas among incurably ill cancer patients, and patients' perspectives on self-management strategies and Oncokompas as an self-management application. A study protocol for a randomized controlled trial (RCT) was described that aimed to examine the efficacy of Oncokompas among incurably ill cancer patients (**chapter 4**). Patients were randomly assigned to the intervention group, getting direct access to Oncokompas in addition to care as usual, or the control group, receiving access after three months. Outcome measures were collected at baseline, two weeks after randomization and three months after the baseline measurement. Results of the RCT showed that Oncokompas did not significantly improve patient activation, self-efficacy and health-related quality of life (HRQOL) among incurably ill cancer patients with a life expectancy of more than three months and recruited in the hospital setting (**chapter 5**). Regarding its cost-utility, it was shown that Oncokompas did not impact incremental costs and seemed slightly less effective in terms of QALYs (**chapter 6**). However, the objectives of self-management interventions as Oncokompas correspond well with the self-management strategies of

patients to cope with cancer; taking a certain responsibility for their own well-being by obtaining automated information and tailored supportive care options (**chapter 7**).
The last part of this thesis (**chapter 8 and 9**) concerned the reach and efficacy of Oncokompas among partners of incurably ill cancer patients. A study protocol for a RCT described the aim to investigate the efficacy of Oncokompas within this population (**chapter 8**), following the same study design as the RCT among incurably ill cancer patients; partners were randomly assigned to the intervention group, which directly got access to Oncokompas, or the control group, which received access to Oncokompas after three months. Outcome measures were asssessed at baseline, two weeks after randomization and three months after the baseline measurement. Results of the RCT showed that Oncokompas had no effect on caregiver burden, self-efficacy or HRQOL among partners of incurably ill cancer patients (**chapter 9**). The reach of Oncokompas among partners with interest in the study was high, but difficulties during the recruitment period suggest that the reach in real life may be lower.

DISCUSSION OF THE MAIN FINDINGS

Patients' preferences for psycho-oncological care and its accessibility

Availability and accessibility of psycho-oncological care services for cancer patients is crucial to provide appropriate care to patients with psychological distress. In **chapter 2**, participants indicated that short time availability of care services are an important reason to choose a specific institute (hospital or a specialized center for psychological cancer care) to receive psycho-oncological care. Furthermore, they described that online therapy and group therapy are acceptable, but they preferred individual face-to-face therapy. With online therapy for example, patients miss non-verbal contact with their therapist and video-consults feel more distant and less personal[1,2]. Insight in patients' preferences enables patient-centered care, taking into account patient preferences, needs and values[3].

Over the past years, there has been ongoing attention for the integration of psycho-oncological care into medical cancer care services[4,5], which highlighs the importance to increase the awareness on psycho-oncological care services among patients and healthcare professionals. Healthcare professionals in the hospital setting – such as oncologists and nurses – play a central role in referral pathways. Paying attention to psycho-oncological needs should be an integrated part of the cancer trajectory[6]. Barriers to receive psycho-oncological care on patient, provider and institutional level might be overcome by implementation of the collaborative care model[7]. The collaborative care model comprises several components to organize psychosocial care across all phases of the medical care trajectory: 1) patient-centered, team-based care to ensure meeting patients' treatment goals, 2) population-based care to review and adjust the care process encouraging assertive outreach for treatment non-responders, 3) measurement-based care, using patient reported outcome measures (PROMs) to encourage shared decision making in order to provide the right care in the right place at the right time, and 4) evidence-based stepped care, providing more intense interventions to patients who did not respond to initial treatment strategies[7]. Collaborative care fits well into quality improvement programs embraced and implemented in hospitals, such as lean management and programs targeting shared decision making, which further advocates for implementation. Based on several components of the collaborative care model[7], such as measurement-based and stepped care, BITs providing an overview of palliative care services, might contribute to this model.

eHealth in palliative cancer care

Previous studies showed positive effects of eHealth interventions on patient empowerment in palliative cancer care, and eHealth contributing to efficient use of palliative care resources[8]. Effects of eHealth in palliative care on health-related quality of life (HRQOL) are ambiguous[9]. It was expected that Oncokompas for incurably ill cancer patients would improve their skills, knowledge and confidence to self-manage their symptoms (i.e., improving patient activation levels), their self-efficacy and HRQOL. However, no improvements on the outcome measures were found within the RCT among these patients (**chapter 5**). The results of this RCT are in line with a pilot study on the feasibility of Oncokompas among incurably ill cancer patients – where Oncokompas was delivered by nurses in the home setting – in which Oncokompas also showed no significant improvements on patient activation and HRQOL[10]. A previous RCT investigating the efficacy of Oncokompas among cancer survivors, also showed that Oncokompas did not improve improve patient activation and self-efficacy[11]. However, Oncokompas did improve HRQOL and reduced symptoms among cancer survivors[11]. Participants of the RCT among incurably ill cancer patients were performing relatively well at baseline. There might have been a ceiling effect of Oncokompas' effects on HRQOL.

Findings of the economic evaluation of Oncokompas among incurably ill cancer patients indicated that Oncokompas does not impact incremental costs and seems slightly less effective than care as usual (**chapter 6**). Evidence on the cost-utility of eHealth interventions is mainly focusing on telemonitoring and video conferencing; to the best of our knowledge this is the first study on cost outcomes regarding a self-guided BIT in palliative cancer care. More studies in palliative cancer care are needed to put our study on the cost-utility of eHealth among incurably ill cancer patients into perspective. This is necessary, because previous research identified the costs of eHealth interventions as a major barrier for its adoption[12] (i.e., the proportion of hospitals wanting to adopt the application and offer it to patients[13]).

In the RCT among incurably ill cancer patients investigating the efficacy of Oncokompas, 26% of the patients in the intervention group did not use Oncokompas as intended, which might have affected its efficacy. Usage as intended was defined as completion of the components 'Measure' and 'Learn' for at least one topic. It was calculated using logging data of Oncokompas[14], which are of added value to gain knowledge of user patterns[15]. However, the percentage of patients that used Oncokompas as intended was higher among incurably ill cancer patients (74%), compared to cancer survivors (52%), which might indicate increased needs for information and advice among this population. In the study among partners of incurably ill cancer patients, an even larger number of partners in the intervention group used Oncokompas as intended (86%). This might be explained by the fact that all partners signed up for the study on their own; therefore, partners might have been motivated to use the application.

Reasons for not using Oncokompas among patients were, among others: no symptom burden, a busy daily schedule, concentration problems, or experiencing technical difficulties[16,17]. Incurably ill cancer patients were included in the RCT irrespective of their palliative care needs. This might provide an explanation for patients not using Oncokompas; experiencing no symptom burden and thereby not needing an application such as Oncokompas. Unfortunately, no qualitative study was performed among partners of incurably ill cancer patients on how they experienced Oncokompas; therefore, no in-depth information is available on the usage of Oncokompas among partners of incurably ill cancer patients. However, perceived usefulness and ease of use of applications are important factors regarding the acceptability of information technologies in healthcare[18].

Besides the efficacy of eHealth, another important factor to take into consideration for implementation of eHealth applications as Oncokompas, is the reach. The reach of interventions provides information on eligibility and participation rates among different user groups[13], and is part of the RE-AIM model which is designed to enhance the quality, speed, and impact of efforts to translate research into practice. Unfortunately, due to privacy regulations it was not possible to gather information on patients who were not interested to participate in the study and no in-depth information was provided on the reach of Oncokompas among incurably ill cancer patients. However, the response rate for this study was 63% (i.e., the percentage of eligible patients wanting to participate in the study), and provides some information on how many patients were interested in participating in the study. Among partners of incurably ill cancer patients the reach was described based on the eligibility rate (83%), participation rate (91%), and the evaluation of differing recruitment methods used for this RCT; partners were most likely reached via patient organizations, palliative care consultants and palliative care networks. However, also for this population no in-depth information is available on partner characteristics in relation to the reach of Oncokompas. Previous research has shown that web-based interventions often reach women with higher education levels[19,20].

Furthermore, health literacy is found to be an important factor for optimizing use of eHealth interventions[21]. Health literacy concerns "the knowledge and competences of persons to meet the complex demands of health in modern society"[22]. In the studies included in this thesis, data on health literacy was not collected; therefore, it was not possible to describe the potential moderating effects of health literacy on the outcome measures. A previous RCT investigating the efficacy of Oncokompas among cancer survivors found that the effect of Oncokompas on HRQOL was moderated by health literacy; survivors with higher health literacy experienced positive effects on HRQOL due to Oncokompas, compared to survivors with lower health literacy[23].

The results of the RCT among incurably ill cancer patients might also be affected by the mixed study population and the possibility of varying stressors and care needs among the included patients, since incurably ill patients with all types of cancer were included with at life expectancy of at least three months, and no upper limit. Oncokompas for use in palliative cancer care was not specifically tailored to specific cancer types; no tumor-specific topics were included. Oncokompas in its current form might not be tailored enough for incurably ill cancer patients. In addition, a relatively large number of patients with brain tumors (28%) were included in the RCT, which might have affected the study results due to cognitive problems as a result of the cancer. Although a participatory design approach was used during the study[24], it might have been valuable to invite specific groups of patients during the development phase (such as patients with brain tumors), to explore their specific wishes and motivations regarding an self-management application as Oncokompas[19] and tailor the application for specific patient groups.

The qualitative study conducted alongside the RCT aimed to obtain insight in patients' self-management strategies to cope with cancer and their experiences with Oncokompas as a fully automated behavioral intervention technology (**chapter 7**). Some participants described Oncokompas' added value on their self-management strategies. For example, prioritizing managing symptoms and comparing your well-being over time, which correspond with earlier studies investigating self-management strategies among incurably ill cancer patients[25,26]. Other participants mentioned that using Oncokompas had no additional value. In addition, it was indicated that people might be more motivated to use the application when they experience symptoms in their daily life. This corresponds with findings on the use of Oncokompas among cancer survivors[17], and is also confirmed by a study on the (non)use of digitally administered patient-reported outcomes in clinical care[27]. Refining the structure of Oncokompas on its technical level to optimize Oncokompas' ease of use and anticipating on reasons for non-use, such as concentration problems or a lack of time, might improve user-friendliness of Oncokompas. This could stimulate patients to use the application more frequently and thereby have a positive effect on patient activation levels.

