KANKER NAZORG WIJZER

DEVELOPMENT AND EVALUATION OF A COMPUTER-TAILORED SELF-MANAGEMENT INTERVENTION PROVIDING PSYCHOSOCIAL SUPPORT FOR CANCER SURVIVORS

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Don’t try too hard to catch the winds
Where they are going and where they have been
Don’t try to outrun what the winds are showing
Just got to give in to where they are blowing

Cause who are we?
Who are we without the ones we love?

- Patrick Watson -

Voor pap en mam
Doortje, Mees en Nora

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General introduction

1

Cancer is one of the leading causes of morbidity and mortality worldwide (International Agency for Research on Cancer, 2014). Fortunately, with advances in cancer detection and treatment, the number of cancer survivors is increasing significantly (de Moor et al., 2013; The Netherlands Cancer Registry, 2017). In 2011, the year this project started, the 5-year prevalence of cancer patients in the Netherlands was 306,583. In 2016, this number had increased to 356,601 patients (The Netherlands Cancer Registry, 2017) – an increase of 16.3% within 5 years – of which 108,402 patients were newly diagnosed patients (see also Table 1.1)[1]. These numbers are expected to increase further over the next decade, which can be explained by an aging population and further improvements in cancer detection and treatment (de Moor et al., 2013).

The period after cancer treatment is accompanied by many hardships. A great proportion of cancer survivors in the re-entry phase (the transition from cancer patient to cancer survivor) and in early survivorship (up to 5 years after diagnosis) experience a variety of psychosocial and physical problems after cancer treatment (Stanton, Rowland, & Ganz, 2015). In particular, during the first year after treatment, cancer survivors are susceptible to experiencing psychosocial and physical problems (Comprehensive Cancer Centre the Netherlands, 2011b; Health Council of the Netherlands, 2007). Frequently occurring problems include anxiety, depression, fear of cancer recurrence, fatigue, sleep problems, difficulties concerning their return to work, pain, difficulties in social relationships, and sexual dysfunction (Aaronson et al., 2014; Brown, Kroenke, Theobald, Wu, & Tu, 2010; Chung & Brock, 2013; Duijts et al., 2014; Foster, Wright, Hill, Hopkinson, & Roffe, 2009; Irwin, Olmstead, Ganz, & Haque, 2013; Lammerink, de Bock, Pras, Reyners, & Mourits, 2012; Paice, 2011; Prue, Rankin, Allen, Gracey, & Cramp, 2006; Simard et al., 2013). These problems may negatively impact cancer survivors' quality of life (Harrington, Hansen, Moskowitz, Todd, & Feuerstein, 2010; Wu & Harden, 2015) and may continue long after treatment has ended (Foster et al., 2009). In addition, an unhealthy lifestyle may also have a negative influence on quality of life: it may impede cancer recovery and increase the risk of cancer recurrence or developing comorbidities (Baena & Salinas, 2015; Baena Ruiz & Salinas Hernandez, 2014; Florou, Gkiozos, Tsagouli, Souliotis, & Syrigos, 2014; Schmid & Leitzmann, 2014; Vijayvergia & Denlinger, 2015). Unfortunately, a great proportion of cancer survivors do not adhere to general health recommendations: more than half are overweight, less than half comply with physical activity recommendations, only one fifth adhere to fruit and vegetable recommendations, and one in ten smokes (Bellizzi, Rowland, Jeffery, & McNeel, 2005; Inoue-Choi, Robien, & Lazovich, 2013; LeMasters, Madhavan, Sambamoorthi, & Kurian, 2014; Petersen et al., 2015; Williams, Steptoe, & Wardle, 2013).

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[1] Data retrieved on September 13th, 2017. Numbers might be subject to small changes.

Table 1.1: Cancer incidence and percentages of diagnosis of the five most common cancer types for men and women in the Netherlands in 2016

Cancer type	Men	Women
Incidence	56,682	51,720
Breast cancer	-	28.1%
Prostate cancer	19.5%	-
Colon cancer	15.5%	12.8%
Skin cancer	14.4%	14.8%
Lung cancer	12.0%	10.4%
Lymphoma and leukemia	9.3%	7.4%

Source: The Netherlands Cancer Registry (2017)

Anxiety, depression, fatigue, and their association with quality of life

Of the problems that cancer survivors may experience after cancer treatment, anxiety, depression, and fatigue are very prominent issues (Brown et al., 2010; Harrington et al., 2010; Prue et al., 2006). Approximately one in five survivors shows symptoms of anxiety and depression within the first two years following diagnosis (Mitchell, Ferguson, Gill, Paul, & Symonds, 2013), and 30–40% experience fatigue within five years after diagnosis (Husson et al., 2015a; Jones et al., 2016). Anxiety, depression, and fatigue can severely affect cancer survivors' quality of life (Wu & Harden, 2015), which can be described as "the patients' appraisal of and satisfaction with their current level of functioning compared to what they perceive to be possible or ideal" (Cella, 1994). Important in understanding this definition is that quality of life must be understood as being *subjective* and *multidimensional* (Cella, 1994). Subjectivity means that it can only be understood from the patient's perspective. For example, given two patients with the same level of functional impairment, the one who is better able to adjust his or her expectations and life goals will most likely experience better quality of life (Cella, 1994; von Blanckenburg et al., 2014). Multidimensionality means that quality of life can be described across a range of areas of the cancer survivor's life, such as functional ability and physical, emotional, and social well-being (Cella, 1994).

An important problem with respect to anxiety, depression, and fatigue is that cancer survivors indicate that they have low self-efficacy or a lower sense of control in managing these issues (Cairns & Hotopf, 2005; Foster et al., 2015; Servaes, Verhagen, & Bleijenberg, 2002b). This can be explained by anxiety, depression, and fatigue being complex problems which are closely related as they share many of the same symptoms (Brown & Kroenke, 2009; Kim et al., 2008; Moss-Morris & Petrie, 2001; Prue et al., 2006; Servaes, Verhagen, & Bleijenberg, 2002a; Servaes et al., 2002b). To better guide survivors in addressing these problems, structured information and support on these areas is highly needed (Husson, Mols, & van de Poll-Franse, 2011; Sarkar et al., 2015). In order to do this, it is important to understand what defines anxiety, depression, and fatigue.

Anxiety

Anxiety can be described as an affective response to a perceived threat (Chernecky & Murphy-Ende, 2009). One of the most important threats that cancer survivors perceive is cancer recurrence (Lee-Jones, Humphris, Dixon, & Hatcher, 1997; Simard & Savard, 2015; Simard et al., 2013). Anxiety, and more specifically fear of cancer recurrence, is a natural response to a life-threatening disease such as cancer, and can be helpful in the detection of newly developing tumors or in encouraging the adoption of better health behaviors (Lee-Jones et al., 1997; Simard et al., 2013; Stark & House, 2000). However, it becomes dysfunctional and problematic when the anxiety is persistent and severely affects daily functioning (Stark & House, 2000). In addition, anxiety is maladaptive when symptoms of anxiety are unacceptable regardless of the level of threat, such as recurring panic attacks, severe physical symptoms, and abnormal beliefs (Stark & House, 2000). Intrusive thoughts are also an important symptom of severe anxiety and can cause considerable disruption in concentration, decision-making, quality of sleep, or social functioning; these thoughts can lead to deficient behavior, such as avoidance, repetitive health checking, and constant seeking of reassurance with regard to somatic symptoms (Die Trill, 2013; Stark & House, 2000). Anxiety can thus severely affect cancer survivors' quality of life (Brown et al., 2010; Stark et al., 2002).

Several factors have been associated with anxiety in general or fear of cancer recurrence (Simard et al., 2013). The severity of somatic symptoms, such as pain, has been associated with anxiety, which can be explained by these symptoms being interpreted as a sign of cancer recurrence (Brown et al., 2010; Lee-Jones et al., 1997; Vahdaninia, Omidvari, & Montazeri, 2010). Another important factor that has been associated with anxiety is fatigue, although it is not clear whether fatigue is an anxiety-provoking cue or whether anxiety leads to increased fatigue (Brown & Kroenke, 2009). Further, psychosocial factors such as lack of social support, family distress, poor coping style, uncertainty, lower self-esteem, or low optimism have been associated with increased anxiety (Koch, Jansen, Brenner, & Arndt, 2013; Mehnert, Berg, Henrich, & Herschbach, 2009; Stark et al., 2002). Psychosocial interventions aimed at facilitating successful adjustment to the cancer experience, such as minimizing disruptions to life, regulating emotional distress, and staying actively involved in meaningful life events, are effective in reducing anxiety (Die Trill, 2013; Osborn, Demoncada, & Feuerstein, 2006).

Depression

Depression can be described as a constant sad mood or loss of interest in pleasurable activities and life, in which the patient can experience the following symptoms: feelings of worthlessness or inappropriate guilt; thoughts of death or suicide; significant weight gain or loss, or an increase or decrease in appetite; severe sleeping problems (inability to sleep or excessive sleeping); psychomotor agitation (restlessness) or retardation (being slowed down); fatigue or loss of energy; or diminished concentration or indecisiveness (Dauchy, Dolbeault, & Reich, 2013). While anxiety and depression are highly comorbid (Brown et al., 2010), it is proposed that anxiety precedes depression, thus that anxiety is a risk factor for depression (Wittchen, Kessler, Pfister, Höfler, & Lieb, 2000). Depression has a major impact on morbidity and mortality, which can be explained by, amongst others, increased sensitivity to pain, disruption in social relationships, increased risk of suicide, and reduced expectations of survival (Dauchy et al., 2013; Fann et al., 2008; Gagliese, Gauthier, & Rodin, 2007; Misono, Weiss, Fann, Redman, & Yueh, 2008; Pitceathly & Maguire, 2003; Satin, Linden, & Phillips, 2009).

Several risk factors for depression are known, including personal (e.g., experience of a stressful life event), psychological (e.g., low self-esteem), social (e.g., low social support), physical (e.g., pain), and disease- and treatment-related factors (e.g., cancer and treatment type) (Dauchy et al., 2013; Fann et al., 2008). Psychosocial interventions, in particular interventions based on cognitive behavioral therapy, are proven to be effective in reducing depression (Dauchy et al., 2013; Osborn et al., 2006). Important components of cognitive behavioral therapy for depression include providing support in problem-solving, supporting the patient in becoming behaviorally activated, and identifying, evaluating, and responding to the patients depressed thinking (Beck, 2011). In addition, lifestyle-related interventions aimed at increasing physical activity or improving sleep have been shown to be effective in reducing depression (Craft, Vaniterson, Helenowski, Rademaker, & Courneya, 2012; Garland et al., 2014).

Fatigue

For healthy individuals, fatigue is a protective response towards physical or psychological stress in order to maintain a healthy balance between rest and activity (Prue et al., 2006; Servaes et al., 2002a). A large proportion of cancer survivors, however, experience fatigue that is different from the fatigue experienced by the general population (Prue et al., 2006). This cancer-related fatigue is being described as continuous, chronic, unpleasant, distressing, and life-limiting (de Jong, Courtens, Abu-Saad, & Schouten, 2002; Servaes et al., 2002a), and can have a major impact on cancer survivors quality of life (Cairns & Hotopf, 2005; Garabeli Cavalli Kluthcovsky et al., 2012; Jones et al., 2016; Kim et al., 2008). Cancer-related fatigue must be understood as a multidimensional concept, consisting of physical, psychological, social, cognitive, and behavioral components (Servaes et al., 2002a; Servaes et al., 2002b; Vercoulen et al., 1994). While depression and fatigue share a number of symptoms, an important distinction is that depressed patients' self-schema are dominated by a negative view of the self, while chronically fatigued patients are primarily concerned with their poor health (Moss-Morris & Petrie, 2001).

There is considerable variability in the results across studies with respect to the factors that are associated with cancer-related fatigue (Cairns & Hotopf, 2005; Prue et al., 2006; Servaes et al., 2002a). Still, some general conclusions can be drawn. In general, fatigue is not clearly associated with demographic or disease-related characteristics (e.g., cancer type or treatment modality) (de Jong et al., 2002; Prue et al., 2006; Servaes et al., 2002a), but it has been associated with psychosocial and lifestyle-related factors, such as psychological well-being (e.g., anxiety or depression), social support and social functioning, quality of sleep, and physical activity (de Jong et al., 2002; Hwang, Chang, Rue, & Kasimis, 2003; Meeske et al., 2007; Prue et al., 2006; Servaes et al., 2002a; Servaes et al., 2002b). In addition, physical symptoms, such as pain, dyspnea, or appetite loss also have been associated with cancer-related fatigue (de Jong et al., 2002; Garabeli Cavalli Kluthcovsky et al., 2012; Hwang et al., 2003; Prue et al., 2006; Servaes et al., 2002a). Interventions aimed at changing behavior and cognitions associated with the persistence of fatigue, including ineffective coping, excessive fear of cancer recurrence, non-helpful thoughts concerning fatigue, dysregulation of daily activities, deviant sleep-wake cycle, lack of social support, and an inactive or overactive lifestyle have been proven effective in reducing experiences of fatigue (Cramp & Byron-Daniel, 2012; Gielissen, Verhagen, & Bleijenberg, 2007; Gielissen, 2007; Heins, Knoop, Burk, & Bleijenberg, 2013; Kangas, Bovbjerg, & Montgomery, 2008; Wiborg, Knoop, Frank, & Bleijenberg, 2012).

Cancer aftercare and the role of self-management

With the number of cancer survivors rising, the number of survivors requiring follow-up care also increases (Davies & Batehup, 2011; Health Council of the Netherlands, 2007; Hewitt, Greenfield, & Stovall, 2006). However, aftercare for cancer survivors is fragmented and not sufficiently organized (Health Council of the Netherlands, 2007; Hewitt et al., 2006; Jacobsen & Wagner, 2012; Stanton, 2012; Stanton et al., 2015). For example, comprehensive and personalized cancer aftercare plans are not structurally implemented, psychological and physical screening after cancer treatment is not standard, and there is little communication between the professionals providing follow-up care on who is responsible for coordinating the care (Comprehensive Cancer Centre the Netherlands, 2011b; Health Council of the Netherlands, 2007; Hewitt et al., 2006; McCorkle et al., 2011). As a consequence, many cancer survivors are left with unmet information and support needs (Hoekstra, Heins, & Korevaar, 2014; Husson et al., 2011).

As a reaction to this need for reorganizing aftercare for cancer patients, the Comprehensive Cancer Center of the Netherlands developed two evidence-based guidelines to help professionals with setting up a care plan after cancer treatment (Comprehensive Cancer Centre the Netherlands, 2011a, 2011b). These guidelines for cancer survivorship care and cancer rehabilitation plead for a programmatic approach, in which the patient is monitored and a personalized aftercare plan is made. More specifically, early detection of psychosocial and physical problems is recommended, by systematically and regularly screening for these problems directly after cancer treatment (Comprehensive Cancer Centre the Netherlands, 2011b). Patients should be informed about possible aftercare programs, such as self-management programs or face-to-face support, and early problems should be treated. After one year, patients should be screened again and a new plan for any remaining problems should be developed if necessary.

Within these guidelines, the patient is mainly held responsible for managing their health, and healthcare professionals should encourage and support them in self-management (Comprehensive Cancer Centre the Netherlands, 2011b; Davies & Batehup, 2011). Self-management in this context can be understood as the cancer survivors' active participation in their recovery and rehabilitation, to minimize the consequences of treatment and promote their health and well-being (Department of Health, Macmillan Cancer Support, & National Health Service Improvement, 2010; Foster et al., 2015). This involves "managing consequences of cancer and its treatment (physical, psychological, social, practical problems), understanding how and when to seek support, recognizing and reporting signs and symptoms of possible disease progression and making lifestyle changes to promote health, well-being and survival" (Foster et al., 2015).

The proposed guideline fits within a stepped-care approach, in which aftercare is provided in a series of steps, with more intensive therapies being reserved for those who do not find sufficient help in more basic forms of support (Bower & Gilbody, 2005; Haaga, 2000). The results of the used support are monitored systematically, and more intensive support is provided if the current support is not achieving a significant health gain ("stepping up") (Andersen et al., 2014; Bower & Gilbody, 2005). The steps in stepped care involve (1) watchful waiting (i.e., no therapist input beyond assessment), (2) guided self-help (e.g., self-help books or internet interventions) and group therapy, (3) brief individual therapy (e.g., cognitive behavioral therapy or problem-solving therapy), and (4) more intensive longer-term individual therapy (e.g., psychotherapy) or medication (Bower & Gilbody, 2005; Krebber et al., 2012). Thus, with a stepped-care approach, low-intensity support becomes more easily accessible for a large proportion of cancer survivors with relatively mild complaints, leaving more intensive support for those with higher needs. Therefore, this approach is argued to make more efficient use of the limited resources available.

Although this vision on cancer aftercare is promising, cancer survivors may still find it difficult to find their way through the cancer aftercare system. Survivors do not always feel confident, or have insufficient skills to manage their own health, which could limit the amount of support they receive during their recovery period (Fenlon & Foster, 2009; Foster et al., 2015; Foster & Fenlon, 2011; Paterson, Robertson, & Nabi, 2015; Shippee, Shah, May, Mair, & Montori, 2012). In addition, little or inadequate preparation by healthcare professionals for managing life after cancer and suboptimal referral to aftercare leaves survivors with prominent information and support needs (Armes et al., 2009; Fenlon & Foster, 2009; Hodgkinson et al., 2007a; Hodgkinson et al., 2007c; James-Martin, Koczwara, Smith, & Miller, 2014; Leykin et al., 2012; Lubberding et al., 2015; Pullar, Chisholm, & Jackson, 2012; Smith et al., 2013; Stanton, 2012). Therefore, informing cancer survivors about what to expect after cancer treatment, building their self-confidence in managing problems, and providing them with knowledge and skills on how to address their problems effectively (setting personal goals and developing effective strategies for achieving them), is very important in psychosocial care (Coulter & Ellins, 2006; Fenlon & Foster, 2009; Stanton, 2012).

eHealth as a self-management tool during cancer survivorship

In managing health after cancer treatment, the Internet has become a key source of information (Chou, Liu, Post, & Hesse, 2011; Clauser, Wagner, Aiello Bowles, Tuzzio, & Greene, 2011; Dolce, 2011; Mayer et al., 2007a; Warren, Footman, Tinelli, McKee, & Knai, 2014). Evidence-based eHealth or internet interventions in psycho-oncology have the potential to fill an important gap in cancer care by making psychosocial care available to a larger group of cancer survivors, and offering tools for better management of life after cancer treatment (Leykin et al., 2012). In general, cancer survivors indicate feeling positive about using such interventions (Jansen, van Uden-Kraan, van Zwieten, Witte, & Verdonck-de Leeuw, 2015; Leykin et al., 2012). Important benefits of eHealth interventions are that they are easily accessible (i.e., no constraints in time and distance), can reach many patients at once, are potentially time and cost-effective, and can offer greater privacy and confidentiality (Leykin et al., 2012; Lustria, Cortese, Noar, & Glueckauf, 2009). In addition, they can also include interactive elements and visually attractive features (e.g., graphics, audio, and video) (Ritterband, Thorndike, Cox, Kovatchev, & Gonder-Frederick, 2009), making the intervention more attractive and the information more easily recalled (Bol et al., 2013). Since, in general, eHealth interventions are low in intensity and might be sufficient to meet the needs of a large proportion of survivors with relatively mild complaints, they might serve as a relevant step in a stepped-care approach (Espie, 2009; Krebber et al., 2016; Krebber et al., 2012).

It is argued that, in order to effectively stimulate self-management among chronically ill patients (including cancer survivors), the information provided should be tailored to the patients' characteristics (Coulter & Ellins, 2006; Davies & Batehup, 2010; Lustria et al., 2009; Noar, Benac, & Harris, 2007). With cancer survivors having a great variety of needs, information should be more targeted toward these specific needs (Fenlon & Foster, 2009). Tailoring comprises the presentation of information to a specific person regarding a particular health outcome, in which the information is based on the unique characteristics of that person and is combined with behavior change strategies (Rimer & Kreuter, 2006). By personalizing information, redundant information is omitted, attention is increased, information is more thoughtfully processed, and behavior change or maintenance is better facilitated, making tailored information more effective than general information (Brug, Oenema, & Campbell, 2003; Krebs, Prochaska, & Rossi, 2010; Lustria et al., 2009; Noar et al., 2007).

A great advantage of eHealth interventions is that information can easily be tailored through *computer tailoring*, providing immediate and highly personalized information and support (Barak, Klein, & Proudfoot, 2009; Lustria et al., 2009). Computer tailoring is a method to provide tailored feedback *automatically*, by assessing individuals' needs and characteristics and selecting communication content using data-driven decision rules that produce feedback from a database of content elements (Krebs et al., 2010). As shown in Figure 1.1, the computer-tailoring procedure consists of three main elements (Peels, 2014; van Stralen, 2010): (1) a data file containing unique information (scores) of every individual on the status of the targeted behavior and its determinants, collected through a screening questionnaire, (2) a server with the intervention components and materials based on theory-informed methods and practical strategies likely to change the targeted behavior, and (3) data-driven decision rules (if-then algorithms) that determine which intervention components, based on the scores of the screening questionnaire, should be presented to the individual to most effectively change the targeted behavior.

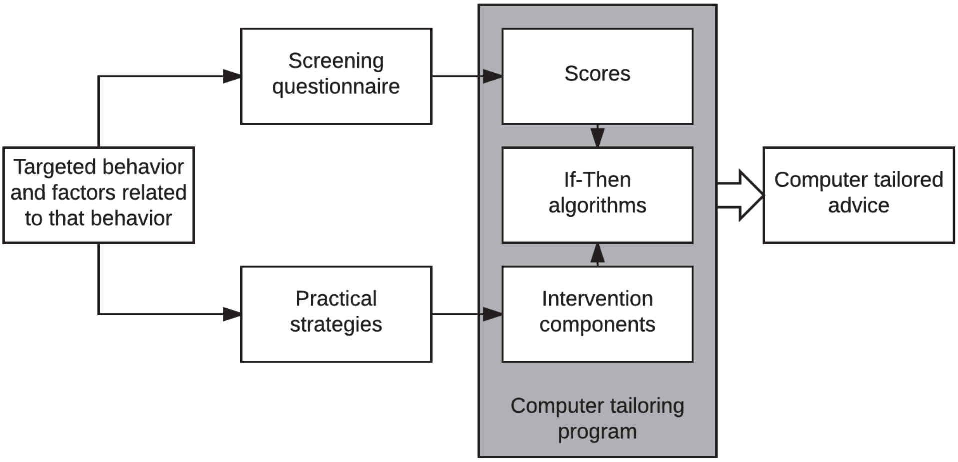

Figure 1.1: Computer tailoring procedure. Adapted from Peels (2014).

In the general population, web-based eHealth interventions for managing anxiety, depression, and fatigue have shown promising results (Spek et al., 2007; van Straten, Cuijpers, & Smits, 2008). However, the evidence on the benefits of such interventions for cancer survivors, and in particular computer-tailored self-management interventions, is limited (McAlpine, Joubert, Martin-Sanchez, Merolli, & Drummond, 2015). More specifically, these interventions were rarely available before the start of the current project. A few recent studies evaluated the effectiveness of web-based psychosocial eHealth interventions without therapist support for cancer survivors (Beatty, Koczwara, & Wade, 2016; Carpenter, Stoner, Schmitz, McGregor, & Doorenbos, 2014; Duffecy et al., 2013; Owen et al., 2005; Ritterband et al., 2012; van den Berg et al., 2015; Wootten et al., 2015; Yun et al., 2012). However, most of these studies only reported preliminary results (Beatty et al., 2016; Duffecy et al., 2013; Owen et al., 2005; Ritterband et al., 2012; Wootten et al., 2015). Three sufficiently powered randomized controlled trials found eHealth interventions for cancer survivors to be effective in reducing psychological distress and fatigue (van den Berg et al., 2015; Yun et al., 2012), and improving quality of life (Yun et al., 2012) and self-efficacy skills (Carpenter et al., 2014). Only one of these three interventions was developed for multiple cancer types and provided tailored information (Yun et al., 2012). In addition, there is little information on the long-term effectiveness of these interventions: only the studies of van den Berg et al. (2015) and Carpenter et al. (2014) tested the long-term effectiveness of their interventions. In the study by van den Berg et al. (2015), the intervention effects did not sustain at any follow-up measures (2 and 6 months after intervention closure). In the study by Carpenter et al. (2014) it is not possible to draw conclusions about the long-term effectiveness (10 weeks after intervention closure), since the control group received access to the intervention before the last measurement. More research on the (long-term) effectiveness of web-based interventions for cancer survivors is therefore urgently needed (McAlpine et al., 2015).

To conclude, web-based computer-tailored self-management interventions for cancer survivors seem to be a promising tool to support cancer survivors in managing psychosocial problems after cancer treatment. It is suggested that they can more effectively meet the needs of the growing population of cancer survivors and fit well in a stepped-care approach. Unfortunately, little evidence exists on the effectiveness of such interventions for cancer survivors. Moreover, to our knowledge, web-based computer-tailored self-management interventions addressing multiple psychosocial problems for cancer survivors of any cancer type have not been developed and tested yet. Therefore, the *Kanker Nazorg Wijzer* (Cancer Aftercare Guide) project was initiated.

THE *KANKER NAZORG WIJZER* PROJECT

The *Kanker Nazorg Wijzer* (KNW) project concerns the development and evaluation of a web-based computer-tailored self-management intervention for cancer survivors within the first year after cancer treatment. The KNW has been developed as a stand-alone intervention (i.e., not combined with face-to-face support) that aims to increase cancer survivors' quality of life by providing psychosocial support and promoting positive lifestyle changes. By means of several scientific studies, this thesis describes the development and the evaluation of the KNW (see Table 1.2 for an overview of the studies conducted). While the KNW provides information and support on psychosocial as well as lifestyle-related problems, this thesis focuses on the evaluation of the effectiveness of the KNW on quality of life, anxiety, depression, and fatigue; outcomes with strong psychosocial components. The evaluation of effectiveness on the lifestyle outcomes is addressed in another thesis (Kanera, 2018). This thesis consists of three parts. The first part describes the developmental process of the KNW. In the second part, the use and appreciation of the KNW is evaluated. In the final part, the effectiveness of the KNW in changing quality of life, anxiety, depression, and fatigue is tested, concluding with a summary and discussion of the findings of the overall project.

Part I: Intervention development

Part I of this thesis describes the intervention development of the KNW. In order to increase the likelihood of intervention effectiveness, it is important that the intervention is systematically developed and based on theory and evidence (Aaronson et al., 2014). Therefore, the KNW was developed using the Intervention Mapping (IM) protocol, a systematic, theory- and empirically-based approach for intervention development (Bartholomew et al., 2016). The IM protocol consists of six steps, which are: (1) conducting a needs assessment, (2) specifying program objectives, (3) selecting theory-informed intervention methods and practical applications, (4) producing program materials, (5) planning program adoption and implementation, and (6) planning for evaluation.