After conducting the RCT among partners of patients with incurable cancer, no evidence was found on the efficacy of Oncokompas among this population; this study showed no effects on caregiver burden, self-efficacy or HRQOL (**chapter 9**). However, difficulties were encountered to include partners (possibly also as a result of the COVID-19 pandemic), resulting in a small sample size. Results of this study should therefore be interpreted with caution. Our findings that Oncokompas had no effect on caregiver burden, is in line with a recent systematic review and meta-analysis which showed that eHealth had no significant effects on caregiver burden[28]. However, earlier studies reported positive effects of eHealth interventions on informal caregivers' HRQOL and self-efficacy[28,29], which is in contrast with our findings. Additionally, earlier research reported that eHealth empowered family caregivers to seek support for their own well-being[30].

The results of this thesis on the effects of Oncokompas should be interpretated taking some considerations into account. Previous research has shown that the process of self-management can vary over time and the time frame of the RCTs may have been too short[25,31]. Factors affecting self-management are personal or lifestyle characteristics (e.g., knowledge, motivation, psychological distress), health status (e.g., comorbidities, illness severity), resources (e.g., financials, equipment and social support), environmental characteristics (e.g., at home or work), and the healthcare system (e.g., access to the system, relationships with healthcare professional)[32]. A better understanding how these factors influence the efficacy and reach of eHealth interventions targeting self-management, and considering tailoring of eHealth interventions based on re-evaluation of users' needs and wishes, might contribute to effective use of and positive outcomes on self-guided BITs such as Oncokompas in palliative cancer care.

STRENGTHS AND LIMITATIONS

The studies included in this thesis contribute to the knowledge on the effectiveness of interventions based on self-management and BITs in palliative cancer care. Both quantitative and qualitative methods were used to investigate the effects of Oncokompas as a specific example of such an intervention. This is a strength of this thesis, because it can be difficult to explore the effects of complex healthcare interventions by using quantitative methods only[33,34].

Two RCTs were conducted – among both incurably ill cancer patients and their partners – to investigate the efficacy of Oncokompas in palliative cancer care. Incurably ill patients with different cancer types and partners of patients with different cancer types were included, resulting in a broad population of participants in both RCTs.

Another strength of this thesis is that a study on the cost-utility of Oncokompas among incurably ill cancer patients was conducted, alongside the study on the efficacy outcomes. To the best of our knowledge, this is the first study describing a cost-evaluation on a self-guided BIT in palliative cancer care; other studies investigating cost-effectiveness of eHealth interventions in palliative cancer care are mainly focusing on telemonitoring and video conferencing[9].

This thesis also has some limitations, which might have affected the study results and require the results to be interpreted with caution. For both RCTs, sample sizes were calculated prior to the start of the trials to determine the number of participants required to detect relevant differences on the primary outcome measures (i.e., patient activation and caregiver burden) between the intervention group and control group. Effects on secondary outcome measures should be interpreted with caution. Multiple testing might have affected the results of secondary outcome measures. In total, 138 participants were included in the RCT among incurably ill cancer patients; slightly more than the required sample size (i.e., n = 136) which is remarkable since inclusion of participants in palliative care research comes with challenges[35]. However, the RCT among partners had to be stopped early because the inclusion period was not considered feasible and only 58 participants were included in a time frame of 18 months. The small sample size affects the power to detect changes in the outcome measures[36]. Although inclusion of participants was challenging, drop-out rates were relatively low in both RCTs (12% among patients and 10% among partners), compared to what was expected (i.e., 25%).

Regarding the RCT among incurably ill patients, it could be argued whether the results on the efficacy of an eHealth application on the entire group of patients (i.e., with different types of cancer) can be interpreted in a meaningful way. However, due to the small sample sizes in both RCTs, no additional analyses were performed to examine whether the efficacy differed among sub groups (e.g., patients with different cancer types, or users versus non-users). This limitation also holds for the RCT that was conducted among partners; although studies have shown that caregiver burden might be affected by the cancer type of the patient[37], no distinctions were made for partners of patients with different cancer types.

It also should be mentioned that a relatively small follow-up time was used in both RCTs (i.e., three months); it is possible that a longer time period is needed for Oncokompas to cause an effect on the outcome measures for incurably ill cancer patients and partners of incurably ill cancer patients.

Another limitation is that in the RCT among partners of incurably ill cancer patients, the planned cost-evaluation could not be performed due to the small sample size. In addition, it is likely that the cost-utility analysis among patients was underpowered to detect differences in costs and QALYS; no power calculation was performed on economic end points[38]. A propabilistic approach was used rather than significance levels to describe the results of the cost-utility analysis[39].

For both RCTs, no data was gathered on responders versus non-responders of the studies, due to privacy regulations. Therefore, it was not possible to compare characteristics of responders versus non-responders to describe which patients or partners are reached by Oncokompas. Furthermore, in both RCTs no inclusion- or exclusion criteria were handled regarding palliative care needs. It might be that we did not succeed in reaching patients and partners who were most in need of support.
Also, in the RCT among patients with incurable cancer, no information was gathered about time since diagnosis. This might have been interesting because efficacy of the application might be different among patients who are aware of the incurability of their cancer for a longer period of time versus patients who just found out that their cancer is incurable.

Due to the context in which the study among incurably ill cancer patients was performed, selection bias may have occurred, for example due to gatekeeping (i.e., “the reluctance of well-meaning healthcare professionals to contribute patients for research studies”)[40,41]. In addition, in the RCT among partners of incurably ill cancer patients, all participants were self-selected. As a result, partners and patients with an increased interest in eHealth or with a positive attitude towards Oncokompas might have been more likely to participate.
Unfortunately, no qualitative study was performed among partners to explore their experiences with Oncokompas, and to investigate their motivations to participate in the RCT. A multi-component recruitment strategy was used in order to reach a broad group of partners of incurably ill cancer patients. However, an additional focus on recruitment through hospitals might have been a more successful strategy; this was considered difficult due to the recruitment of incurably ill cancer patients for the RCT among patients.

Lastly, for the RCT among incurably ill cancer patients, the most optimal primary outcome measure is a point for discussion. Although patient activation is a widely recognized ouctome to measure self-management skills and Oncokompas primarily aims to stimulate self-management among patients, HRQOL also might have been a sufficient primary outcome, due to the multiple domains covered within the EORTC-QLQ-C15-PAL questionnaire and available in Oncokompas as eHealth application. However, the effects on HRQOL also depend on whether people actually use the resources recommended in Oncokompas; since this could not be influenced by the research team, the primary outcome measure ‘patient activation’ was chosen.

Effects of the COVID-19 pandemic

All studies within this thesis were partly conducted during the COVID-19 pandemic. At the 12th of March 2020, the Dutch government advised all citizens to stay at home[42]. Although it has been reported that the pandemic has served as a catalyst for implementation of telehealth and digital tools[43,44], it probably might have negatively affected the results of the studies in this thesis. This should be noted, to ensure a comprehensive interpretation of the findings.

The pandemic influenced routine palliative care[45,46], which might have effected the results of the RCTs. Patients and partners experienced additional challenges regarding their psychological, social, physical and spiritual well-being[46,47]. Contacts with cancer patients partly changed from face-to-face contacts to telephone or video consultations, and due to social distancing patients might have experienced social isolation, besides anxiety to get infected with COVID-19[46]. Additional challenges due to the pandemic which have been reported among informal caregivers are, among others, increased caring responsibilities, financial insecurities, and adapting to changes in the usual care for the person they care for[47,48].

The eHealth application Oncokompas provides a personalized overview of palliative care options for patients and partners (the ‘Act’ component). The pandemic has affected the availability of certain palliative care options[49,50], and thereby might have influenced the study results; people who did participate in the RCTs during the COVID-19 pandemic may not have had (timely) access to the supportive care options recommended in Oncokompas.

To include partners of incurably ill cancer patients for the RCT among partners, a multi-component recruitment strategy was used. Difficulties were encountered to include partners for participation in the RCT. Among others, healthcare professionals in various settings were asked to inform partners on the study. As reported in chapter 9, many organzations were not able to continue their services as usually, due to the national lockdown, which might have affected the inclusion of partners for the study. Due to this small sample size, the RCT among partners did not create sufficient evidence on the efficacy of Oncokompas in this population, and future studies should try include a larger sample.

IMPLICATIONS FOR CLINICAL PRACTICE

This thesis contributes to the growing awareness on the importance to support cancer patients and their partners to adopt an active role in managing the challenging situation of being confronted with cancer. The numbers of cancer patients are increasing each year and better treatment options make it possible to live with cancer for a longer period of time, challenging both patients and their partners to be in control of their lives as long as possible. At the same time, an increasing demand for care puts the Dutch healthcare system under pressure while human and financial resources are limited. A shift towards prevention and increased attention on self-management behaviors asks for easily accessible interventions to support cancer patients and their partners to take actions regarding their health and well-being. Self-guided eHealth interventions are easily accessible with 24/7 availability and enable users to manage their symptoms on their own, with professional guidance if needed[8,51].

To the best of our knowledge, little evidence is available on the efficacy and costs of self-guided behavioral intervention technologies such as Oncokompas in palliative cancer care. The quantitative studies in this thesis suggest that Oncokompas in its current form is not effective to improve primary outcomes as patient activation among incurably ill cancer patients and caregiver burden among partners of incurably ill cancer patients. Also, no effects were found on secondary outcomes as general self-efficacy and HRQOL. Furthermore, regarding its cost-utility among patients, the application does not impact costs and seems slightly less effective in terms of QALYs. More studies are needed to gain more insight into the use of behavioral intervention technologies in palliative cancer care.