In the first step of the IM protocol, the needs assessment, the health problem and its impact on the quality of life of the at-risk group is assessed (Bartholomew et al., 2016). Understanding cancer survivors' experienced problems and support needs is a crucial step in determining the intervention's content (Rutten, Arora, Bakos, Aziz, & Rowland, 2005). Therefore, focus groups and a survey study were conducted. The aim of the focus groups, of which the results are described in Chapter 3, was to qualitatively investigate (a) experienced problems during survivorship, (b) experiences with current aftercare and aftercare needs, and (c) the desired content of the KNW intervention. The aim of the survey (**Chapter 2**) was to get further quantitative in-depth insight into (a) what extent cancer survivors experience unmet needs (necessity of developing the intervention), (b) what the most prominent needs are (determining the contents of the intervention), and (c) what extent these needs differ among patient characteristics (determining the necessity of tailoring information). The results of the needs assessment provided important input in the topics that should be addressed in the intervention.

Chapter 3 provides an overview of the systematic development of the KNW according to the six steps of the IM protocol (Bartholomew et al., 2016). First, the chapter provides a short overview of the results of the needs assessment. Second, based on the needs assessment, the program goals and objectives are described, and the behaviors and problems that should be addressed in the intervention in order to improve quality of life among cancer survivors are determined. Third, methods and strategies are selected in order to improve self-management skills and facilitate behavioral change. Fourth, the content and the structure of the intervention is described in detail. Finally, the plan for program implementation and evaluation is described.

Part II: Process evaluation

A process evaluation is necessary to gain more insight into whether components of the intervention are effective or not and how the intervention is evaluated by its users (Linnan & Steckler, 2002). Thus, the process evaluation aids in understanding the relationship between specific program elements and program outcomes (Saunders, Evans, & Joshi, 2005). **Chapter 4** describes the process evaluation of the KNW, which investigates the use of the KNW modules, predictors of module usage, the extent to which participants adhered to the tailored advice on which modules to visit, the appreciation of the KNW, and whether the appreciation differed among participant characteristics. The results provide valuable information about the context in which the intervention and possible effects occurred. In addition, the process evaluation provides valuable information and recommendations for improvement of the KNW intervention.

Part III: Effect evaluation

While the process evaluation aims to gain insight into the use and appreciation of the intervention, the effect evaluation describes the differences in outcomes between the participants who were and who were not exposed to the KNW (Bartholomew et al., 2016). As explained earlier, while the KNW provides information and support on psychosocial as well as lifestyle-related problems, this thesis will focus on the evaluation of the effectiveness of the KNW on quality of life, anxiety, depression, and fatigue.

Short- and long-term effectiveness

The short- and long-term effects of the KNW were tested in a randomized controlled trial, 6 (i.e., directly after intervention closure) and 12 months (i.e., 6 months after intervention closure) after completion of the baseline assessment, respectively. In the short term, the effects of the KNW on quality of life, anxiety, depression, and fatigue were evaluated (**Chapter 5**). At the long term, it was tested whether the short-term effects for participants remained at 12 months after their baseline assessment (**Chapter 6**). In addition, both studies evaluated whether participants' module usage influenced the intervention effects.

Next to knowing whether the KNW is effective in changing the targeted health outcomes for the whole group of participants, it is also important to investigate whether the intervention effects might differ among participant subgroups (Tamagawa, Garland, Vaska, & Carlson, 2012) (**Chapter 6**). There is little evidence regarding which factors or participant characteristics might influence the effectiveness of eHealth interventions aimed at cancer survivors. For the use of the KNW in clinical practice, it is valuable to have indications for whom the intervention is most effective. While there is some evidence that demographic and treatment-related characteristics may influence effectiveness of psycho-oncological interventions (Kalter et al., 2015; Tamagawa et al., 2012), there is, to our knowledge, no specific evidence whether these factors influence the effectiveness of web-based self-management interventions for cancer survivors specifically. Therefore, it was investigated whether gender, age, educational level, and treatment type moderated intervention effectiveness in the short term as well as the long term. If differences in intervention effectiveness exist among patient subgroups, this can have important implications for intervention adaption and implementation.

Analyses of working mechanisms

As with other theory-based interventions, the effectiveness of the KNW is expected to result from change in the underlying hypothesized causal processes. Thus, by changing relevant behavioral determinants, change in the targeted health outcome is expected (Bartholomew et al., 2016; Michie, Johnston, Francis, Hardeman, & Eccles, 2008). For the KNW, it was expected that use of the KNW intervention would result in increased problem-solving skills (D'Zurilla & Nezu, 2007) and in greater perceived personal control over cancer recovery (Hagger & Orbell, 2003; Leventhal, Meyer, & Nerenz, 1980), which in turn would result in change in targeted health outcomes (i.e., depression and fatigue). By means of mediation analyses, insight is provided into whether the intervention influences the targeted determinants (measured at 3 months from baseline), and to what extent changes in these determinants explain the effects of the intervention (measured at 6 months from baseline) (**Chapter 7**). The results of these analyses provide information on whether the intervention worked as expected and gives directions for further improvement of the intervention.

Table 1.2: Overview of the studies in this thesis

Chapter	Study objective	Design and follow-up	Sample size
Part I: Intervention development			
2	To explore cancer survivors' unmet needs in the first year after primary treatment and to investigate how these needs differ among cancer survivors	Cross-sectional	*n* = 255
3	To describe the systematic development and study design for evaluation of the Cancer Aftercare Guide	N/A	N/A
Part II: Intervention process evaluation			
4	To describe the use and appreciation of the KNW intervention and to investigate to what extent participants adhered to the advice on which intervention modules to visit	Longitudinal; 6 months	*n* = 231
Part III: Intervention effect evaluation			
5	To evaluate the short-term effectiveness of the KNW on quality of life, anxiety, depression, and fatigue, and to evaluate whether these effects are influenced by module use	Longitudinal; 6 months	*n* = 462
6	To evaluate whether (a) the significant short-term effects remain in the long term, (b) the long-term effects are influenced by module use, and (c) the short- and long-term effects differ among participant subgroups	Longitudinal; 6 and 12 months	*n* = 462
7	To investigate whether problem-solving skills and personal control mediate the short-term intervention effects on depression and fatigue	Longitudinal; 3 and 6 months	*n* = 409

N/A: Not applicable

PART I

INTERVENTION DEVELOPMENT

Cancer survivors in the first year after treatment: The prevalence and correlates of unmet needs in different domains

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ABSTRACT

Objective: To explore cancer survivors' unmet needs in the first year after primary treatment, and to investigate the relationship between demographic, disease-related, and psychosocial characteristics and the number of unmet needs in different domains.

Methods: Cancer survivors were recruited through eight Dutch hospitals (November 2012–January 2013). In a cross-sectional survey, 255 survivors were asked about unmet needs across several domains (CaSUN) and demographic, disease-related, and psychosocial characteristics, comprising quality of life (EORTC QLQ-C30), psychological distress (HADS), mental adjustment (MAC), and problem solving (SPSI-R:S).

Results: Sixty-three percent of survivors reported one or more unmet needs ($M = 5.13$, $SD = 6.98$, range = 0–34). Common unmet needs concerned emotional support (31.3%), smoking cessation (26.7% of smokers), managing side effects/complications (25.9%), fear of recurrence (23.0%), cancer care (22.0%), social support (22.0%), up-to-date information (19.8%), and carrying out work (19.6%). Regression analysis showed that age, higher education, participation in support programs, anxiety, depression, and negative adjustment style correlated positively, while being female, time since last treatment, and quality of life correlated negatively with the number of unmet needs. Lower number of unmet needs also accounted for other types of cancer (except colon cancer) than breast cancer. These relationships differed per need domain.

Conclusion: The heterogeneity in unmet needs complicates the provision of adequate support for survivors.

INTRODUCTION

Cancer survivors often experience psychosocial and physical problems after treatment, such as anxiety, depression, fear of recurrence, fatigue, difficulties with employment, and sexual dysfunction (Duijts et al., 2014; Kattlove & Winn, 2003; Mehnert & Koch, 2008; Prue et al., 2006; Simard et al., 2013; Valdivieso, Kujawa, Jones, & Baker, 2012). These problems vary across cancer and treatment types (Kattlove & Winn, 2003; Mah, Bezjak, Loblaw, Gotowiec, & Devins, 2011) and may continue long after treatment completion (Foster et al., 2009).

A majority of survivors report having unmet information and support needs, such as needs concerning health promotion, treatment and follow-up care, side-effects, finances, emotional and social support, and dealing with fear or stress (Beckjord et al., 2008; Bender et al., 2012; Hodgkinson et al., 2007a; Hodgkinson et al., 2007b; Hodgkinson et al., 2007c; Rowlands et al., 2015; Rutten et al., 2005; Smith et al., 2013). Younger survivors, women, survivors with higher incomes, and survivors with more co-morbid conditions generally have more needs (Beckjord et al., 2008; Rowlands et al., 2015; Rutten et al., 2005; Smith et al., 2013). Unmet needs are more prevalent among unemployed survivors (Bender et al., 2012) and survivors of a more advanced stage of cancer (Hodgkinson et al., 2007a; Rowlands et al., 2015). The relationship between cancer type and unmet needs is unclear (Harrison, Young, Price, Butow, & Solomon, 2009). Furthermore, having unmet needs is associated with higher psychological distress and lower quality of life (Beckjord et al., 2008; Hodgkinson et al., 2007a; Hodgkinson et al., 2007b; Hodgkinson et al., 2007c; Rowlands et al., 2015; Smith et al., 2013).

However, further insight is needed. First, unmet needs can be categorized into several domains, such as unmet needs concerning existential issues, comprehensive cancer care, information, relationships, and quality of life (Hodgkinson et al., 2007b). However, previous researchers only studied the total number of unmet needs as dependent variable (Bender et al., 2012; Harrison et al., 2011; Hodgkinson et al., 2007a; Hodgkinson et al., 2007b; Hodgkinson et al., 2007c; Rowlands et al., 2015; Smith et al., 2013). We expect the significance of these correlates to differ per domain.

Second, some factors important in cancer survivorship have not been clearly linked to having unmet needs. *Participation in support programs* after treatment (e.g., revalidation programs, psychological support) has beneficial effects on cancer recovery (Osborn et al., 2006; Speck, Courneya, Masse, Duval, & Schmitz, 2010). Next, *coping* with challenging situations, which comprise unmet needs, remains important during cancer survivorship (Stein, Syrjala, & Andrykowski, 2008). Survivors continue to engage in cancer-specific coping strategies many years after diagnosis (Zucca, Boyes, Lecathelinais, & Girgis, 2010). Furthermore, an intervention study demonstrated that training in *problem solving* led to fewer unmet needs in managing daily activities (Allen et al., 2002). We propose these factors to relate to having unmet needs across different domains.

In this study, we aim to explore (a) the prevalence of unmet needs, and (b) the relationship between demographic, disease-related, and psychosocial characteristics and the number of unmet needs in different domains. The results can be expected to provide detailed information on the main correlates of unmet needs and might reveal implications for how survivors' unmet needs can best be addressed.

METHODS

Participants and procedure

This study was approved by the Ethical Research Board of the Open University of the Netherlands. Patients could be included in the study if they were 18 years or older; they had been diagnosed with any cancer type; primary treatment (surgery, chemotherapy, and/or radiotherapy) had been completed successfully for at least six weeks but no more than one year; there was no sign of recurrence in the latest follow-up visit; they were able to read and speak Dutch; and there was no serious medical, psychiatric, or cognitive illness that would interfere participation.

Eighteen hospitals in the southern Netherlands were asked to assist in the recruitment process. Eight hospitals agreed to participate and recruited patients between November 2012 and January 2013 for 11 weeks on average. Patients were selected either during follow-up visits or review of their files. Oncologists, research nurses, and nurse practitioners from the outpatient clinics internal medicine, oncology, and urology invited patients who met the inclusion criteria to participate by giving them an information package during a follow-up visit or sending the package following file review. The information package consisted of an information letter, an informed consent form, and a survey booklet. A reminder survey was send after two weeks. Patients who agreed to participate were required to sign the informed consent form and return it with the completed survey to the Open University. Patients who returned the questionnaire but not the consent form received a reminder letter.

Measurements

Demographic characteristics included age, sex, relationship status, education level, and employment status. Disease-related characteristics included cancer type, treatment type, participation in support programs after treatment, and time since last treatment. To create groups of meaningful size, cancer type was categorized into "breast", "colon", and "other" (i.e., bladder, cervix, ovarian, stomach, and testicular cancer; Hodgkin and non-Hodgkin lymphoma).

Table 2.1 gives an overview of the psychosocial measurements. *Unmet needs* were measured using the Cancer Survivors' Unmet Needs questionnaire (CaSUN)[1] (Hodgkinson et al., 2007b), containing 35 items asking about needs over the past month. Twenty-eight items fall within one of five need domains: existential survivorship (14 items, α = .90; e.g., emotional support), comprehensive cancer care (six items, α = .81; e.g., best medical care), information (three items, α = .84; e.g., up-to-date information), quality of life (two items, α = .73; e.g., manage side effects/complications), and relationships (three items, α = .74; e.g., partner/family support). Seven separate items concern complementary therapy, fertility issues, employment, financial support, insurance, legal services, and having a case manager. Respondents indicate whether they have *no need/not applicable*, a *met need*, or an *unmet need*. Strength of unmet needs is rated as *weak* (1), *moderate* (2), or *strong* (3). We extended the CaSUN with four items concerning lifestyle changes (e.g., help to quit smoking) and five items concerning return to work (e.g., making work adjustments; see Appendix A), resulting in a total of 44 items. Factor analysis demonstrated a separate factor for return to work and showed good reliability (α = .84).

Statistical analysis

Missing values for the EORTC QLQ-C30, SPSI-R:S, HADS, and MAC were resolved by using the mean of the remaining items in the particular (sub)scale. The maximum permitted number of missing values was one for the scales of the EORTC QLQ-C30, HADS, and MAC and two for the SPSI-R:S. For the CaSUN, missing items were counted as "no need/not applicable". If all items of a domain were missing, the domain score was considered missing (Smith et al., 2013).