This thesis emphasizes the field of tension regarding the potential of eHealth in cancer care and the results that have been obtained in randomized controlled trials. The studies in this thesis showed no significant effects of Oncokompas regarding its efficacy and cost-utility in palliative cancer care. However, due to uncertainties and limitations of the research, and the possible negative effect of the COVID-19 pandemic, it is not possible to draw firm conclusions. Nevertheless, the studies provide food for thought regarding further development of an eHealth application as Oncokompas and regarding the willingness of healthcare professionals to adopt Oncokompas. A question that remains to be answered is whether further investments in Oncokompas to optimize the application regarding its content (e.g., tailoring the application for specific groups of patients or partners) and its structure (i.e., improving user-friendliness) will lead to higher efficacy and cost-utility. Additionally, concerning the implementation of Oncokompas in palliative cancer care, healthcare professionals might wonder whether they should provide access to Oncokompas to their patients and their patients' partners when scientific studies showed no positive effects on outcome measures. A pilot study exploring the adoption and implementation of Oncokompas in routine clinical practice – conducted in 2015 and 2016 – already showed hospitals resistance to implement Oncokompas due to lack of evidence regarding its (cost-)effectiveness[52].

However, the qualitative study among patients, as described in chapter 7, has shown that patients are open to eHealth applications as Oncokompas. Also, during the development of the palliative version of Oncokompas[53], patients and partners were enthusiastic to cooperate as stakeholders and indicated that they were positive about the development of a supportive intervention as Oncokompas. Different advantages of the application – such as raising the awareness on certain symptoms, stimulating users to prepare themselves for their consult with their healthcare professional and to discuss difficult symptoms or questions with a healthcare professional – could still encourage patients and partners to get the most out of their (often) short consultation time with their healthcare professional. Besides, the application provides information and advice to deal with symptoms on your own. Therefore, it is questionable whether access to Oncokompas should be denied to patients and partners in palliative cancer care despite the findings of the RCTs in this thesis. This question was presented to patients and healthcare providers in clinical practice; based on their answers it was concluded that it would be a waste not to provide access to patients and partners, since Oncokompas is thought to be of value to certain patients and it is expected that Oncokompas would do no harm. They advised to provide access to Oncokompas and monitor the use and efficacy of the application during and after implementation in routine palliative cancer care. Furthermore, also costs of the intervention should be monitored closely; the costs of BITs include not only costs to develop and test the intervention, but also includes maintenance costs and financial resources are often limited[54]. Costs and benefits should be carefully weighed while monitoring the intervention effects.

This thesis also raises the awareness on the importance to facilitate the uptake of self-management behaviors in palliative cancer care. Nowadays people are expected to take a certain responsibility in managing their own well-being and healthcare. Among other things, this is reflected in certain national health programmes in the Netherlands; for example, the health program targeting value-based health care (VBHC), which focuses on patient-oriented care in which patients are stimulated to take an active role in their health[55]. One of the main goals of this health programme is to increase shared-decision making and empower healthcare users such as incurably ill cancer patients and their partners to collaborate with their healthcare professional to receive the care that fits their individual needs and preferences[55]. A self-management intervention such as Oncokompas – although not proven effective in study context – might contribute to the collaboration between healthcare professional and incurably ill cancer patients and their partners, by enabling them with reliable information on different domains on HRQOL. Discussing patients' and partners' individual needs and preferences in palliative cancer care also comprises advanced care planning (ACP), which is defined as "a process that supports adults at any age or stage of health in understanding and sharing their personal values, life goals, and preferences regarding future medical care"[56], to ensure care that fits personal needs and preferences. Investing in self-management behaviors seems rewarding in relation to ACP; higher activation levels are associated with higher levels of ACP engagement[57]. In addition, regarding partner caregivers, ACP might lead to decreased caregiver burden, since it is known that caregivers' unmet needs are negatively associated with caregiver burden[58]. Thus, interventions based on self-management and behavioral intervention technologies in palliative cancer care could contribute to shared decision making in clinical practice – by providing patients and partners with information and advice on their symptoms – and indirectly lead to healthcare that fits the needs and preferences of patients and partner caregivers.

Healthcare professionals also play an important role in adoption of eHealth self-management applications; their attitude and enthusiasm could motivate patients and partners to use an application[8] and prepare patients and caregivers for active involvement in their healthcare[59]. However, self-management also comes with challenges for healthcare professionals[60], since patients and partners of patients have varying self-management strategies, preferences and needs. In order to successfully deliver support to patients and partners also views of healthcare professionals themselves on self-management support play a role for successful implementation of applications in clinical practice[60,61]. Differing approaches regarding self-management support roles of healthcare professionals, such as instructive, collaborative, and advisory support roles, are considered useful under certain circumstances[60] to engage patients and their families in their healthcare. Healthcare professionals themselves also need support, tools and skills for the enhancement of their self-management support role[59,62,63].

Lastly, the importance of psycho-oncological care was highlighted in this thesis. It is well known that the integration of psycho-oncological care as part of medical cancer care is challenging[4]. eHealth applications such as Oncokompas, providing an overview of palliative care services, could facilitate the access to these services and be part of a stepped care model in which self-management applications could serve as low intensity interventions being the first step of a stepped care model. However, it remains important to align delivery mechanisms of self-management interventions depending on the specific population wanting to be reached[59].

RECOMMENDATIONS FOR FUTURE RESEARCH

The studies included in this thesis provide several recommendations for future research regarding behavioral intervention technologies such as Oncokompas.

There has been an ongoing debate whether conducting a randomized controlled trial to examine the efficacy of eHealth interventions is the most appropriate research method. Even when the effects of eHealth are positive in the context of a randomized controlled trial, this does not guarantee similar results in another context[64]. RCTs are often considered als the "gold standard" to examine the effects of interventions. Although RCTs often provide high-quality evidence, other research designs (e.g., stepped wedge) may also be considered highly efficient to gather information on outcomes of interest while offering the possibility during the research process to explore whether manipulations of the intervention lead to meaningful changes regarding the outcome measures[65,66]. It might be interesting to perform certain studies to examine efficiently whether changes regarding Oncokompas' structure or content, might lead to different outcomes. In addition, it is important to perform real world studies to build evidence on the usage and effects of self-management applications as Oncokompas in palliative cancer care.

Furthermore, it would be interesting to examine the effects of BITs such as Oncokompas during the different phases of palliative cancer care. The time since diagnosis and the phase of illness might affect the efficacy of behavioral interventions. Earlier research has shown that different phases of the cancer trajectory are distuingished by differences in physical, psychological and existential symptoms among patients, and differing needs among patients' informal caregivers[67]. For informal caregivers, sources of burden could vary by the phase of the cancer trajectory; caregivers often experience higher burden in the advanced stage of the disease and the end-of-life phase, compared to the survivorship phase[68]. In line with this, it might be interesting for future eHealth studies to conduct the research particularly among those patients and partners who have expressed high distress levels or a need for palliative care. Earlier research indicated that self-guided interventions are possibly more effective when they are offered to user groups with higher needs[69]. Previous research also mentioned the great variance of palliative care needs over the cancer trajectory[70], which indicates the importance to offer eHealth interventions rather based upon care needs, than based upon the stage in the illness trajectory.

Regarding specific follow-up studies for Oncokompas, future research should examine the effects of Oncokompas among incurably ill cancer patients and their partners who have used Oncokompas in a varying degree. This would be interesting to gain knowlegde on the amount of time that people have spent on using the appliation, and plot this against the efficacy of the application.

Lastly, Oncokompas was researched among patients with incurable cancer and among partners of patients with incurable cancer. It would be interesting to examine the effects of Oncokompas when dyads use the application together, since there is growing literature supporting dyadic eHealth interventions[71]. Joint use of Oncokompas may enhance the effects of the intervention on outcome measures regarding self-management, HRQOL and caregiver burden.

CONCLUSIONS

This thesis contributes to the knowledge on the efficacy and cost-utility of eHealth applications stimulating self-management in palliative cancer care, in particular among incurably ill cancer patients and their partners. This knowledge can be used to develop eHealth self-management interventions as part of palliative cancer care, and for their implementation and evaluation. This thesis showed no significant effects of Oncokompas regarding its efficacy and cost-utility among incurably ill cancer patients and their partners. More studies are needed on self-guided behavioral self-management interventions to be able to make a comprehensive and well-founded statement of their role in supporting self-management in palliative cancer care. However, it is important for palliative care services and psycho-oncological care that those services are easily available and accessible, to optimally support incurably ill cancer patients and partner caregivers with care needs when facing challenges as a result of cancer.

REFERENCES

1. van der Lee ML, Schellekens MPJ. Bridging the distance: Continuing psycho-oncological care via video-consults during the COVID-19 pandemic. Psychooncology. 2020;29(9):1421–1423.
2. Wallin EEK, Mattsson S, Olsson EMG. The Preference for Internet-Based Psychological Interventions by Individuals Without Past or Current Use of Mental Health Treatment Delivered Online: A Survey Study With Mixed-Methods Analysis. JMIR Ment Heal. 2016;3(2):e25.
3. Loiselle CG, Brown TL. Increasing access to psychosocial oncology services means becoming more person-centered and situation-responsive. Support Care Cancer. 2020;28:5601-5603.
4. Fann JR, Ell K, Sharpe M. Integrating psychosocial care into cancer services. J Clin Oncol. 2012;30(11):1178–1186.
5. Jacobsen PB, Wagner LI. A new quality standard: The integration of psychosocial care into routine cancer care. J Clin Oncol. 2012;30(11):1154–1159.
6. Frey Nascimento A, Tondorf T, Rothschild SI, Koller MT, Rochlitz C, Kiss A, et al. Oncologist recommendation matters!—Predictors of psycho-oncological service uptake in oncology outpatients. Psychooncology. 2019;28(2):351–357.
7. Fann JR, Ruark J, Sharpe M. Delivering Integrated Psychosocial Oncology Care. The Collaborative Care Model. Psychooncology. 2021;385.
8. Widberg C, Wiklund B, Klarare A. Patients' experiences of eHealth in palliative care: an integrative review. BMC Palliat Care. 2020;19:158.
9. Finucane AM, O'Donnell H, Lugton J, Gibson-Watt T, Swenson C, Pagliari C. Digital health interventions in palliative care: a systematic meta-review. npj Digit Med. 2021;4:64.
10. de Veer AJE, Slev VN, Roeline Pasman H, Verdonck-De Leeuw IM, Francke AL, van Uden-Kraan CF. Assessment of a structured self-management support intervention by nurses for patients with incurable cancer. Oncol Nurs Forum. 2020;47(3):305–317.
11. van der Hout A, van Uden-Kraan CF, Holtmaat K, Jansen F, Lissenberg-Witte BI, Nieuwenhuijzen GAP, et al. Role of eHealth application Oncokompas in supporting self-management of symptoms and health-related quality of life in cancer survivors: a randomised, controlled trial. Lancet Oncol. 2020;21(1):80–94.
12. Granja C, Janssen W, Johansen MA. Factors determining the success and failure of ehealth interventions: Systematic review of the literature. J Med Internet Res. 2018;20(5):e10235.
13. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. Am J Public Health. 1999;89(9):1322–1327.
14. Schuit AS, Holtmaat K, Lissenberg-Witte BI, Eerenstein SEJ, Zijlstra JM, Eeltink C, et al. Efficacy of the eHealth application Oncokompas, facilitating incurably ill cancer patients to self-manage their palliative care needs: A randomized controlled trial. Lancet Reg Heal - Eur. 2022;18:100390.
15. Sieverink F, Kelders S, Poel M, van Gemert-Pijnen L. Opening the black box of electronic health: Collecting, analyzing, and interpreting log data. JMIR Res Protoc. 2017;6(8):e156.
16. Schuit AS, van Zwieten V, Holtmaat K, Cuijpers P, Eerenstein SEJ, Leemans CR, et al. Symptom monitoring in cancer and fully automated advice on supportive care: Patients' perspectives on self-management strategies and the eHealth self-management application Oncokompas. Eur J Cancer Care. 2021;30(6):e13497.
17. van der Hout A, van Uden-Kraan CF, Holtmaat K, Jansen F, Lissenberg-Witte BI, Nieuwenhuijzen GAP, et al. Reasons for not reaching or using web-based self-management applications, and the use and evaluation of Oncokompas among cancer survivors, in the context of a randomised controlled trial. Internet Interv. 2021;25:100429.
18. Venkatesh V, Morris MG, Davis GB, Davis FD. User Acceptance of Information Technology: Toward a Unified View. MIS Q. 2003;27(3):425–78.

19. Ludden GDS, Van Rompay TJL, Kelders SM, Van Gemert-Pijnen JEWC. How to increase reach and adherence of web-based interventions: A design research viewpoint. J Med Internet Res. 2015;17(7):e172.
20. Kelders SM, T. Bohlmeijer E, Van Gemert-Pijnen JEWC. Participants, usage, and use patterns of a web-based intervention for the prevention of depression within a randomized controlled trial. J Med Internet Res. 2013;15(8):e172.
21. Halwas N, Griebel L, Huebner J. eHealth literacy, Internet and eHealth service usage: a survey among cancer patients and their relatives. J Cancer Res Clin Oncol. 2017;143(11):2291–2299.
22. Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy and public health: A systematic review and integration of definitions and models. BMC Public Health. 2012;12:80.
23. van der Hout A, Holtmaat K, Jansen F, Lissenberg-Witte BI, van Uden-Kraan CF, Nieuwenhuijzen GAP, et al. The eHealth self-management application 'Oncokompas' that supports cancer survivors to improve health-related quality of life and reduce symptoms: which groups benefit most? Acta Oncol. 2021;60(4):403-411.
24. van Gemert-Pijnen JEWC, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res. 2011;13(4):e111.
25. van Dongen SI, de Nooijer K, Cramm JM, Francke AL, Oldenmenger WH, Korfage IJ, et al. Self-management of patients with advanced cancer: A systematic review of experiences and attitudes. Palliat Med. 2020;34(2):160–78.
26. Budhwani S, Wodchis WP, Zimmermann C, Moineddin R, Howell D. Self-management, self-management support needs and interventions in advanced cancer: A scoping review. BMJ Support Palliat Care. 2019;9(1):12–25.
27. Nielsen AS, Kidholm K, Kayser L. Patients' reasons for non-use of digital patient-reported outcome concepts: A scoping review. Health Informatics J. 2020;26(4):2811–2833.
28. Li Y, Li J, Zhang Y, Ding Y, Hu X. The effectiveness of e-Health interventions on caregiver burden, depression, and quality of life in informal caregivers of patients with cancer: A systematic review and meta-analysis of randomized controlled trials. Int J Nurs Stud. 2022;127:104179.
29. Ploeg J, Ali MU, Markle-Reid M, Valaitis R, Bartholomew A, Fitzpatrick-Lewis D, et al. Caregiver-focused, web-based interventions: Systematic review and meta-analysis (Part 2). J Med Internet Res. 2018;20(10):e11247.
30. Darley A, Coughlan B, Furlong E. People with cancer and their family caregivers' personal experience of using supportive eHealth technology: A narrative review. Eur J Oncol Nurs. 2021;54:102030.
31. Schulman-Green D, Martin F, Alonzo A, Grey M, McCorkle R, Redeker NS, et al. Process of Self-management in Chronic Illness. J Nurs Scholarsh. 2012;44(2):136–144.
32. Schulman-Green D, Jaser SS, Park C, Whittemore R. A metasynthesis of factors affecting self-management of chronic illness. J Adv Nurs. 2016;72(7):1469–1489.
33. O'Cathain A, Thomas KJ, Drabble SJ, Rudolph A, Hewison J. What can qualitative research do for randomised controlled trials? A systematic mapping review. BMJ Open. 2013;3:e002889.
34. Lewin S, Glenton C, Oxman AD. Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: Methodological study. BMJ. 2009;339:b3496.
35. ZonMw. Succesvol Includeren in de palliatieve zorg. 2014. Available from:https://www.zonmw.nl/uploads/tx_vipublicaties/Rapport_Succesvol_includeren_in_de_palliatieve_zorg_DEF.pdf. (accessed May 28, 2022)
36. Jones SR, Carley S, Harrison M. An introduction to power and sample size estimation The importance of power and sample size estimation for study design and analysis. Emerg Med J. 2003;20:453–458.

37. Ge L, Mordiffi SZ. Factors Associated with Higher Caregiver Burden among Family Caregivers of Elderly Cancer Patients: A Systematic Review. Cancer Nurs. 2017;40(6):471–478.

38. Hollingworth W, McKell-Redwood D, Hampson L, Metcalfe C. Cost-utility analysis conducted alongside randomized controlled trials: Are economic end points considered in sample size calculations and does it matter? Clin Trials. 2013;10(1):43–53.

39. Elliott R, Payne K. Statistical handling of data in economic analysis Essentials of Economic Evaluation in Healthcare. Pharmaceutical Press. London, UK: 2004.

40. White C, Gilshenan K, Hardy J. A survey of the views of palliative care healthcare professionals towards referring cancer patients to participate in randomized controlled trials in palliative care. Support Care Cancer. 2008;16(12):1397–1405.

41. Kars MC, Van Thiel GJMW, Van Der Graaf R, Moors M, De Graeff A, Van Delden JJM. A systematic review of reasons for gatekeeping in palliative care research. Palliat Med. 2016;30(6):533–548.

42. Rijksoverheid. New measures to stop spread of coronavirus in the Netherlands. 2020. Available from: https://www.government.nl/topics/coronavirus-covid-19/news/2020/03/12/new-measures-to-stop-spread-of-coronavirus-in-the-netherlands. (accessed May 28, 2022)

43. Wind TR, Rijkeboer M, Andersson G, Riper H. The COVID-19 pandemic: The ‘black swan’ for mental health care and a turning point for e-health. Internet Interv. 2020;20:10037.

44. Torous J, Myrick KJ, Rauseo-Ricupero N, Firth J. Digital mental health and COVID-19: Using technology today to accelerate the curve on access and quality tomorrow. J Med Internet Res. 2020;7(3):e18848.

45. Mehta AK, Smith TJ. Palliative Care for Patients With Cancer in the COVID-19 Era. JAMA Oncol. 2020;6(10):1527–1528.

46. Schoenmaekers JJAO, Hendriks LEL, van den Beuken-van Everdingen MHJ. Palliative Care for Cancer Patients During the COVID-19 Pandemic, With Special Focus on Lung Cancer. Front Oncol. 2020;10:1405.

47. Egan K. Digital Technology, Health and Well-Being and the Covid-19 Pandemic: It’s Time to Call Forward Informal Carers from the Back of the Queue. Semin Oncol Nurs. 2020;36(6):151088.

48. Tokarz J, Tokarz JA, Hold J. Being a Caregiver in the Time of a Pandemic: An Integrative Review. MSN Leadersh Nurs Final Proj. 2021;16.

49. Chavez MN, Marshall V, Tyson DM, Mason T, Rechenberg K. Oncology Health Care Providers’ Perceptions of the Psychological Impact of COVID-19 on Oncology Patients. 2021;1–17.

50. Wang Y, Bi N. The Impact of the COVID-19 Pandemic on Palliative Care Practice for Cancer : A Qualitative Study among Clinical Oncologists. Prepr under Rev. 2022;1–13.

51. Aapro M, Bossi P, Dasari A, Fallowfield L, Gascón P, Geller M, et al. Digital health for optimal supportive care in oncology: benefits, limits, and future perspectives. Support Care Cancer. 2020;28(10):4589–4612.

52. Matthijs de Wit L, van Uden-Kraan CF, Lissenberg-Witte BI, Melissant HC, Fleuren MAH, Cuijpers P, et al. Adoption and implementation of a web-based self-management application “Oncokompas” in routine cancer care: a national pilot study. Support Care Cancer. 2019;27(8):2911–2920.