We treated the number of unmet needs as a count variable and, therefore, assessed the correlation between the number of unmet needs and the variables by means of Poisson and negative binomial regression analyses (Gardner, Mulvey, & Shaw, 1995). In cases of overdispersion we conducted negative binomial regressions, otherwise Poisson regressions. The variables were entered in three steps: demographic characteristics first, disease-related characteristics second, and psychosocial characteristics in the final step. The results are presented for the final step only. The contribution of the second and third step is reported by presenting the log likelihood values of each step. For the regression model concerning return to work only respondents who were employed before diagnoses were included. Descriptive statistics were examined using SPSS 22.0 and regression analyses were analyzed using Stata 12.1. Statistical tests were two-sided ($p < .05$).

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[1] Two researchers independently translated the CaSUN into Dutch and merged both versions into an initial version. Feedback from a native English speaker was incorporated. The text was piloted for comprehensibility and the results were incorporated into a final version.

Table 2.1: Psychosocial measurements and their properties

Concept	Instrument	N items	Item range	Timespan	Subscales used	N items subscale	Subscale range	α^a	Higher score indicates
Quality of life	EORTC QLQ-C30	30	1–7	Past week	Global health status	2	0–100	.88	Better overall health and quality of life
Psychological distress	HADS	14	0–3	Past week	Anxiety Depression	7 7	0–21 0–21	.85 .81	Greater morbidity
Coping/Mental adjustment to cancer	MAC	33	1–4	Time since last treatment	Positive adjustment[b] Negative adjustment	17 16	17–68 16–64	.78 .84	More positive or negative adjustment
Problem-solving ability	SPSI-R:S	25	0–4	No timespan	Total score	25	0–20	.79	Better problem-solving ability

QLQ-C30: Quality of Life Questionnaire (Aaronson et al., 1993); HADS: Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983); MAC: Mental Adjustment to Cancer scale (Watson & Homewood, 2008); SPSI-R:S: Short Social Problem Solving Inventory-Revised (D'Zurilla, Nezu, & Maydeu-Olivares, 2002). [a] All Cronbach's alphas are based on the study sample. [b] The positive and negative adjustment scales constitute an updated scoring procedure measuring two higher-order factors representing global adjustment (Watson & Homewood, 2008).

RESULTS

The hospital staff invited 455 patients for study participation. Of these, 172 patients declined to participate; 3 had metastases; 1 had not had cancer; 8 had finished primary treatment in fewer than six weeks; 10 had finished primary treatment longer than a year prior to the study; and 6 did not return the informed consent form. Data from 255 patients were therefore used in the analysis.

The mean age of the respondents was 60.57 years (*SD* = 10.74, range = 25–88) and 69.0% were female. The mean number of weeks since treatment completion was 26.51 (*SD* = 12.66, range = 6–52). Before diagnosis, 107 (42.6%) respondents were employed and 93 (37.1%) were retired; after treatment, these figures were 89 (36.0%) and 104 (42.1%), respectively. A total of 134 (52.5%) respondents made use of at least one support program. See Table 2.2 for additional sample characteristics.

Table 2.2: Demographic and disease-related characteristics (*n* = 255)

Characteristic	*n* (%)	Characteristic	*n* (%)
Age		*Treatment type*	
18-45	22 (8.6)	Surgery	32 (12.6)
45-65	130 (51.0)	Surgery and chemotherapy	55 (21.7)
65-older	103 (40.4)	Surgery and radiotherapy	46 (18.1)
Relationship status		Surgery, chemotherapy and radiotherapy	92 (36.2)
Partner	217 (86.5)	Other	29 (11.4)
No Partner	34 (13.5)	*Participation in support program*	
Education level[a]		No aftercare used	121 (47.5%)
Low	137 (54.6)	(Oncological) physiotherapy	72 (28.2%)
Middle	47 (18.7)	Recovery and Balance[b]	50 (19.6%)
High	67 (26.7)	Aftercare provided by hospital	28 (11%)
Employment		General practitioner	25 (9.8%)
Employed	89 (36.0)	Social work	9 (3.5%)
Unemployed	54 (21.9)	Psychological support	7 (2.7%)
Retired	104 (42.1)	Walk-in consultation services	7 (2.7%)
Cancer type		Dietitian	6 (2.4%)
Breast	150 (58.8)	Mindfulness therapy	4 (1.6%)
Colon	51 (20.0)	Rehabilitation specialist	4 (1.6%)
Prostate	23 (9.0)	Other	6 (2.4%)
Non-Hodgkin lymphoma	15 (5.3)	*Smoking*	
Ovarian	8 (3.1)	Yes	45 (17.7%)
Bladder	3 (1.2)	No	209 (82.3%)
Stomach	2 (0.8)		
Cervix	1 (0.4)		
Hodgkin lymphoma	1 (0.4)		
Testicular	1 (0.4)		

[a] Low: lower vocational education, medium general secondary education; Medium: secondary vocational education, higher general secondary education; High: higher vocational education, university education.
[b] Recovery and Balance ("Herstel en Balans") is a national revalidation program aimed at physical and psychological recovery after cancer treatment.

Prevalence of unmet needs

Table 2.3 shows the 10 most frequently cited unmet needs and their strength rating. Almost two-thirds (63.1%) reported at least one unmet need. The mean number of total unmet needs was 5.13 (*SD* = 6.98, σ^2 = 48.77, range = 0–34). The mean numbers of unmet needs in the different need domains were: existential survivorship 2.05 (*SD* = 3.12, σ^2 = 9.76, range = 0–13), comprehensive cancer care 0.85 (*SD* = 1.43, σ^2 = 2.06, range = 0–6), information 0.56 (*SD* = 0.98, σ^2 = 0.95, range = 0–3), quality of life 0.43 (*SD* = 0.72, σ^2 = 0.52, range = 0–2), relationships 0.35 (*SD* = 0.79, σ^2 = 0.62, range = 0–3), and return to work 0.70 (*SD* = 1.34, σ^2 = 1.80, range = 0–5). Concerning lifestyle, there was a high need for help to quit smoking (26.7%) and increasing exercise (18.0%; see Appendix A).

Table 2.3: Ten most frequently reported unmet needs

CaSUN need description I need…	Domain	% (Reporting unmet need/ completing item)	Mean (*SD*) strength rating
emotional support to be provided for me	ES	31.3 (79/252)	1.59 (0.78)
help to quit smoking[a]	None	26.7 (12/45)	2.17 (0.83)
help to manage ongoing side effects and/or complications of treatment	QL	25.9 (66/255)	1.80 (0.85)
help to manage my concerns about the cancer coming back	ES	23.0 (58/252)	1.55 (0.73)
to feel like I am managing my health together with the medical team	CC	22.0 (56/254)	2.02 (0.84)
to talk to others who have experienced cancer	ES	22.0 (56/254)	1.66 (0.75)
to know that all my doctors talk to each other to coordinate my care	CC	20.1 (51/254)	2.16 (0.78)
up to date information	IN	19.8 (50/252)	1.82 (0.87)
help with carrying out my work[a]	RW	19.6 (21/107)	2.14 (0.91)
the very best medical care	CC	19.3 (49/254)	2.27 (0.86)

ES: Existential Survivorship; CC: Comprehensive Cancer Care; IN: Information; QL: Quality of Life; RW: Return to Work.
[a] Item developed for this study. In total, 63.1% reported at least one unmet need. Discounting the items developed for this study, this percentage was 59.6%.

Correlates of unmet needs

Table 2.4 shows the results of the final regression models. With respect to demographic characteristics, women had fewer unmet needs in the information domain. Older survivors had more needs concerning comprehensive cancer care. Highly educated survivors had more unmet needs in total, and in the existential survivorship and comprehensive cancer care domains. Concerning disease-related characteristics, survivors of types of cancer other than breast or colon cancer – in comparison to breast cancer survivors – and survivors with a relatively longer time since last treatment had fewer, while survivors who participated in a support program had more unmet needs in several domains. Concerning psychosocial characteristics, survivors with a more negative adjustment style had more unmet needs in several domains. Survivors with higher quality of life had fewer unmet needs in total and in the comprehensive cancer care domain. Survivors with higher levels of anxiety had more unmet needs in total, and in the existential survivorship and comprehensive cancer care domains. Higher levels of depression were significantly associated with more unmet needs in the relationships domain.

The addition of disease-related characteristics to the models led to no or slight improvements in the models. In contrast, the addition of psychosocial characteristics led to major improvements in all models.

Table 2.4: Results of Poisson and negative binomial regression analyses of demographic, disease-related, and psychosocial characteristics on the number of unmet needs

Variable	Number of unmet needs							
	Total needs (*n* = 235)		Existential survivorship (*n* = 235)		Comprehensive cancer care (*n* = 235)		Information (*n* = 234)	
	IRR[a] [95% CI]	*p*	*IRR* [95% CI]	*p*	*IRR* [95% CI]	*p*	*IRR* [95% CI]	*p*
Demographic characteristics[b]	−635.42		−445.00		−300.52		−243.92	
Gender *(ref. male)*	0.72 [0.40, 1.29]	.269	1.04 [0.53, 2.05]	.906	0.62 [0.29, 1.31]	.211	0.37 [0.15, 0.93]	**.034**
Age (years)	1.01 [0.99, 1.03]	.558	1.00 [0.98, 1.02]	.945	1.04 [1.01, 1.07]	**.003**	1.03 [1.00, 1.06]	.063
Education *(ref. low)*								
Middle	1.14 [0.70, 1.86]	.587	1.16 [0.66, 2.03]	.612	1.65 [0.92, 2.99]	.096	0.76 [0.36, 1.61]	.470
High	2.06 [1.33, 3.19]	**.001**	2.14 [1.32, 3.47]	**.002**	1.92 [1.11, 3.33]	**.019**	1.60 [0.86, 2.99]	.136
Relationship status *(ref. partner)*	1.03 [0.63, 1.68]	.913	1.21 [0.71, 2.06]	.480	0.77 [0.39, 1.48]	.429	0.63 [0.28, 1.40]	.253
Disease-related characteristics	−626.80	**.028**	−439.84	.243	−292.43	**.040**	−237.85	.145
Cancer type *(ref. breast)*								
Colon	0.76 [0.41, 1.42]	.389	0.73 [0.35, 1.50]	.392	0.54 [0.23, 1.26]	.153	0.48 [0.18, 1.29]	.146
Other	0.41 [0.19, 0.88]	**.022**	0.40 [0.17, 0.99]	**.047**	0.62 [0.26, 1.48]	.277	0.22 [0.06, 0.79]	**.020**
Treatment type *(ref. surgery)*								
Surgery and chemotherapy	1.28 [0.64, 2.54]	.482	1.44 [0.68, 3.07]	.343	1.44 [0.60, 3.49]	.418	1.15 [0.40, 3.26]	.795
Surgery and radiotherapy	0.60 [0.28, 1.29]	.188	0.73 [0.30, 1.75]	.480	0.44 [0.15, 1.34]	.149	0.49 [0.14, 1.67]	.253
Surgery, chemotherapy and radiotherapy	0.90 [0.46, 1.77]	.765	0.90 [0.42, 1.92]	.779	0.98 [0.41, 2.39]	.973	0.80 [0.28, 2.28]	.675
Other	2.23 [0.95, 5.22]	.064	1.97 [0.73, 5.33]	.180	1.47 [0.52, 4.19]	.470	2.73 [0.74, 10.11]	.134
Time since last treatment (weeks)	0.99 [0.98, 1.01]	.309	0.99 [0.98, 1.01]	.498	0.98 [0.97, 1.00]	.068	0.98 [0.96, 1.00]	**.036**
Participation in support program *(ref. none)*	1.65 [1.06, 2.55]	**.026**	1.27 [0.78, 2.06]	.335	1.84 [1.04, 3.26]	**.036**	1.80 [0.97, 3.31]	.061
Psychosocial characteristics	−547.63	**.000**	−375.03	**.000**	−249.11	**.000**	−206.64	**.000**
Quality of life (0–100)	0.98 [0.96, 1.00]	**.014**	0.99 [0.97, 1.01]	.295	0.98 [0.96, 1.00]	**.049**	0.98 [0.96, 1.00]	.063
Anxiety (0–21)	1.11 [1.03, 1.19]	**.005**	1.14 [1.06, 1.24]	**.001**	1.14 [1.04, 1.23]	**.002**	1.07 [0.97, 1.18]	.172
Depression (0–21)	1.06 [0.98, 1.14]	.140	1.07 [0.99, 1.15]	.105	0.98 [0.90, 1.07]	.631	1.02 [0.92, 1.12]	.717

Table 2.4: Results of Poisson and negative binomial regression analyses of demographic, disease-related, and psychosocial characteristics on the number of unmet needs (*Continued)*

Variable	Number of unmet needs							
	Total needs ($n = 235$)		Existential survivorship ($n = 235$)		Comprehensive cancer care ($n = 235$)		Information ($n = 234$)	
	IRR [95% CI]	*p*	*IRR* [95% CI]	*p*	*IRR* [95% CI]	*p*	*IRR* [95% CI]	*p*
Mental adjustment								
Positive (17–68)	0.99 [0.96, 1.02]	.596	1.00 [0.97, 1.03]	.926	1.00 [0.96, 1.04]	.991	1.00 [0.96, 1.04]	.827
Negative (16–64)	1.04 [1.01, 1.08]	**.016**	1.05 [1.01, 1.09]	**.019**	1.05 [1.02, 1.10]	**.008**	1.03 [0.98, 1.08]	.270
Problem solving (0–20)	0.97 [0.89, 1.06]	.520	0.99 [0.90, 1.09]	.898	1.06 [0.94, 1.18]	.333	0.93 [0.82, 1.06]	.278
Likelihood ratio test of alpha = 0 [c]	$\chi^2(1) = 542.08, p < .001$		$\chi^2(1) = 138.11, p < .001$		$\chi^2(1) = 30.26, p < .001$		$\chi^2(1) = 21.89, p < .001$	
Pseudo R^2 (final model)	0.10		0.13		0.14		0.11	

[a] The incidence rate ratio (IRR) explains that if the independent variable increases by one unit, the number of unmet needs changes with one time the IRR (given that the other variables are held constant) (Hilbe, 2008). [b] Values reported next to each dimension are the log likelihood values of each step. A significant value indicates that the dimension improved the model. [c] A significant value in this test of overdispersion indicates that a Poisson distribution is not appropriate.