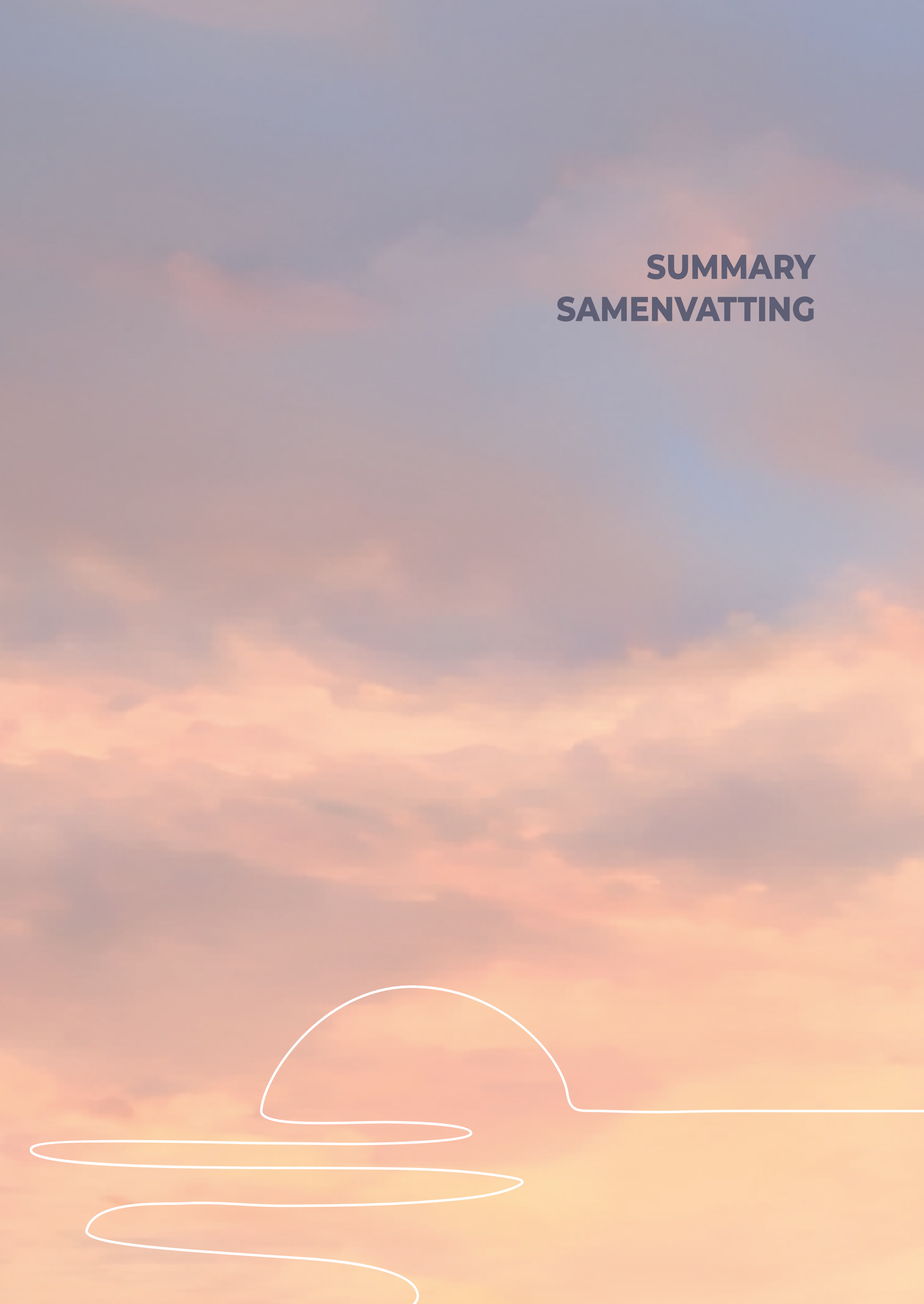
53. Schuit AS, Holtmaat K, Hooghiemstra N, Jansen F, Lissenberg-Witte BI, Coupé VMH, et al. Efficacy and cost-utility of the eHealth application “Oncokompas”, supporting patients with incurable cancer in finding optimal palliative care, tailored to their quality of life and personal preferences: A study protocol of a randomized controlled trial. BMC Palliat Care. 2019;18:85.

54. Hermes EDA, Lyon AR, Schueller SM, Glass JE. Measuring the implementation of behavioral intervention technologies: Recharacterization of established outcomes. J Med Internet Res. 2019;21(1):e11752.

55. Ministerie van Volksgezondheid W en S. Programma Uitkomstgerichte Zorg. 2018. Available from: https://www.uitkomstgerichtezorg.nl/over-uitkomstgerichte-zorg. (accessed June 18, 2022)

56. Sudore RL, Lum HD, You JJ, Hanson LC, Meier DE, Pantilat SZ, et al. Defining Advance Care Planning for Adults: A Consensus Definition From a Multidisciplinary Delphi Panel. J Pain Symptom Manage. 2017;53(5):821-832.e1.
57. David D, Barnes DE, McMahan RD, Shi Y, Katen MT, Sudore RL. Patient Activation: A Key Component of Successful Advance Care Planning. J Palliat Med. 2018;21(12):1778–1782.
58. Sharpe L, Butow P, Smith C, McConnell D, Clarke S. The relationship between available support, unmet needs and caregiver burden in patients with advanced cancer and their carers. Psychooncology. 2005;14(2):102–114.
59. Howell D, Mayer DK, Fielding R, Eicher M, Verdonck-De Leeuw IM, Johansen C, et al. Management of cancer and health after the clinic visit: A call to action for self-management in cancer care. J Natl Cancer Inst. 2021;113(5):523–531.
60. van Dongen SI, Stoevelaar R, Kranenburg LW, Noorlandt HW, Witkamp FE, van der Rijt CCD, et al. The views of healthcare professionals on self-management of patients with advanced cancer: An interview study. Patient Educ Couns. 2022;105(1):136–144.
61. Foster C, Calman L, Richardson A, Pimperton H, Nash R. Improving the lives of people living with and beyond cancer: Generating the evidence needed to inform policy and practice. J Cancer Policy. 2018;15:92–95.
62. Foster C. The need for quality self-management support in cancer care. BMJ Qual Saf. 2022;31(1):1-4.
63. de Silva D. Evidence: helping people help themselves. A review of the evidence considering whether it is worthwile to support self-management. London: Health Foundation; 2011.
64. Zorginstituut Nederland. Evaluatie van eHealth-technologie in de context van beleid. 2017. Available from: https://www.zorginstituutnederland.nl/publicaties/publicatie/2017/05/17/evaluatie-van-ehealth-technologie. (accessed June 11, 2022)
65. Baker TB, Gustafson DH, Shah D. How can research keep up with eHealth? Ten strategies for increasing the timeliness and usefulness of Ehealth research. J Med Internet Res. 2014;16(2):e36.
66. Lyons VH, Li L, Hughes JP, Rowhani-Rahbar A. Proposed variations of the stepped-wedge design can be used to accommodate multiple interventions. J Clin Epidemiol. 2017;86:160–167.
67. Mather H, Guo P, Firth A, Davies JM, Sykes N, Landon A, et al. Phase of Illness in palliative care: Cross-sectional analysis of clinical data from community, hospital and hospice patients. Palliat Med. 2018;32(2):404–412.
68. Northouse LL, Katapodi MC, Schafenacker AM, Weiss D. The Impact of Caregiving on the Psychological Well-Being of Family Caregivers and Cancer Patients. Semin Oncol Nurs. 2012;28(4):236–245.
69. Ugalde A, Haynes K, Boltong A, White V, Krishnasamy M, Schofield P, et al. Self-guided interventions for managing psychological distress in people with cancer – A systematic review. Patient Educ Couns. 2017;100(5):846–857.
70. Vogt J, Beyer F, Sistermanns J, Kuon J, Kahl C, Alt-Epping B, et al. Symptom Burden and Palliative Care Needs of Patients with Incurable Cancer at Diagnosis and During the Disease Course. Oncologist. 2021;26(6):e1058–e1065.
71. Shaffer KM, Tigershtrom A, Badr H, Benvengo S, Hernandez M, Ritterband LM. Dyadic psychosocial eHealth interventions: Systematic scoping review. J Med Internet Res. 2020;22(3):e15509.

SUMMARY
SAMENVATTING



SUMMARY

Chapter 1 presents the general introduction of this thesis. This chapter gives a description of the impact of cancer on the lives of incurably ill cancer patients and their partners. They experience symptoms affecting their health-related quality of life. Palliative care is an approach to improve the quality of life of patients and their partners, facing problems with a life-limiting illness. This chapter also provides an introduction on self-management and describes how eHealth could support people in their daily lives. The eHealth application Oncokompas was developed to support users to take an active role in managing their symptoms, by using patient-reported outcome measures (PROMs). Background information is provided on the development of Oncokompas to make the content suitable for use in palliative cancer care. The overall aim of this thesis was to provide insight into the role of the web-based self-management intervention Oncokompas in palliative care, targeting patients with incurable cancer and their partners. Furthermore, patients' perspectives on organizing psycho-oncological cancer care were investigated.

Chapter 2 describes a qualitative study investigating patients' perspectives on the organization of psycho-oncological cancer care. The study aimed to obtain insight into cancer patients' preferences and the barriers and facilitators they experienced to receive psycho-oncological treatment. In total, 18 semi-structured interviews were conducted among cancer patients who completed psycho-oncological treatment between 2015 and 2020, at the psychology department in a general hospital, or a center specialized in psychological cancer care. Patients indicated that the organization of psycho-oncological care for cancer should focus on easy accessibility and availability, delivered by specialized psychologists, and integrated in medical cancer care. Individual therapy is preferred above online and group therapy. Increasing the awareness on psycho-oncological care among patients and healthcare providers is warranted.

Chapter 3 presents the Intermezzo, in which Oncokompas is described in detail. Screenshots are provided of the three components within Oncokompas: 1) Measure, 2) Learn, and 3) Act. Initially, Oncokompas was developed targeting cancer survivors, but the application was further developed to make it suitable for patients with incurable cancer and their partners. By using PROMs, users can monitor their physical, psychological, social and existential well-being ('Measure'), get tailored feedback and advice ('Learn'), and receive an overview of supportive care options ('Act'). A three-color system (green, orange and red) is used to present well-being scores to the users; each color indicates whether attention and support is needed for a specific topic.

Chapter 4 provides the study protocol of the randomized controlled trial (RCT) to investigate the efficacy and cost-utility of Oncokompas among patients with incurable cancer. Patients were referred to the study by their healthcare professional in the participating hospitals. Participants were randomly assigned to the intervention group, getting direct access to Oncokompas in addition to care as usual, or the control group, receiving access after three months. Outcome measures were collected at baseline, two weeks after randomization and three months after the baseline measurement. The primary outcome measure was the Patient Activation Measure (PAM), measuring patients' knowledge, skills and confidence for self-management. Secondary outcome measures were general self-efficacy (GSE), and health-related quality of life (HRQOL). In addition, cost outcomes included quality-adjusted life years (QALYs) and incremental costs.