Table 2.4: Results of Poisson and negative binomial regression analyses of demographic, disease-related, and psychosocial characteristics on the number of unmet needs (*Continued)*

Variable	Number of unmet needs					
	Quality of life ($n = 235$)		Relationships ($n = 235$)		Return to work ($n = 99$)	
	IRR [95% CI]	*p*	*IRR* [95% CI]	*p*	*IRR* [95% CI]	*p*
Demographic characteristics	−207.24		−178.96		−105.08	
Gender *(ref. male)*	0.68 [0.30, 1.52]	.349	0.45 [0.17, 1.21]	.112	2.00 [0.31, 12.88]	.466
Age (years)	0.99 [0.97, 1.02]	.611	1.00 [0.97, 1.04]	.987	0.99 [0.94, 1.04]	.655
Education *(ref. low)*						
Middle	1.50 [0.85, 2.66]	.165	1.33 [0.63, 2.84]	.454	0.42 [0.11, 1.61]	.207
High	1.54 [0.92, 2.57]	.098	1.53 [0.76, 3.06]	.233	1.39 [0.58, 3.36]	.458
Relationship status *(ref. partner)*	1.17 [0.65, 2.11]	.601	0.83 [0.36, 1.92]	.670	1.81 [0.67, 4.90]	.244

Table 2.4: Results of Poisson and negative binomial regression analyses of demographic, disease-related, and psychosocial characteristics on the number of unmet needs (*Continued)*

Variable	Number of unmet needs					
	Quality of life (*n* = 235)		Relationships (*n* = 235)		Return to work (*n* = 99)	
	IRR [95% CI]	*p*	*IRR* [95% CI]	*p*	*IRR* [95% CI]	*p*
Disease-related characteristics	−197.29	**.010**	−172.99	.154	−101.68	.558
Cancer type *(ref. breast)*						
Colon	0.64 [0.26, 1.58]	.336	0.71 [0.23, 2.15]	.540	0.70 [0.09, 5.32]	.727
Other	0.55 [0.21, 1.49]	.240	0.34 [0.09, 1.28]	.110	0.62 [0.10, 3.66]	.593
Treatment type *(ref. surgery)*						
Surgery and chemotherapy	0.93 [0.37, 2.32]	.876	0.92 [0.30, 2.84]	.883	0.92 [0.10, 8.10]	.940
Surgery and radiotherapy	0.88 [0.29, 2.64]	.816	0.28 [0.06, 1.36]	.115	2.44 [0.24, 25.32]	.454
Surgery, chemotherapy and radiotherapy	0.89 [0.36, 2.24]	.808	0.58 [0.18, 1.85]	.360	1.56 [0.19, 12.80]	.680
Other	1.38 [0.42, 4.53]	.598	1.72 [0.44, 6.74]	.440	-	-
Time since last treatment (weeks)	0.98 [0.96, 0.99]	**.014**	0.97 [0.95, 1.00]	**.031**	0.99 [0.94, 1.04]	.597
Participation in support program *(ref. none)*	2.40 [1.34, 4.27]	**.003**	2.67 [1.24, 5.74]	**.012**	0.90 [0.23, 3.50]	.881
Psychosocial characteristics	−163.11	**.000**	−145.89	**.000**	−86.12	**.000**
Quality of life (0–100)	0.99 [0.97, 1.01]	.186	0.99 [0.97, 1.01]	.268	0.98 [0.95, 1.02]	.260
Anxiety (0–21)	1.02 [0.94, 1.10]	.702	1.06 [0.96, 1.18]	.263	1.07 [0.91, 1.26]	.392
Depression (0–21)	1.05 [0.97, 1.12]	.220	1.11 [1.01, 1.22]	**.034**	1.00 [0.86, 1.15]	.948
Mental adjustment						
Positive (17–68)	1.00 [0.96, 1.03]	.886	1.00 [0.95, 1.05]	.969	0.99 [0.93, 1.05]	.646
Negative (16–64)	1.06 [1.02, 1.11]	**.004**	1.03 [0.98, 1.09]	.276	1.07 [0.99, 1.15]	.093
Problem solving (0–20)	1.02 [0.93, 1.12]	.708	0.96 [0.85, 1.09]	.537	0.88 [0.70, 1.09]	.243
Likelihood ratio test of alpha = 0	$\chi^2(1) = 0.00, p = 0.500$		$\chi^2(1) = 2.85, p < .05$		$\chi^2(1) = 5.85, p < .01$	
Pseudo R^2 (final model)	0.21		0.18		0.19	

DISCUSSION

This study explored the prevalence of cancer survivors' unmet needs and correlates of the number of unmet needs across different domains. Sixty-three percent reported one or more unmet needs. Frequently cited unmet needs concerned emotional and social support, help to deal with fear of recurrence, management of healthcare and complications, and up-to-date information. With respect to the additional work- and lifestyle-related items, survivors reported high unmet needs concerning help to quit smoking, increasing exercise, and return to work related situations. Previous research highlighted the importance of these issues (LeMasters et al., 2014; Mayer & Carlson, 2011; Spelten, Sprangers, & Verbeek, 2002). We suggest these items to be included in the CaSUN.

Discounting the additional items, 59.6% reported at least one unmet need. This is similar to other studies, reporting percentages of 47–54% among a mixed group (Harrison et al., 2011; Hodgkinson et al., 2007b), 66% among testicular (Smith et al., 2013), 52% among gynecological (Hodgkinson et al., 2007a), and 61% among breast cancer survivors (Hodgkinson et al., 2007c), except for a study on endometrial cancer (24%) (Rowlands et al., 2015). These studies included participants many years after treatment or diagnosis. We found that, within the first year after primary treatment, greater time since treatment was associated with having less unmet needs, but only for the domains information, quality of life, and relationships. This suggests that while unmet needs remain long after treatment, they do decline to some extent (Harrison et al., 2011; Matsuyama, Kuhn, Molisani, & Wilson-Genderson, 2013).

We then explored the correlates of the number of unmet needs in different domains, leading to new insights. Of the demographic characteristics, men reported having more unmet needs in the information domain than women. Research shows that, in general, women seek information more actively than men (Mayer et al., 2007a; Rutten et al., 2005), which may explain their lesser unmet need for information. Older survivors had more unmet needs in the domain comprehensive cancer care. Older survivors already showed to be more susceptible to complications after treatment (Balducci & Extermann, 2000), making comprehensive medical care more important.

Of the disease-related characteristics, survivors who participated in support programs reported more unmet needs in general and in the comprehensive cancer care, quality of life, and information domains than survivors who did not participate in such programs. Possibly, survivors with relatively many unmet needs are more likely to participate in support programs. Furthermore, survivors of types of cancer other than breast or colon cancer had fewer unmet needs than breast cancer survivors in general and in the existential survivorship and information domains. However, caution is needed, because the "other" group was underrepresented in this study.

Of the psychosocial characteristics, better quality of life was associated with fewer, while higher anxiety levels were associated with more unmet needs. This supports the results of other studies (Harrison et al., 2011; Hodgkinson et al., 2007a; Hodgkinson et al., 2007b; Hodgkinson et al., 2007c; Smith et al., 2013). A more negative adjustment to cancer was associated with more unmet needs, while a positive adjustment was not related to the number of unmet needs. This might indicate that survivors with a positive adjustment do not necessarily have fewer unmet needs, but are more accepting of it. Research shows that positive coping with cancer is related to satisfaction with one's current life, while negative coping is related to loss of meaning and confusion (Jim, Richardson, Golden-Kreutz, & Andersen, 2006). Furthermore, there was no association between problem-solving ability and the number of unmet needs. In the study that did find a relationship, participants were exposed to problem-solving training, and unmet needs were measured only with regard to managing daily activities (Allen et al., 2002).

Overall, the significance of the demographic, disease-related, and psychosocial characteristics differed per domain. Comprehensive cancer care had relatively many significant correlates, which indicates that these needs vary across survivors in particular. Although many survivors had unmet needs concerning return to work, these needs did not relate to the survivors' characteristics. This was against our expectations, because physical and psychosocial problems may cause serious difficulties at work (Duijts et al., 2014). A higher number of respondents (±200) in the model would be preferable to draw better conclusions (Green, 1991).

Implications

This study makes valuable contributions to the state of knowledge. For research implications, it is important to distinguish between different unmet needs domains. Our results revealed important relationships that would have not been found if only the total number of unmet needs were studied. For practical implications, providing support to cancer survivors seems to be a complex endeavor. Survivors experience unmet needs in different domains, which are influenced by demographic characteristics, disease history, and psychosocial functioning. Providing information that covers all these aspects would leave survivors with too general or too much information. To provide the right amount of support, tailored interventions may be an effective solution (Leykin et al., 2012).

Limitations

This study is subject to some limitations. First, the cross-sectional design makes it difficult to interpret the nature of the relationships identified. Second, while quality of life encompasses multiple dimensions (Cella, 1994), we only focused on a global indication of quality of life.

Therefore, quality of life results need to be interpreted with caution. Finally, because of an error in the compilation of the questionnaire, one item of the CaSUN ("Due to my cancer, I need help accessing legal services") was not measured. As this item did not belong to one of the domains, the results of the regression models were not affected. Also, this item was not of importance in previous studies, suggesting that the impact of the missing item on the results is small.

CONCLUSION

With the number of cancer survivors set to increase in the coming years (Hewitt et al., 2006), meeting the needs of all survivors will become more challenging. Our study demonstrates that the heterogeneity in unmet needs complicates the provision of adequate support for survivors.

3

The *Kanker Nazorg Wijzer* (Cancer Aftercare Guide) protocol: The systematic development of a web-based computer-tailored intervention providing psychosocial and lifestyle support for cancer survivors

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ABSTRACT

Objective: After primary treatment, many cancer survivors experience psychosocial, physical, and lifestyle problems. To address these issues, we developed a web-based computer-tailored intervention, the *Kanker Nazorg Wijzer* (Cancer Aftercare Guide), aimed at providing psychosocial and lifestyle support for cancer survivors. The purpose of this article is to describe the systematic development and the study design for evaluation of this theory- and empirically-based intervention.

Methods/Design: For the development of the intervention, the steps of the Intervention Mapping protocol were followed. A needs assessment was performed consisting of a literature study, focus group interviews, and a survey study to gain more insight into cancer survivors' health issues. This resulted in seven problem areas that were addressed in the intervention: cancer-related fatigue, return to work, anxiety and depression, social relationships and intimacy, physical activity, diet, and smoking. To address these problem areas, the principles of problem-solving therapy and cognitive behavioral therapy are used. At the start of the intervention, participants have to fill in a screening questionnaire. Based on their answers, participants receive tailored advice about which problem areas deserve their attention. Participants were recruited from November 2013 through June 2014 by hospital staff from 21 hospitals in the Netherlands. Patients were selected either during follow-up visits to the hospital or from reviews of the patients' files. The effectiveness of the intervention is being tested in a randomized controlled trial consisting of an intervention group (n = 231) and waiting list control group (n = 231) with a baseline measurement and follow-up measurements at 3, 6, and 12 months.

Conclusion: Using the Intervention Mapping protocol resulted in a theory- and evidence-based intervention providing tailored advice to cancer survivors on how to cope with psychosocial and lifestyle issues after primary treatment.

INTRODUCTION

With advances in cancer detection and treatment and an aging population, the number of cancer survivors is increasing significantly (Dutch Cancer Society, 2011). It is well-known that survivors face a variety of difficulties and challenges after treatment, such as anxiety, depression, fear of recurrence, fatigue, pain, physical and cognitive limitations, difficulties with employment, and sexual dysfunctions (Duijts et al., 2014; Harrington et al., 2010; Kattlove & Winn, 2003; Mehnert & Koch, 2008; Prue et al., 2006; Simard et al., 2013; Valdivieso et al., 2012; Wu & Harden, 2015). These issues can have a negative impact on quality of life (Harrington et al., 2010; Wu & Harden, 2015) and may continue long after treatment has ended (Foster et al., 2009). Cancer patients experience a peak level of distress within the first year after treatment, which might be partially explained by loss of security associated with being in treatment and loss of regular contact with health professionals (Hinnen et al., 2008). Moreover, having a healthy lifestyle expedites recovery and, therefore, is of special importance for survivors. However, many survivors do not have a healthier lifestyle than people without a history of cancer (Mayer et al., 2007b): more than half are overweight, less than half comply with physical activity recommendations, only one fifth adheres to fruit and vegetable recommendations, and one in ten smokes (Bellizzi et al., 2005; Inoue-Choi et al., 2013; LeMasters et al., 2014; Williams et al., 2013).

More than half of the survivors report having unmet information and support needs on how to deal with issues such as emotional and social support, fear and stress, and treatment and follow-up care (Hodgkinson et al., 2007a; Hodgkinson et al., 2007c; Smith et al., 2013; Willems et al., 2016). Concerning lifestyle, survivors express a need for information and support regarding increasing exercise, improving diet, and smoking cessation (James-Martin et al., 2014; Pullar et al., 2012; Willems et al., 2016). To improve the aftercare for cancer survivors, a national guideline for cancer survivorship care was developed in the Netherlands (Comprehensive Cancer Centre the Netherlands, 2011b). This guideline describes the importance of a broad programmatic approach for oncology aftercare in which self-management should be stimulated.

The Internet has become a key source of health-related information for cancer survivors (Chou et al., 2011; Mayer et al., 2007a; Warren et al., 2014) and has the potential to fill an important gap in cancer care (Leykin et al., 2012). A great advantage of web-based interventions is that they can reach many patients at once and are accessible anytime and anywhere (Lustria et al., 2009). However, due to the broad variety of difficulties experienced and the different characteristics of the survivors, it is challenging to provide individually relevant information and support (Willems et al., 2016). By means of computer tailoring, information and support can be provided that is adapted to the individual's needs and characteristics, while still reaching large groups.

To provide cancer survivors personalized information and support and stimulating self-management during life after cancer, we developed the web-based computer-tailored intervention the *Kanker Nazorg Wijzer* (Cancer Aftercare Guide; KNW). To increase the likelihood of reaching intervention effectiveness, the Intervention Mapping (IM) protocol was used (Bartholomew et al., 2016). This is a systematic, theory- and empirically-based approach for intervention development. In this article, the development of the KNW according to the steps of IM and the evaluation of the intervention's effectiveness is described.

METHODS/DESIGN

The IM protocol consists of six steps (Bartholomew et al., 2016): (1) a needs assessment of the study population, (2) specification of performance objectives and crossing them with relevant determinants into change objectives, (3) selecting theory-informed intervention methods and practical applications to change the determinants of the health behavior, (4) producing and pretesting program materials, (5) planning program adoption and implementation, and (6) planning for evaluation.

Step 1: Needs assessment

In the needs assessment, the health problem and its impact on the quality of life of the at-risk group is assessed (Bartholomew et al., 2016). Understanding cancer survivors' experienced problems and information and support needs is a crucial step in designing interventions that meet survivors' needs (Rutten et al., 2005). Since it was clear that an overall problem among cancer survivors is a reduced quality of life (Harrington et al., 2010; Wu & Harden, 2015), the following program goal was stated: At 6 and 12 months after the start of the KNW program, cancer survivors will report an increased quality of life. The needs assessment aimed to disclose which problem areas should be addressed to achieve this goal.

We conducted a needs assessment consisting of a literature study, focus group interviews, and a survey. The literature provided an overview of cancer survivors' health-related problems. Anxiety and depression (Brown et al., 2010), fear of recurrence (Simard et al., 2013), fatigue (Prue et al., 2006), sleep problems (Irwin et al., 2013), difficulties concerning return to work (Duijts et al., 2014), pain (Paice, 2011), and sexual dysfunction (Chung & Brock, 2013; Lammerink et al., 2012) are frequently identified problems. Furthermore, a healthy lifestyle is associated with positive health outcomes in cancer survivors, while unhealthy lifestyle behaviors may lead to the development of other chronic diseases, new primary tumors, and cancer recurrence (Aleksandrova et al., 2014; Baena Ruiz & Salinas Hernandez, 2014; Petersen et al., 2015; Schmid & Leitzmann, 2014). Unfortunately, a large proportion of cancer survivors do not adhere to recommendations concerning physical activity, dietary, and smoking behavior (Inoue-Choi et al., 2013; Rock et al., 2012).

Then, we conducted six focus group interviews with 33 cancer survivors using a predefined protocol (Morgan & Krueger, 1998). The topics discussed included experienced problems during survivorship and aftercare needs. Most survivors indicated that they did not know what to expect after treatment or how to cope with their experienced problems. Commonly indicated problems included pain, fear of recurrence, fatigue, concentration problems, insomnia, sadness, insecurity, dealing with social relationships, and work-related problems. Many survivors reported difficulties in adhering to physical activity and diet recommendations. However, physical activity was seen as an important contributor to recovery. Furthermore, many survivors indicated that they did not always know where they could get aftercare or that the aftercare was not easily accessible. Most survivors expressed the need for more attention from the hospital staff to their psychological, physical, and lifestyle issues. Moreover, the information provided by hospitals concerning aftercare possibilities was described as insufficient. The information on the Internet was described as cluttered and bulky.

Finally, the prevalence and correlates of unmet information and support needs and healthy lifestyle behaviors were investigated in a survey conducted among 255 cancer survivors within the first year after their primary treatment (Kanera et al., 2016a; Willems et al., 2016). The results indicated that almost two-thirds of the survivors reported having unmet needs. Frequently cited unmet needs concerned emotional and social support, help to deal with fear of recurrence, management of healthcare and complications, up-to-date information, management of return to work, increasing exercise, and help to quit smoking. While help to eat healthier was not a frequently mentioned unmet need (Willems et al., 2016), adherence to fruit and vegetable recommendations was poor (Kanera et al., 2016a). High education, having breast cancer, participation in support programs, low quality of life, high levels of anxiety, and a more negative adjustment to cancer were associated with having more unmet needs in general (Willems et al., 2016). Self-efficacy, attitude, and intention were the strongest correlates of lifestyle behaviors (Kanera et al., 2016a).

Step 2: Matrices of change objectives

Step 2 provides the foundation of the intervention by specifying what will change as a result of the intervention (Bartholomew et al., 2016). For this purpose, performance objectives (POs) are formulated. These are statements of what the program participants need to do to perform the intended health-promoting behavior. Then, important and changeable determinants for the POs are selected. This is necessary for creating change objectives (COs). COs specify what changes in the determinants are needed to make the attainment of the POs most likely.

To specify POs, it needs to be clear what the program outcome should be (i.e., what the program aims to achieve). Based on the needs assessment, the focus of the program was set to significantly reduce experienced problems in seven areas, namely (1) cancer-related fatigue, (2) difficulties concerning return to work, (3) anxiety and depression, (4) social relationship and intimacy issues, (5) a lack of physical activity, (6) a lack of healthy food intake, and (7) difficulties in preparing or maintaining smoking cessation. By effectively managing these problems, improved outcomes in these problem areas are expected, ultimately resulting in a better quality of life.

Several POs were formulated for each problem area. An example of a PO for the program outcome "Reduce cancer-related fatigue" is "Say 'no' to a request when it is too much to handle" (see Table 3.1). Then, the most important and changeable behavioral determinants of the POs were selected from theory and literature. The most relevant determinants differed for each problem area. For example, relevant determinants for reducing cancer-related fatigue included knowledge, awareness, attitude, skills, self-efficacy, perceived behavior of others, and outcome expectations. Relevant determinants of engagement in sufficient physical activity included attitude, self-efficacy, social support, and perceived barriers. Next, COs were stated. Examples of COs for the PO "Say 'no' to a request when it is too much to handle" were "Describe steps to undertake to effectively say 'no' to others" (knowledge) and "See fellow survivors acknowledging the importance of saying 'no' to others" (perceived behavior of others) (see Table 3.2).

Table 3.1: Performance objectives for the program outcome "Reduce cancer-related fatigue"

PO 1	**Manage daily tasks efficiently**
PO 1.1	Alternate mental and physical activities
PO 1.2	Take small moments of rest divided over the day
PO 1.3	Take adequate measures so not to exceed personal limits
PO 1.4	Say "no" to a request when it is too much to handle
PO 1.5	Make a structured plan of daily activities
PO 2	**Turn non-helpful thoughts about fatigue into helpful thoughts**
PO 2.1	Recognize common non-helpful thoughts about fatigue
PO 2.2	Identify personal non-helpful thoughts
PO 2.3	Generate helpful thoughts
PO 2.4	Replace non-helpful thoughts with helpful thoughts
PO 2.5	Implement personal strategies to cope with rumination
PO 2.6	Use relaxation or mindfulness techniques
PO 3	**Take sleep hygiene measures**
PO 3.1	Identify the type of sleeping problem one is experiencing
PO 3.2	Go to bed and get out of bed at set times every day of the week
PO 3.3	Take care of optimal sleeping conditions
PO 3.4	Identify behaviors that interfere with sleep and replace these with helpful behaviors
PO 3.5	Use relaxation or mindfulness techniques

Table 3.2: Matrix of change objectives for the performance objective "Manage daily tasks efficiently"

Reduce cancer-related fatigue	Knowledge	Awareness	Attitude	Skills and Self-Efficacy	Perceived Behavior of Others	Outcome Expectations
PO.1. Manage daily tasks efficiently		Aw.1. Become aware of planning and structure of own daily activities	At.1. Feel positive about reorganizing daily activities	SSE.1. Feel confident about managing daily activities	PBO.1. See fellow survivors acknowledging the importance managing daily activities	OE.1. Expect that managing daily tasks efficiently can reduce feelings of fatigue
PO.1.1. Alternate mental and physical activities	K.1a. Describe the importance of alternating mental and physical activities K.1b. Recall advice on alternating activities	Aw.2. Become aware whether mental and physical activities are alternated in own daily scheme				OE.2. Expect that alternating mental and physical activities can reduce experiences of fatigue
PO.1.2. Take small moments of rest divided over the day	K.2a. Describe the importance of taking small moments of rest K.2b. Recall advice on taking rest	Aw.3. Become aware whether daily rest is divided in small moments over the day				OE.3. Expect that taking small moments of rest divided over the day can reduce experiences of fatigue
PO.1.3. Take adequate measures to not exceed personal limits	K.3a. Recall possible signals of exceeding personal limits K.3b. Recall effective measures when exceeding limits		At.2. Feel positive about guarding personal boundaries	SSE.2. Feel confident about recognizing signals and taking adequate measures	PBO.2. See fellow survivors acknowledging the importance of not exceeding personal limits	OE.4. Expect that taking adequate measures when exceeding limits can reduce experiences of fatigue
PO.1.4. Say "no" to a request when it is too much to handle	K.4. Describe steps to undertake to effectively say "no" to others		At.3. Feel positive about saying "no" to others	SSE.3. Feel confident about saying "no" to others	PBO.3. See fellow survivors acknowledging the importance of saying "no" to others	OE.5. Expect that others generally accept when receiving "no" to a request
PO.1.5. Make a structured plan of daily activities	K.5. Summarize advice on making a structured plan			SSE.4. Demonstrate ability of making an efficient plan by incorporating advice in the new plan		OE.6. Expect that making a new plan will help in dealing with fatigue

Step 3: Selecting theoretical methods and practical applications

In this step, theoretical methods and practical applications for achieving the COs and POs are selected (Bartholomew et al., 2016). A theoretical method is a technique or process for influencing change in the determinants of the targeted behavior. A practical application is a specific technique for practical use of a theoretical method. For example, by means of self-monitoring of behavior (method) we aimed to change cancer survivors' awareness of how they scheduled their daily activities (determinant) by encouraging them to register their daily activities for five to seven days (practical application) (see Table 3.3). Methods and applications were derived from literature, focus group interviews, and existing interventions (see Step 4, Reviewing available materials).

Several methods were used in the KNW, such as feedback, personalizing risk, consciousness raising, belief selection, modeling, active learning, persuasive communication, argumentation, goal setting, action planning, and implementation intentions. Two methods formed the core of the KNW: *tailoring* and *skills training for self-management*. These two methods were used throughout the entire intervention and were combined with the other methods to change the determinants of the targeted behaviors.

Tailoring

Tailoring is a technique in which information is provided that is adapted to the personal characteristics, circumstances, beliefs, motivations, and behavior of the receiver (de Vries & Brug, 1999; Noar et al., 2007). Thus, by means of tailoring, personalized advice can be provided that suits the cancer survivors' needs. Overall, tailoring is proven to be an effective technique in health promotion and communication (de Nooijer, Lechner, Candel, & de Vries, 2004; Kuijpers, Groen, Aaronson, & van Harten, 2013; Noar et al., 2007; Oenema, Brug, Dijkstra, de Weerdt, & de Vries, 2008; Peels et al., 2013). Since the information is personalized, less redundant information is provided, attention is increased, information is more thoughtfully processed, and behavior change or maintenance is better facilitated (Brug et al., 2003; de Vries & Brug, 1999; Noar et al., 2007; Rimal & Adkins, 2003). The KNW starts with a screening questionnaire that enables tailoring. Based on their answers, participants receive feedback about which of the seven problem areas deserve their attention (see also Step 4, Screening questionnaire). When selecting a problem area that the participant wants to work on, the information on that problem is tailored further, eventually resulting in a personalized action plan.

Table 3.3: Methods and applications to change the determinants of the performance objective "Manage daily tasks efficiently"

Determinant	Theoretical methods	Practical applications
Knowledge	• Chunking • Elaboration • Cues	• Advice provided is divided in several topics and is summarized when participants make their own planning. • After providing advice, personally relevant messages encourage participants to incorporate this advice with their situation. • Cues are provided that help saying "no" to a request and to recognize when personal limits are exceeded.
Awareness	• Consciousness raising • Self-monitoring of behavior	• Cancer survivors are encouraged to register their daily activities for five to seven days. After registration, survivors are given advice on effectively planning their day, asked to compare their plan with the advice received, and encouraged to adjust their plan to meet this advice.
Attitude	• Arguments	• Cancer survivors are given arguments why efficiently planning daily activities is beneficial for reducing fatigue, why guarding personal boundaries is important, and why saying "no" to some requests is important.
Skills and Self-efficacy	• Active learning • Action planning	• Cancer survivors are encouraged to make their own weekly plan using the advice given. • Cancer survivors are encouraged to make a list of personal signals indicating that limits are exceeded and select adequate measures for each signal. • Cancer survivors are encouraged to make their own action plan for when they are in a situation in which they want to say "no" to a request.
Perceived Behavior of Others	• Modeling	• Cancer survivors are provided with narratives of other survivors who are further along in their recovery process. In these narratives, the importance and effectiveness of planning daily activities, setting personal boundaries, and saying "no" to others is explained.
Outcome Expectations	• Persuasive communication • Active learning • Modeling	• By providing information from different sources (e.g., peers) on managing daily activities and by making assignments, cancer survivors are encouraged to expect that fatigue can be dealt with when taking adequate measures.