Chapter 5 presents the results of the RCT on the efficacy of Oncokompas among patients with incurable cancer. In total, 138 patients were randomly assigned to the intervention group (n=69), getting direct access to Oncokompas, or the control group (n=69), getting access to Oncokompas after three months. The study was partly conducted during the COVID-19 pandemic. No significant differences between the intervention and control group were found over time in patient activation (estimated difference in change T0-T2; 1·8 (90% CI: -1·0 to 4·7)), neither in general self-efficacy and HRQOL. Of the patients in the intervention group who activated their account, 74% used Oncokompas as intended. The course of patient activation, general self-efficacy, and HRQOL was not significantly different between patients who used Oncokompas as intended versus those who did not.

Chapter 6 shows the results on the cost-utility study of Oncokompas among patients with incurable cancer. Costs were calculated from a societal perspective and included costs of healthcare, costs for patients and their families (e.g., travelling costs, help received from family and friends), costs within other sectors (e.g., productivity losses), and intervention costs. In the base case analysis, mean total costs and mean total effects were non-significantly lower in the intervention group (–€806 and –0.01 QALYs, respectively). The probability that the intervention was more effective and less costly was 4%, whereas the probability that it was less effective and less costly was 74%. All sensitivity analyses showed non-significantly lower costs (–€990 to –€401) and non-significantly lower QALYs (–0.02 to –0.01) for the intervention group compared to the control group. The only exceptions were the base case analysis with no corrections for baseline EQ5D and costs, and the complete case analysis in which significantly lower QALYs were found in the intervention group compared to the control group (–0.02 and –0.01, respectively). It was concluded that Oncokompas does not impact incremental costs and seems slightly less effective in terms of QALYs, compared to care as usual.

Chapter 7 reports on the results of the qualitative study among cancer patients to get insight in patients' self-management strategies to cope with cancer and their experiences with Oncokompas. In total, 22 participants were interviewed. Participants applied several self-management strategies, in which trying to stay in control and make the best of their situation. The added value of Oncokompas was described as being able to monitor symptoms and having access to a personal online library. The main reasons not to use Oncokompas were concentration problems, lack of time or having technical issues. Participants described recommendations for further development of Oncokompas, relating to its content, technical and functional aspects. The objectives of self-management interventions as Oncokompas correspond well with these strategies: taking a certain responsibility for your well-being and being in charge of your life as long as possible by obtaining automated information (24/7) on symptoms and tailored supportive care options.

Chapter 8 shows the study protocol of the RCT on the efficacy of Oncokompas among partners of patients with incurable cancer. A multi-component recruitment strategy was followed as partners were recruited through (online) recruitment materials, healthcare professionals, and direct contact with the researcher. Partners were randomly assigned to the intervention group, getting direct access to Oncokompas, or the control group, receiving access after three months. Outcome measures were collected at baseline, two weeks after randomization and three months after the baseline measurement. The primary outcome measure was caregiver burden. Secondary outcome measures comprised general self-efficacy, HRQOL, and cost outcomes.

Chapter 9 describes the results of the RCT on the efficacy of Oncokompas among partners of patients with incurable cancer. In total, 58 partners were included in the RCT, partly during the COVID-19 pandemic. Reaching the target of 136 included partners was considered not to be feasible after an inclusion period of 18 months. Therefore, the study stopped early. The results showed no significant effects of Oncokompas on caregiver burden, self-efficacy or HRQOL. The reach was estimated based on eligibility, participation rate, and evaluation of the recruitment process, and estimated at 83-91%. Partners were most likely reached via palliative care consultants, patient organizations and palliative care networks and less likely via home care organizations, general practitioners, and hospitals. The reach of Oncokompas among interested individuals was high, but the difficulties that were encountered to include partners suggest that the reach in real life may be lower. Due to the small sample size, the cost-utility analysis was deemed not to be feasible and was not carried out.

Chapter 10 presents the general discussion of this thesis. An overview is provided of all chapters and the main findings of all studies are discussed. The strengths and limitations of this thesis are provided. In addition, the implications for clinical practice are described. Furthermore, several recommendations for future research were proposed. This thesis contributes to the knowledge on the efficacy and cost-utility of eHealth applications stimulating self-management in palliative cancer care, in particular among incurably ill cancer patients and their partners. No significant effects were found of Oncokompas regarding its efficacy and cost-utility among incurably ill cancer patients and their partners. More studies are needed on self-guided self-management interventions to be able to make a comprehensive and well-founded statement of their role in supporting self-management in palliative cancer care. However, it is important that palliative care services and psycho-oncological care are easily available and accessible, to optimally support incurably ill cancer patients and partner caregivers with care needs when facing challenges as a result of cancer.

SAMENVATTING

Hoofdstuk 1 omvat de algemene introductie van dit proefschrift. Dit hoofdstuk geeft een beschrijving van de impact die kanker heeft op patiënten met een ongeneeslijke vorm van kanker en hun partners. Zij kunnen symptomen ervaren die hun kwaliteit van leven beïnvloeden. Palliatieve zorg heeft als doel om de kwaliteit van leven van ongeneeslijk zieke patiënten en hun naasten te verbeteren. In dit hoodfstuk wordt daarnaast het begrip zelfmanagement beschreven, en wordt uitgelegd hoe eHealth mensen kan ondersteunen in hun dagelijks leven. De eHealth applicatie Oncokompas is ontwikkeld om gebruikers te ondersteunen een actieve rol aan te nemen ten aanzien van hun gezondheid door gebruik te maken van *patient reported outcome measures* (PROMs). Er wordt achtergrondinformatie gegeven over de ontwikkeling van Oncokompas om de inhoud van de applicatie geschikt te maken voor gebruik binnen de palliatieve zorg voor mensen met kanker en hun partners. Het doel van dit proefschrift is om inzicht te verschaffen in de rol van de eHealth applicatie Oncokompas binnen de palliatieve zorg, gericht op patiënten met een ongeneeslijke vorm van kanker en hun partners. Ook is onderzocht hoe patiënten aankijken tegen de organisatie van psycho-oncologische zorg.

Hoofdstuk 2 beschrijft de resultaten van een kwalitatieve studie, waarin mensen met en na kanker zijn geïnterviewd over hun ervaring met en ideeën over de organisatie van psycho-oncologische zorg. Het doel van dit onderzoek was om inzicht te verkrijgen in de voorkeuren van mensen met en na kanker wat betreft psycho-oncologische zorg, en na te gaan welke factoren dit vergemakkelijken of juist moeilijker maken. In totaal zijn 18 semi-gestructureerde interviews uitgevoerd onder mensen die tussen 2015 en 2020 een psycho-oncologische behandeling hebben afgerond op de afdeling Psychologie van een algemeen ziekenhuis, of in een centrum gespecialiseerd in psycho-oncologische zorg. De geïnterviewden gaven aan dat de organisatie van psycho-oncologische zorg voor kanker zich moet richten op een goede toegankelijkheid en beschikbaarheid van zorg. Zij hadden de voorkeur voor zorg geleverd door gespecialiseerde psychologen en benadrukten het belang om psycho-oncologische zorg te integreren in de medische zorg voor mensen met kanker. Individuele therapie heeft de voorkeur boven online therapie en groepstherapie. Het is noodzakelijk om het bewustzijn rondom psycho-oncologische zorg onder (ex-) patiënten en zorgverleners verder te vergroten.

Hoofdstuk 3 betreft het Intermezzo, waarin Oncokompas meer in detail is beschreven. Aan de hand van screenshots uit Oncokompas, worden de verschillende onderdelen in Oncokompas besproken: 1) Meten, 2) Weten en 3) Doen. Oncokompas is in eerste instantie ontwikkeld voor overlevers van kanker, maar de applicatie is verder uitgebreid om de inhoud ook geschikt te maken voor mensen met een ongeneeslijke vorm van kanker en hun partners. Door middel van PROMs kunnen gebruikers hun lichamelijke, psychologische, sociale en existentiële welzijn monitoren (‘Meten’), ontvangen zij feedback en advies op maat (‘Weten’), en krijgen zij een overzicht van begeleidende zorgmogelijkheden (‘Doen’). Een drie-kleurensysteem (groen, oranje en rood) wordt gebruikt om welzijnsscores aan de gebruiker te presenteren; elke kleur geeft aan of er aandacht en ondersteuning nodig is op een bepaald onderwerp.

Hoofdstuk 4 omschrijft het studie protocol van de gerandomiseerde gecontroleerde studie (*randomized controlled trial* (RCT)) naar de effectiviteit en kostenutiliteit van Oncokompas onder patiënten met een ongeneeslijke vorm van kanker. Patiënten werden door hun zorgverlener in de deelnemende ziekenhuizen naar het onderzoek verwezen. Geïncludeerde patiënten werden willekeurig toegewezen aan de interventiegroep (direct toegang tot Oncokompas naast de gebruikelijke zorg), of de controle groep (gebruikelijke zorg; toegang tot Oncokompas na drie maanden). Uitkomstmaten werden verzameld op baseline, twee weken na de randomisatie, en drie maanden na de baseline meting. De primaire uitkomstmaat was de *Patient Activation Measure* (PAM); deze meet de kennis, vaardigheden en het zelfvertrouwen van mensen in zelfmanagement van hun ziekte en welzijn. Secundaire uitkomstmaten waren *General Self-Efficacy* (GSE), en gezondheidsgerelateerde kwaliteit van leven (*health-related quality of life* (HRQOL)). De uitkomstmaten voor de kostenutiliteitsanalyse waren voor kwaliteit gecorrigeerde levensjaren (*quality-adjusted life years* (QALY’s)) en incrementele kosten.

Hoofdstuk 5 presenteert de resultaten van de RCT naar het effect van Oncokompas onder patiënten met een ongeneeslijke vorm van kanker. In totaal werden 138 patiënten gerandomiseerd over de interventiegroep (n=69) en de controlegroep (n=69). De studie werd deels uitgevoerd tijdens de COVID-19 pandemie. Er werden geen significante verschillen over tijd gevonden tussen de interventiegroep en de controlegroep wat betreft *patient activation* (geschat verschil in verandering T0-T2; 1.8 (90% BI; -1.0 tot 4.7), *general self-efficacy* en HRQOL. Van de patiënten die hun account activeerden, heeft 74% gebruik gemaakt van Oncokompas zoals bedoeld. Het verloop van *patient activation*, *general self-efficacy* en HRQOL was niet significant verschillend tussen patiënten die Oncokompas gebruikten zoals bedoeld, en degenen die Oncokompas niet hadden gebruikt zoals bedoeld.