Skills training for self-management

Self-management is an iterative process that comprises observation of one's behavior (monitoring), making judgments of behavior based on the observation (evaluation), setting goals, and choosing and applying strategies to achieve these goals (action) (Bartholomew et al., 2016; Clark, 2003; Scheier & Carver, 2003). The principles of problem-solving therapy (PST) (D'Zurilla & Nezu, 2007; Nezu, Nezu, Houts, Friedman, & Faddis, 1999) and cognitive behavioral therapy (CBT) (Gielissen, 2007) were used as applications to increase cancer survivors' self-management skills. PST and CBT for cancer patients and survivors have been found effective for, amongst others, improving symptom management (Doorenbos et al., 2005; Mishel et al., 2002), improving mental health and quality of life (Allen et al., 2002; Fors et al., 2011), dealing with uncertainty (Mishel et al., 2002), reducing fatigue and insomnia (Garland et al., 2014; Goedendorp, Gielissen, Peters, Verhagen, & Bleijenberg, 2012;

Goedendorp, Gielissen, Verhagen, & Bleijenberg, 2009; Heins et al., 2013), and reducing psychological distress (Nezu, Nezu, Felgoise, McClure, & Houts, 2003; Osborn et al., 2006).

PST comprises five steps in which the patient (1) needs to adopt a positive attitude towards facing the problem, (2) defines what the exact problem is, (3) makes a list of alternatives to tackle the problem, (4) predicts the benefits and consequences of each alternative, and (5) implements the best alternative in daily life and evaluates the result (D'Zurilla & Nezu, 2007). In the KNW, each problem area is addressed following the structure of PST; that is, identifying the problem and selecting a goal, getting informed about different solutions, making a personalized action plan, and trying out the action plan and evaluating the progress.

The basic principles of CBT are covered by providing psychoeducation and giving assignments, such as monitoring behavior or thoughts, challenging dysfunctional cognitions, and encouraging patients to set new goals. In addition, elements were used from a treatment protocol proven effective for treating cancer-related fatigue among cancer survivors (Gielissen, 2007). The protocol links six factors to fatigue: (1) poor coping with cancer, (2) fear of cancer recurrence, (3) dysfunctional cognitions, (4) dysregulation of sleep, (5) dysregulation of activity, and (6) low social support. All these factors are addressed in the KNW.

Step 4: Producing program components and materials

With the end products of the previous steps, the program components and materials were produced. This included describing the program scope and sequence, preparing design documents, reviewing available materials, and developing and testing the program materials (Bartholomew et al., 2016).

Scope and sequence

The KNW (http://www.kankernazorgwijzer.nl) covers seven self-management training modules. The modules Fatigue, Return to Work, Mood (i.e., anxiety and depression), and Relationships mainly cover psychosocial and mental health-related issues, while the modules Physical Activity, Diet, and Smoking cover lifestyle-related issues. The modules are interrelated. For example, within the Fatigue module, participants receive the advice to also visit the Physical Activity module if there is an indication that the participant is getting too little physical activity. As discussed in Step 3, the sequence within the modules is based on PST (D'Zurilla & Nezu, 2007). In general, the modules consist of four components divided over two sessions. In the first session, participants (1) identify their problem, (2) select a goal and receive psychoeducation and assignments on how to deal with their problem, and (3) personalize their goal through action plans. (4) After 30 days, participants are invited for a second session in which they can evaluate the progress of their goal. If successful, participants are encouraged to maintain their behavior. Otherwise, participants are encouraged to try again, try another solution, or adjust their goal and receive additional advice on how to deal with difficult situations. Furthermore, all modules provide links to other relevant and reliable websites.

Participants of the focus groups (see Step 1) expressed the need to be informed about commonly experienced complaints after cancer treatment. Therefore, an additional module covering residual symptoms from cancer treatment was added to the KNW. In this module, general information is given on the most common physical complaints experienced after primary treatment, tips are given on how to deal with these symptoms, and advice is given to seek medical assistance for more information or help. For an overview of the scope and sequence of all modules, see Figure 3.1.

To keep participants involved in the program, several types of e-mails were sent. First, participants received reminder e-mails when they completed the screening questionnaire but did not visit any of the modules. Second, participants received an e-mail to invite them to the second session of a module. Third, participants received a postcard in spring wishing them Happy Easter and an eCard around the Holidays wishing them Happy Holidays. Fourth, monthly news items were placed on the website in which professionals from different fields talk about cancer recovery (see Step 4, "Video material"). Participants received an invitation e-mail to see the latest news item.

Suggestions from the target group

During the focus group interviews (see Step 1), the preferences for the look and feel of the future program were discussed. First, survivors suggested messages to be framed positively and that the program should have a calm and friendly appearance (see Figure 3.2). Second, survivors indicated that they preferred an open and unrestrictive program. Therefore, the KNW is programmed in such a way that users can choose which modules of the intervention they want to follow, even if they get the advice that they are doing well in this area. Third, survivors mentioned that the intervention should be easy to use. Therefore, a website with clear and distinctive buttons was designed with an emphasis on preventing an overload of information. Finally, it was suggested that the written information should be supported with video material. We adhered to this by providing informational videos from professionals from different fields. Also, there was a high demand for videos of fellow survivors, who were further into their recovery process, discussing their experiences of their life after cancer treatment. Therefore, we interviewed eight former patients discussing their cancer recovery and giving advice on how to deal with certain issues (see Step 4, "Video material").

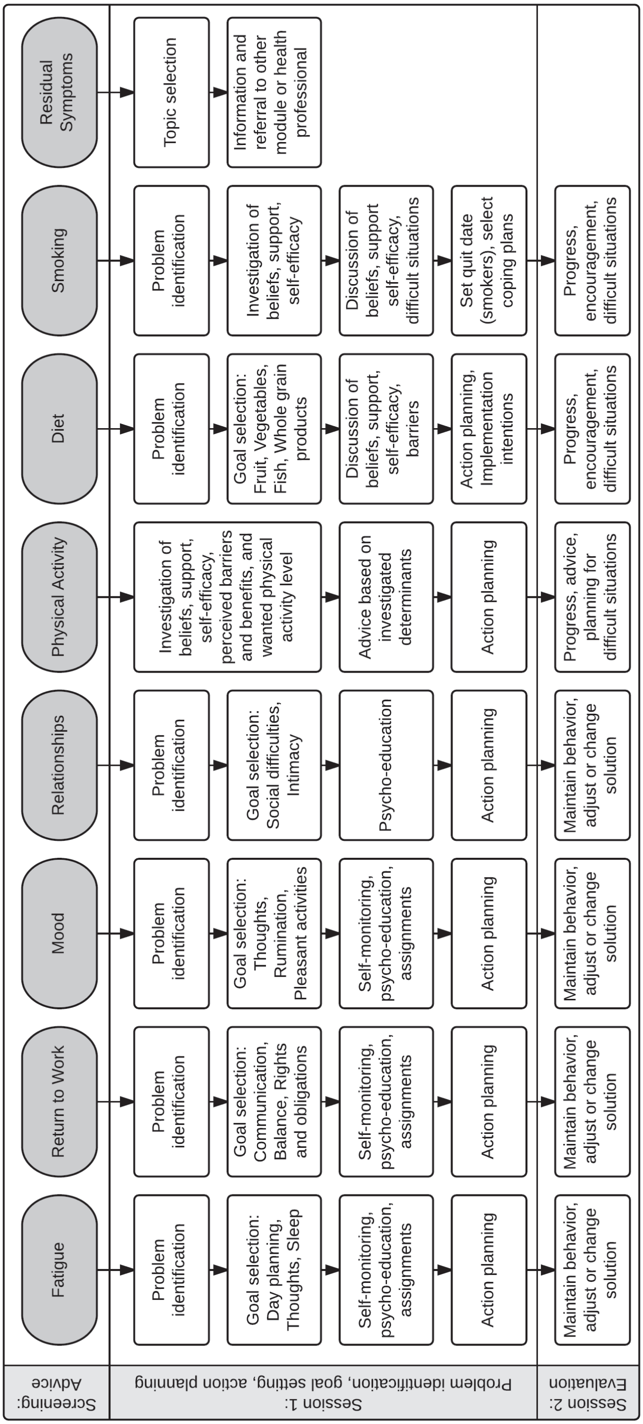


Figure 3.1: Overview of the scope and sequence of the modules

DE KANKER NAZORG WIJZER

Wat is het en voor wie is het bedoeld?

De Kanker Nazorg Wijzer is een online informatie- en ondersteuningsprogramma voor mensen bij wie de primaire behandeling succesvol is afgerond. Het programma is gericht is op herstel na kanker. Gelijktijdig is er een onderzoek aan gekoppeld om te beoordelen wat de gebruikers van het programma vinden en of het hen helpt. Het project wordt uitgevoerd door de Open Universiteit in samenwerking met de Universiteit Maastricht. Het project wordt gefinancierd door KWF Kankerbestrijding.

De Kanker Nazorg Wijzer is alleen toegankelijk voor personen die hiervoor een uitnodiging ontvangen. Gegevens van deelnemers zijn zorgvuldig afgeschermd en worden veilig bewaard. Alleen de onderzoekers hebben toegang tot deze gegevens.

Hoe is het project opgezet?

Deelnemers vullen verspreid over één jaar vier online vragenlijsten in. Een deel van de deelnemers krijgt meteen na het invullen van de eerste vragenlijst toegang tot het programma. De andere deelnemers krijgen na één jaar toegang. Door deze twee groepen te vergelijken kunnen we beoordelen of de Kanker Nazorg Wijzer heeft gewerkt.

Wachtwoord vergeten?

Neem contact op met het Kanker Nazorg Wijzer team (info@kankernazorgwijzer.nl).

NIEUWS

In november 2013 gaat het project van start. Tot en met juni 2014 kunnen nieuwe deelnemers instromen. Er zullen ongeveer 450

Figure 3.2: The appearance of the KNW

Reviewing available materials

Before developing the program materials, available program materials of others were reviewed for a possible match with the COs, methods, and applications of the KNW (Bartholomew et al., 2016). There were some computer-tailored interventions from which elements were usable for the modules of the KNW. For the Physical Activity module, we shortened and adjusted the Active Plus intervention (Peels et al., 2012, 2014; van Stralen, de Vries, Mudde, Bolman, & Lechner, 2009; van Stralen et al., 2008) to meet the characteristics of our target group. We also used elements from computer-tailored interventions on smoking cessation (Stanczyk, Bolman, Muris, & de Vries, 2011; Te Poel, Bolman, Reubsaet, & de Vries, 2009; van Berkel, 2000) and nutrition (Oenema, Brug, & Lechner, 2001; Springvloet, Lechner, & Oenema, 2014; van Keulen, 2010; van Keulen et al., 2008; Walthouwer, Oenema, Soetens, Lechner, & de Vries, 2013). As mentioned in Step 3, the Fatigue module was based on a protocol for treating cancer-related fatigue (Gielissen, 2007).

The intervention

Screening questionnaire

The KNW starts with a screening questionnaire measuring several concepts, including fatigue, work limitations, psychological distress, social support, physical activity, food intake, and smoking behavior (see Step 6, "Measurements"). Based on their answers, participants receive personal advice about which modules deserves their further attention. For this, a thermometer is used as visual aid (see Figure 3.3). "Green" advice indicates that the participant is doing well in this area and visiting the corresponding module is not necessary. "Orange" advice indicates that the participant is doing reasonably well, but there still is room for improvement. "Red" advice indicates that the participant is strongly advised to visit the corresponding module.

Uw persoonlijk profiel
Hieronder ziet u uw advies over de modules die u het beste kunt volgen. De kleur van de thermometers geeft aan wat goed gaat en waar u aan kunt gaan werken:

- **Groen:** U bent goed op weg. Het is niet noodzakelijk om deze module te volgen.
- **Oranje:** U bent al aardig op weg. Wilt u hier graag nog verder aan werken, kunt u deze module bekijken.
- **Rood:** We adviseren u om deze module te bekijken.

Werk
Uw antwoorden wijzen erop dat u geen duidelijke hulpvraag heeft wat betreft (terugkeer naar) werk. De module 'Werk' is voor u wellicht wat minder relevant. Wilt u toch graag wat meer informatie over terugkeer naar werk of over wat uw rechten en plichten zijn bij terugkeer naar werk, dan kunt u gerust een kijkje nemen in deze module.

Vermoeidheid
Uw antwoorden wijzen erop dat u veel last heeft van vermoeidheid. We adviseren u om een kijkje te nemen in de module 'Vermoeidheid'. In deze module wordt gekeken op welke manier u vermoeidheid ervaart en krijgt u advies om beter met vermoeidheid om te gaan. Ook kunt u opdrachten uitvoeren om uw vermoeidheid aan te pakken.

Relaties
Uw antwoorden wijzen erop dat u regelmatig moeilijkheden ervaart met uw sociale contacten of op het gebied van intimiteit. We adviseren u om een kijkje te nemen in de module 'Relaties'. In deze module krijgt u adviezen over hoe u steun kunt vragen, kanker bespreekbaar maakt, of hoe u om kunt gaan

Figure 3.3: After screening, participants are advised which modules deserve their attention

Modules

Fatigue. In the Fatigue module, cancer-related fatigue is addressed. Based on the answers of the screening questionnaire, participants receive a description of the type of fatigue they are most likely experiencing. Participants receive an improvement proposal, comprising the themes day plan, fatigue-related thoughts, sleeping behavior, feelings of anxiety or depression, relationships, and physical activity. When participants want to work on physical activity, relationships, or feelings of anxiety and depression, they are referred to the module Physical Activity, Relationships, or Mood, respectively.