Hoofdstuk 6 schetst de resultaten met betrekking tot de kostenutiliteit van Oncokompas onder patiënten met een ongeneeslijke vorm van kanker. De kostenutiliteit analyses werden uitgevoerd vanuit een maatschappelijk perspectief, en omvatten de kosten binnen de gezondheidszorg, kosten van patiënten en hun families (e.g., reiskosten, hulp van familie en vrienden), kosten in andere sectoren (e.g., productiviteitsverliezen) en interventiekosten. In de base-case analyse waren de gemiddelde totale kosten en de totale effecten lager dan in de interventiegroep, maar niet significant (respectievelijk –€806 en –0.01 QALY's). De kans dat de interventie effectiever en goedkoper is, is 4%. De kans dat de interventie minder effectief en goedkoper is, is 74%. Alle sensitiviteitsanalyses lieten lagere kosten (–€990 tot –€401) en lagere QALY's (–0.02 tot –0.01) zien voor de interventiegroep in vergelijking met de controlegroep, ook niet significant. De enige uitzonderingen waren de base-case analyse zonder correcties voor baseline EQ-5D en kosten, en de analyse met alleen complete data, waarin significant lagere QALY's werden gevonden in de interventiegroep in vergelijking met de controlegroep (respectievelijk –0.02 en –0.01). De conclusie met betrekking tot de kostenutiltiteit is dat Oncokompas geen invloed heeft op de incrementele kosten en iets minder effectief lijkt op het gebied van QALY's, vergeleken met gebruikelijke zorg.

Hoofdstuk 7 rapporteert de resultaten van de kwalitatieve studie onder mensen met en na kanker, om inzicht te verkrijgen in zelfmanagement strategieën voor het omgaan met kanker, en hun ervaringen met Oncokompas. In totaal zijn 22 deelnemers geïnterviewd. De deelnemers pasten verschillende zelfmanagement strategieën toe. Voorbeelden zijn het zoveel mogelijk proberen controle te houden over het leven, en het beste uit de situatie proberen te halen. De toegevoegde waarde van Oncokompas is onder andere het kunnen monitoren van symptomen en toegang hebben tot een persoonlijke, online bibliotheek. De belangrijkste redenen om Oncokompas niet te gebruiken waren concentratieproblemen, tijdgebrek of technische problemen. Deelnemers beschreven aanbevelingen voor de verdere ontwikkeling van Oncokompas met betrekking tot de inhoud, en technische en functionele aspecten. De doelstellingen van zelfmanagement interventies als Oncokompas sluiten goed aan bij de genoemde zelfmanagement strategieën; een zekere verantwoordelijkheid nemen voor je eigen welzijn en zo lang mogelijk de regie over je leven voeren, door het verkrijgen van (24/7) geautomatiseerde informatie over symptomen en begeleidende zorgmogelijkheden, die zijn afgestemd op de persoonlijke behoeften.

Hoofdstuk 8 beschrijft het onderzoeksprotocol van de RCT naar het effect van Oncokompas onder partners van patiënten met een ongeneeslijke vorm van kanker. Er werd gebruik gemaakt van een wervingsstrategie die uit meerdere componenten bestond; partners werden geworven via (online) wervingsmaterialen, via zorgprofessionals en door middel van direct contact met de onderzoeker. Partners werden willekeurig toegewezen aan de interventiegroep, waar men direct toegang kreeg tot Oncokompas, of de controlegroep, waar men pas na drie maanden toegang tot Oncokompas kreeg. Uitkomstmaten werden verzameld bij baseline, twee weken na de randomisatie, en drie maanden na de baseline meting. De primaire uitkomstmaat was belasting van de mantelzorger. Secundaire uitkomstmaten waren *general self-efficacy*, HRQOL en kostenuitkomsten.

Hoofdstuk 9 beschrijft de resultaten van de RCT naar de effectiviteit van Oncokompas onder partners van patiënten met een ongeneeslijke vorm van kanker. In totaal zijn 58 partners geïncludeerd, deels tijdens de COVID-19 pandemie. De doelstelling om 136 patiënten te includeren bleek niet haalbaar na een inclusieperiode van 18 maanden. Het onderzoek is daarom voortijdig gestopt. De resultaten toonden geen significante effecten van Oncokompas op de belasting van de mantelzorger, *general self-efficacy* en HRQOL. Het bereik is berekend op basis van *eligibility*, het percentage partners dat deelnam aan de studie, en een evaluatie van het wervingsproces; het bereik werd geschat op 83-91%. Partners werden het best bereikt via palliatieve zorgconsulenten, patiëntenorganisaties en netwerken palliatieve zorg. Minder vaak werden zij bereikt via thuiszorgorganisaties, huisartsen en ziekenhuizen. Het bereik van Oncokompas onder geïnteresseerde partners was groot, maar de moeilijkheden die zijn ondervonden gedurende de werving van de studie, suggereren dat het bereik in de dagelijkse praktijk lager zou kunnen zijn. Door het lage aantal deelnemers dat is geïncludeerd, werd de studie naar de kostenutiliteit niet haalbaar geacht. Om deze reden is de kostenanalyse niet uitgevoerd.

Hoofdstuk 10 betreft de algemene discussie van dit proefschrift. Er wordt een overzicht gegeven van alle hoofdstukken en de belangrijkste bevindingen vanuit de studies worden besproken. De sterke punten en de beperkingen van dit proefschrift worden beschreven. Daarnaast zijn er aanbevelingen gedaan voor toekomstig onderzoek. Dit proefschrift draagt bij aan de kennis over de effectiviteit en kostenutiliteit van eHealth-toepassingen ter bevordering van zelfmanagement in de palliatieve zorg voor patiënten met een ongeneeslijke vorm van kanker en hun partners. Er is meer onderzoek nodig naar *self-guided* zelfmanagement interventies om een alomvattende en onderbouwde uitspraak te kunnen doel over de rol van deze interventies bij het ondersteunen van zelfmanagement in de palliatieve zorg rondom kanker. Het is van belang dat palliatieve zorg en psycho-oncologische zorg beschikbaar en toegankelijk zijn, zodat patiënten met een ongeneeslijke vorm van kanker en hun partners optimaal kunnen worden ondersteund bij de uitdagingen die zij ondervinden als gevolg van kanker.

ADDENDUM

Dankwoord

About the author

List of publications

DANKWOORD

Het moment is daar; het schrijven van een dankwoord als slotwoord van mijn proefschrift! Heel veel dank aan alle mensen die hebben geholpen bij de totstandkoming van dit proefschrift.

Mijn speciale dank gaat uit naar **alle deelnemers die hebben meegewerkt aan de onderzoeken** die onderdeel zijn van dit proefschrift. Ik vond het bijzonder om te merken dat veel mensen graag willen helpen om de psychosociale zorg voor mensen met kanker en hun partners verder te verbeteren. Bedankt voor jullie vertrouwen en het delen van jullie persoonlijke ervaringen. Ook **alle patiënten en naasten die zich hebben ingezet voor de doorontwikkeling van Oncokompas** wil ik bedanken voor het delen van hun ervaringen en hun inzet om Oncokompas verder door te ontwikkelen. Mijn dank gaat ook uit naar **alle zorgverleners, onderzoekers en beleidsmakers die hebben meegewerkt aan de doorontwikkeling van Oncokompas** voor mensen met ongeneeslijke kanker en hun partners.

Daarnaast wil ik graag **alle zorgverleners die hun steentje hebben bijgedragen aan de studies** vanuit het Amsterdam UMC (locatie VUmc en AMC), Universitair Medisch Centrum Utrecht, St. Antonius ziekenhuis, Haaglanden MC, het RadboudUMC en het Jeroen Bosch Ziekenhuis bedanken. Alle artsen, verpleegkundigen en verpleegkundig specialisten die patiënten hebben uitgenodigd om deel te nemen aan de studies, bedankt! Ook alle **mensen die hebben geholpen om de oproep voor het onderzoek onder partners te verspreiden** wil ik bedanken. Ook wil ik graag het **Ingeborg Douwes Centrum** en de **afdeling Psychiatrie en Medische psychologie van het OLVG** bedanken voor de samenwerking gedurende de studie.

Ook wil ik graag mijn promotieteam bedanken. Mijn promotor **prof.dr. I.M. Verdonck-de Leeuw**. Beste Irma, dankjewel voor jouw begeleiding tijdens mijn promotietraject. Jouw kritische, maar optimische blik, positieve feedback en vertrouwen hebben mij erg geholpen gedurende het traject. Bedankt hiervoor!

Mijn promotor **prof.dr. W.J.M.J. Cuijpers**. Beste Pim, bedankt voor het meedenken bij het uitvoeren van het onderzoek en jouw altijd tijdige en nuttige feedback op de artikelen. Dit was heel waardevol!

Mijn co-promotor **dr. C.J.M. Holtmaat**. Beste Karen, tijdens mijn promotietraject had ik de vrijheid om veel dingen zelf uit te zoeken, wat voor mij heel leerzaam was. Dankjewel daarvoor!

Beste leden van de leescommissie; **prof.dr. M.M. Riper**, **prof.dr. J.E. Bosmans**, **prof. dr. A.L. Francke**, **prof.dr. M. van der Lee**, **prof.dr. C.C.D. van der Rijt** en **dr. M.M.H. Lahr**. Bedankt voor jullie bereidheid om zitting te nemen in de leescommissie en het beoordelen van mijn proefschrift.

Alle **co-auteurs**, bedankt voor jullie inzet en de samenwerking in het kader van de onderzoeken. Ook jullie kritische blik en adviezen als bijdrage aan de artikelen die onderdeel zijn van dit proefschrift, vond ik heel waardevol.

Iedereen van de **onderzoeksgroep Samen Leven met Kanker** en **het Oncokompas team**; bedankt voor jullie gezelligheid, het delen van jullie kennis tijdens de SLMK-bijeenkomsten en de samenwerking rondom Oncokompas. In het bijzonder wil ik **Birgit** en **Femke** bedanken. Jullie begeleiding en advies bij de statistische analyses heeft mij veel geleerd over de wondere wereld van de statistiek, en maakte bovendien dat ik lol kreeg in de analyses, bedankt daarvoor! Ook **Sandra** wil ik graag bedanken voor de fijne samenwerking bij het regelen van praktische zaken rondom de studies en de lancering van Oncokompas. **Nelly** en **Margot**, bedankt voor jullie inzet bij de doorontwikkeling van Oncokompas en het meedenken in de eerste fase van het onderzoekstraject. Het was fijn om met jullie van gedachten te kunnen wisselen en bij het testen van Oncokompas samen op te kunnen trekken.

Ook een bedankje voor **mijn K&I-collega's van Alrijne**. Door meteen met een nieuwe baan te beginnen nadat mijn contract bij de VU was beëindigd, heb ik het mezelf niet makkelijker gemaakt; toch ben ik blij dat ik die stap heb gezet. Bedankt voor jullie interesse in mijn proefschrift!

Dank ook aan de VU-collega's, en een aantal mensen in het bijzonder; **Sherida**, **Johan**, **Eugène** en **Deborah** van het KNOP secretariaat; dank voor jullie administratieve hulp en interesse in de studies! **Angelina**, **Florie**, **Anne** en **Jaël**; dank voor jullie hulp bij de randomisatie van deelnemers voor de studies.

Natuurlijk ook een speciaal dankjewel aan mijn kamergenoten gedurende mijn tijd bij de VU: **Angelina**, **Anja**, **Florie**, **Matthijs** en **Nienke**. Naast het werk konden we ook het leven vieren met veel gezelligheid op de kamer tijdens onze koffiemomentjes. Bedankt daarvoor! **Nienke**, in aanvulling daarop bedankt voor je ondersteuning bij de RCTs, je positiviteit en nuchtere blik. **Anja**, op mijn eerste dag bij de VU maakte jij me wegwijs op de afdeling en daarna waren we al die jaren kamergenoten. Ik vond het fijn om tips en adviezen met elkaar te delen. En wat heb ik genoten van onze reis door Amerika; het congres in San Francisco en de prachtige hikes die we erna maakten in de mooiste parken van California!

Lieve **Valesca**, wat hebben wij veel uren doorgebracht om interviews te coderen. Vanaf het eerste moment hebben we een goede klik. Een lekkere dosis humor en gezelligheid maakte het werk eigenlijk altijd een klein feestje. En de gezelligheid is er nog steeds, samen op het terras of al wandelend door de Waterleidingduinen! Dankjewel voor je hulp bij de studies en dat je mijn paranimf wilt zijn!

Lieve vrienden, in het bijzonder **Noortje**, **Roos**, en wandel- & eetclub – **Jessica**, **Lisa**, **Bo**, **Hadewich**, **Jojanneke**, **Femke** en **Nicole**. Soms is het juist lekker om even niet met je proefschrift bezig te zijn. De momenten waarin wij samen spelletjes deden, kletsen over van alles en nogwat, drankjes dronken thuis of in de kroeg, een dansje deden op een festival, samen sportten, en noem verder nog maar op, hielpen daar enorm bij! Bedankt daarvoor!

Lieve **familie** en **schoonfamilie**. Ik bof met zoveel lieve mensen om mij heen. Jullie hadden de afgelopen jaren altijd interesse om meer over mijn promotieonderzoek te horen. Ik vind het heel leuk om jullie nu het resultaat te kunnen laten zien!

Lieve **mamma**, **pappa**, **Miriam** & **Rick**, **David** en **Esther**. Bedankt allemaal voor jullie liefde, steun en betrokkenheid! **Mam** en **pap**, mede door jullie bemoedigende woorden, stevige knuffels en rotsvaste vertrouwen is het dat ik nu het slothoofdstuk van mijn proefschrift schrijf. Ik kan altijd bij jullie terecht voor gezelligheid, of voor een luisterend oor of advies. **Mir**, jouw lieve berichtjes en onze gesprekken tijdens onder andere onze vele wandelingen hebben mij zoveel geholpen om telkens weer nieuwe motivatie te vinden om naast mijn (nieuwe) baan aan mijn proefschrift te werken. Dankjewel daarvoor; ik ben heel blij en trots om jou als paranimf aan mijn zijde te hebben staan! **Daaf** en **Es**, ik ben er trots op met jullie de voorkant van mijn proefschrift te hebben ontworpen! De kers op de taart, dankjulliewel!

En dan tot slot, lieve **Paolo**, jij hebt alle stappen die hebben geleid tot dit proefschrift van heel dichtbij meegemaakt. Vanaf mijn sollicitatie bij de VU tot nu; het moment dat mijn proefschrift klaar is, met alle pieken en dalen die daar onderdeel van waren. Jij vierde samen met mij de mijlpalen binnen mijn promotietraject, hielp me te relativeren en kan met jouw gevoel voor humor altijd een lach op mijn gezicht toveren. Dankjewel voor je geduld, vertrouwen en liefde!

ABOUT THE AUTHOR

Anouk Suzanne Schuit was born in Leiderdorp (The Netherlands) on August 24th, 1991. In 2009 she completed her secondary education at Stedelijk Gymnasium Leiden.
After six months of travelling in South-East Asia, she began her bachelor study ‘Medical Informatics’ at the University of Amsterdam (UvA) in 2010. This study focuses on improving healthcare with help of information technologies. She finished her bachelor in the summer of 2013. Subsequently, she followed a premaster at the Vrije Universiteit Amsterdam, so she could attend the Dutch master ‘Beleid, Communicatie en Organisatie’. During this master – with a special focus on healthcare – she learned about change management, the importance of communication within organizations and the practice of organizational sciences. Anouk received her Master’s degree in 2015.

After her graduation she worked at the Communication department of the OLVG hospital in Amsterdam. In May 2016, she started as a PhD-candidate at the department of Clinical, Neuro- and Developmental Psychology at the Vrije Universiteit Amsterdam. Her PhD-project, with a main focus on the eHealth application Oncokompas for patients with incurable cancer and their partners, was part of the research group ‘Living together with cancer’ (chair prof.dr. Irma Verdonck-de Leeuw).

Anouk currently works in Alrijne Hospital as a project leader on Digital Care.

LIST OF PUBLICATIONS

Included in this thesis

Schuit AS, Holtmaat K, Hooghiemstra N, Jansen F, Lissenberg-Witte BI, Coupé VMH, Van Linde ME, Becker-Commissaris A, Reijneveld JC, Zijlstra JM, Sommeijer DW, Eerenstein SEJ, Verdonck-de Leeuw IM. Efficacy and cost-utility of the eHealth application 'Oncokompas', supporting patients with incurable cancer in finding optimal palliative care, tailored to their quality of life and personal preferences: a study protocol of a randomized controlled trial. *BMC palliative care*. 2019;18:85.

Schuit AS, Holtmaat K, Hooghiemstra N, Jansen F, Lissenberg-Witte BI, Coupé VMH, & Verdonck-de Leeuw IM. Efficacy and cost-utility of the eHealth self-management application 'Oncokompas', helping partners of patients with incurable cancer to identify their unmet supportive care needs and to take actions to meet their needs: a study protocol of a randomized controlled trial. *Trials*. 2020;21:124.

Schuit AS, Holtmaat K, Van Zwieten V, Aukema, EJ, Gransier L, Cuijpers P, Verdonck-de Leeuw, IM. Organizing psycho-oncological care for cancer patients: the patient's perspective. *Frontiers in Psychology*. 2021;12:625117.

Schuit AS, van Zwieten V, Holtmaat K, Cuijpers P, Eerenstein SEJ, Leemans CR, Vergeer MR, Karagozoglu H, Van Weert S, Korte M, Frambach R, Fleuren M, Hendrickx J, Verdonck-de Leeuw IM. Symptom monitoring in cancer and fully automated advice on supportive care: Patients' perspectives on self-management strategies and the eHealth self-management application Oncokompas. *European Journal of Cancer Care*. 2021;30(6):e13497.

Schuit AS, Holtmaat K, Lissenberg-Witte BI, Eerenstein SEJ, Zijlstra JM, Eeltink C, Becker-Commissaris A, Van Zuylen L, Van Linde ME, Menke-van der Houven van Oordt CW, Sommeijer DW, Verbeek N, Bosscha K, Nandoe Tewarie R, Sedee RJ, De Bree R, De Graeff A, De Vos F, Cuijpers P & Verdonck-de Leeuw IM (2022). Efficacy of the eHealth application Oncokompas, facilitating incurably ill cancer patients to self-manage their palliative care needs: A randomized controlled trial. *The Lancet Regional Health-Europe*. 2022;18:100390.

Schuit AS, Holtmaat K, Coupe VMH, Eerenstein SE, Zijlstra JM, Eeltink C, Becker-Commissaris A, Van Zuylen L, Van Linde ME, Menke-van der Houven van Oordt CW, Sommeijer DW, Verbeek N, Bosscha K, Nandoe Tewarie R, Sedee RJ, De Bree R, De Graeff A, De Vos F, Cuijpers P, Verdonck-de Leeuw IM, Jansen F. Cost-utility of the eHealth application Oncokompas, supporting incurably ill cancer patients to self-manage their cancer-related symptoms: results of a randomized controlled trial. 2022. *Current Oncology.* 2022;29:6186-6202.

Schuit AS, Rienks MM, Hooghiemstra N, Jansen F, Lissenberg-Witte BI, Cuijpers P, Verdonck-de Leeuw IM, Holtmaat K. Reach and efficacy of the eHealth application Oncokompas, facilitating partners of incurably ill cancer patients to self-manage their caregiver needs: a randomized controlled trial. 2022. *Submitted.*

Not included in this thesis

Schuit AS & Nies H. Wat is waardigheid? volgens familieleden van dementerenden, opgenomen in verpleeghuis. *Kwaliteit in Zorg.* 2016.

Melissant HC, Jansen F, Eerenstein SEJ, Cuijpers P, Laan E, Lissenberg-Witte BI, **Schuit AS**, Sherman KA, Leemans CR, Verdonck-de Leeuw IM (2021). Body image distress in head and neck cancer patients: what are we looking at? *Supportive Care in Cancer.* 2021;*29*(4): 2161-2169.