The theme "Day Plan" discusses the importance of a structured day plan. Participants are encouraged to monitor their daily activities for five to seven days. Then, psychoeducation and assignments are given concerning planning activities and rest, not to exceed personal limits, and saying "no" to requests. Finally, participants are encouraged to make a weekly plan.

The theme "Thoughts About Fatigue" discusses beliefs concerning fatigue that are fatigue enhancing. Psychoeducation and assignments are given on recognizing and identifying non-helpful thoughts. Participants are encouraged to register their own non-helpful thoughts for one week. Then, these thoughts are challenged by discussing their credibility and usefulness and advice is given on how to replace these thoughts with helpful thoughts. Furthermore, advice is given on how to deal with rumination. Finally, to deal with stress related to dysfunctional cognitions, information and assignments are given concerning relaxation and mindfulness.

The theme "A Good Night's Sleep" discusses participants' sleeping behavior. Participants are encouraged to monitor their sleep and wake times for one week. Then, psychoeducation and assignments are given concerning types of sleeping problems, the importance of a consistent sleep-wake pattern, and sleeping hygiene. Also, information and assignments are given concerning relaxation and mindfulness.

Return to Work. In the Return to Work module, difficulties and rights and obligations concerning returning to work are discussed. Based on the answers of the screening questionnaire, participants receive an overview of their indicated problems concerning return to work and are given the opportunity to further specify these problems. Then, participants select a goal that they want to achieve (e.g., learning to ask for help). Depending on the chosen goal, participants are advised to continue with one of the three themes: Communication, Balance, and Rights and Obligations.

The theme "Communication" discusses the preparation of difficult work-related conversations. Psychoeducation and assignments are given on preparing work-related conversations with different persons, such as one's occupational physician, supervisor, or colleague. Advice is given on, amongst others, how to indicate possibilities and limitations with regard to work tasks, asking for help, dealing with incomprehension from the manager or colleagues, or preparing a job application. Moreover, advice and assignments are given on how to increase feelings of confidence and decrease feelings of stress in difficult interactions.

The theme "Balance" focuses on finding a balance between the participants' work abilities and their workload. Participants are encouraged to monitor for several workdays how much energy certain work-related tasks cost. Then, psychoeducation and assignments are given concerning planning the workday, not to exceed personal limits, making adjustments at work, dealing with limited concentration and memory problems, relaxation, and thinking positively.

The theme "Rights and Obligations" provides information on cancer survivors' rights and obligations concerning working with a long-term illness. Information is provided on topics such as re-integration, unemployment, searching for a new job, social welfare payments, insurances, legal advice, or rights on facilities to perform one's job properly, given the limitations caused by the disease or treatment.

Mood. The Mood module focuses on feelings of anxiety and depression. More specifically, the module discusses common anxiety and depression provoking thoughts and how to cope with these thoughts more effectively. Based on the answers of the screening questionnaire, participants receive feedback on their current state of anxiety, depression, and adjustment to cancer. When there is an indication that the participant is experiencing severe levels of psychological distress, a recommendation is given to visit one's general practitioner to get a referral for help. In the module, participants first set a goal they want to achieve (e.g., to reduce feelings of sadness). Then, psychoeducation and assignments are given concerning non-helpful or anxiety provoking thoughts, such as feelings of failure or fear of cancer recurrence. Participants are encouraged to monitor their inefficient thoughts for one week. Then, these thoughts are challenged by discussing their credibility and usefulness and advice is given on how to replace these thoughts with helpful thoughts. Furthermore, advice and assignments are given concerning planning pleasant activities, how to deal with rumination, and how to reduce feelings of anxiety or sadness by means of relaxation and mindfulness.

Relationships. The Relationships module addresses coping with difficult social situations and intimacy problems. Difficult social situations are discussed, such as receiving inadequate help from others, social isolation, experiencing social pressure, and talking about having had cancer. Based on the answers of the screening questionnaire, participants receive an overview of social situations in which they wish change. After selecting such a social situation, psychoeducation is given on how to constructively deal with this situation.

Concerning intimacy, psychoeducation is given on discussing intimacy and sexuality with significant others and how to cope with sexuality with respect to physical and functional changes due to cancer treatment. Coping with physical and functional changes is tailored to gender. For example, men receive advice on how to cope with issues such as erectile dysfunction or dry orgasms, while women receive advice on how to cope with issues such as menopausal symptoms or vaginal problems.

Physical Activity. In the Physical Activity module, participants are encouraged to increase their level of physical activity. Based on the answers of the screening questionnaire in combination with the Dutch physical activity guidelines, participants receive feedback on their own level of physical activity and to which extent it reaches the recommended level. Then, participants are encouraged to set a goal, for example, increasing physical activity during commuting, daily activities, leisure time, or sports. Subsequently, advice is given based on the participant's beliefs about the pros and cons of exercising, perceived barriers and benefits, self-efficacy, and social support. Next, participants are encouraged to make a personal exercise plan. The module provides information on specific exercises and sport activities tailored to participant's individual situation, physical limitations and social cognitive determinants.

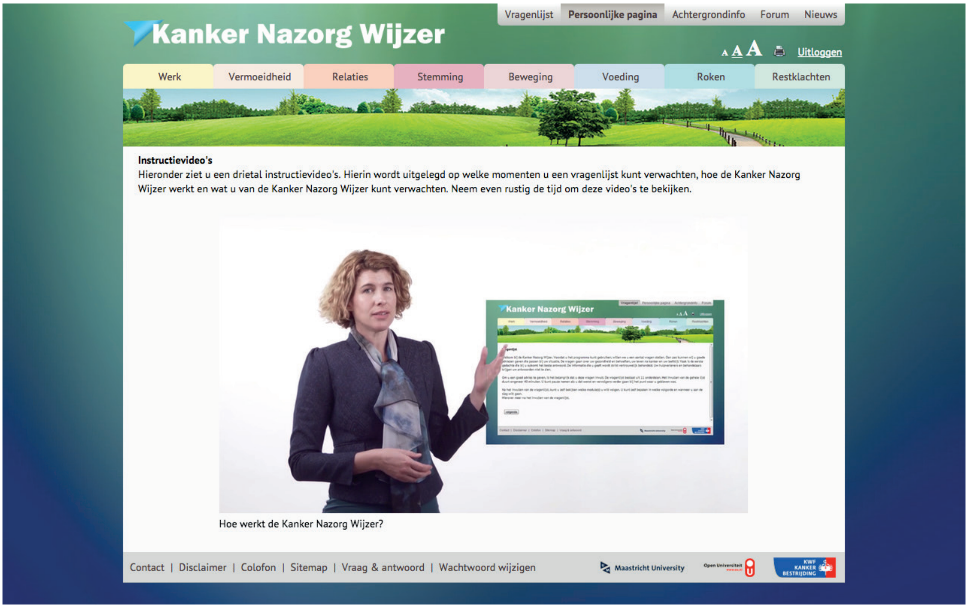
Diet. The Diet module focuses on increasing fruit, vegetables, whole grain bread, and fish consumption. Based on the answers of the screening questionnaire in combination with the Dutch nutritional guidelines, participants receive feedback on their dietary habits and the extent to which it reaches the recommended level. The module subsequently provides a standard, non-personalized overview of a healthy diet, including desirable and undesirable foods and an indication of the recommended servings. Afterwards, participants are encouraged to set one or two goals, for example, eating two pieces of fruit per day or eating 200 grams of vegetables per day. Subsequently, dietary advice is given, personalized to the participant's individual situation, experienced medical or treatment related problems, and the participant's attitudes, self-efficacy, and social support toward performing the desired dietary behavior.

Smoking. The Smoking module is developed for smokers to stimulate them to refrain from smoking and for former smokers to prevent relapse. Based on the answers of the screening questionnaire, participants' current smoking behavior is discussed. Smokers are encouraged to quit and to set a quit date. Advice is given on how to anticipate risky situations for a lapse and how to deal with withdrawal symptoms. Smokers are encouraged to develop an individual coping plan to prepare their quit attempt and to deal with difficult moments to maintain abstinence. Former smokers also receive advice based on their individual situation and social cognitive determinants, aimed at the prevention of relapse. They are also encouraged to develop coping strategies to prevent relapse.

Residual Symptoms. In the Residual Symptoms module, brief information is given about complaints, such as pain, lymphedema, osteoporosis, or neuropathy. If a certain topic is covered in one of the other modules, referral to the respective module is also given. Next to some basic tips on how to deal with these symptoms, participants are given advice to contact their physician or other health professional when they experience serious problems.

Other website elements

Personal page. On the personal page, participants can find an overview of the personal advice they received from the screening questionnaire and the modules. Also, the personal page contains a few instructional videos on how to use the KNW (see Figure 3.4).



Instructievideo's
Hieronder ziet u een drietal instructievideo's. Hierin wordt uitgelegd op welke momenten u een vragenlijst kunt verwachten, hoe de Kanker Nazorg Wijzer werkt en wat u van de Kanker Nazorg Wijzer kunt verwachten. Neem even rustig de tijd om deze video's te bekijken.

Hoe werkt de Kanker Nazorg Wijzer?

Figure 3.4: Example of an instructional video explaining how to use the KNW

Video material. The use of videos is an important component of the KNW. Text messages accompanied with video are more appreciated and better recalled than text messages only (Bol et al., 2013; Idriss, Alikhan, Baba, & Armstrong, 2009). There are four types of videos implemented. First, *instructional videos* explain what participants can expect from the KNW and how they should navigate the program. Second, *videos of fellow survivors* were included for which we interviewed eight cancer survivors who were further along in their recovery process and willing to share their experiences of their life after cancer treatment and give advice to deal with certain issues. Since men and women interviewed were from different age groups and recovering from different types of cancer, it is more likely that participants identify with one of these role models. Third, *videos of professionals* were included for which we interviewed a sexologist and two clinical psychologists. These professionals give psychoeducation and advice from clinical practice. Fourth, with monthly *news items* participants were provided with extra information on specific areas. We interviewed professionals from different fields, talking about topics such as exercise, diet, return to work, anxiety and depression, lymphedema, and peer support groups. With these news items, we aim to keep the participants involved in the KNW by referring them to the module that is related to the topic discussed in the news item.

Forum. The KNW has a forum where fellow survivors can meet and ask each other or members of the KNW team questions. Participants are kept anonymous and the KNW team monitors the forum to control for advice contradicting the advice given in the modules.

Pretesting and revising

The KNW was pretested among 13 cancer survivors. In general, the appearance and content of the KNW was highly appreciated. The modules were evaluated positively (M = 7.6, range = 1–10). Particularly, the videos of fellow survivors and professionals were highly rated (M = 8.0, range = 1–10). The mean scores for understanding, usefulness, reliability, applicability, completeness, and appearance of the KNW ranged from 3.3 to 3.7 (range = 1–4) and, therefore, were also highly appreciated. Some of the texts were evaluated as fairly long. Consequently, an editor reviewed and edited the text on readability and length. Furthermore, the tailored advice was evaluated to be of great value. While the tailored messages were computer generated, some participants initially thought that a person provided these messages. Although this demonstrated the power of tailoring, it also confused the participant when an answer did not fully match his or her expectations. Further, while the aim of the KNW is to stimulate participants to create their own solutions, some participants expected to receive personalized solutions to their problems. To address these issues, we included the previously mentioned instructional videos to explain how the KNW works and what participants can expect. After some final adjustments, the KNW was ready for implementation and effectiveness testing.

Step 5: Adoption and implementation

In the fifth step, a plan for program adoption and implementation was developed (Bartholomew et al., 2016) in the context of testing the effectiveness of the KNW in a randomized controlled trial (RCT). We created a network with representatives (e.g., department heads, oncologists, research nurses, and nurse practitioners) from several hospitals' outpatient clinics in internal medicine, oncology, gynecology, urology, and the breast clinic. Forty-five hospitals in the Netherlands were contacted for assistance in the recruitment. Twenty-two hospitals agreed to participate, with 21 hospitals eventually participating in patient recruitment. Reasons for refusing participation included: hospital was already participating in other research projects, lack of time or excessive workload, too few staff members to recruit participants, or insufficient number of patients who met the inclusion criteria. Creating this network was a very time-consuming process; it easily could take more than half a year from the moment of contacting a representative of a clinic until staff members began recruiting participants. Next, maintaining contact with multiple hospitals required good planning. To keep the staff members involved, we send out monthly newsletters with updates of the research project. Also, we regularly send "thank you" cards. To conclude, timely planning of program adoption and implementation is essential.

Step 6: Planning for evaluation

In the final step, a plan for the effect and process evaluation of the intervention was developed. While the effect evaluation describes the differences in outcomes between the participants who were and were not exposed to the KNW, the process evaluation aims to gain insight into the use and appreciation of the intervention (Bartholomew et al., 2016). For the evaluation of the KNW, an RCT comparing the intervention group with a waiting list control group was conducted. The RCT is approved by the Medical Ethics Committee Zuyderland-Zuyd (NL41445.096.12) and is registered in the Dutch Trial Register (NTR3375).

Participants

Patients were eligible for participation if they were 18 years or older, they had been diagnosed with any cancer type, primary treatment (surgery, chemotherapy, and/or radiotherapy) had been completed successfully for at least 6 weeks but no more than 52 weeks, there was no sign of recurrence in the latest follow-up visit, they were able to read and speak Dutch, and there was no serious medical, psychiatric, or cognitive illness that would interfere with participation. Computer literacy was not an explicit inclusion criterion, since the hospital staff was not able to screen for this. We expected that patients who were not computer literate would not participate in the study.

Design and procedure

Staff members of 21 hospitals (see Step 5) recruited patients from November 2013 through June 2014. The recruitment period varied per hospital. Patients were selected either during follow-up visits to the hospital or from reviews of patients' files. Oncologists, research nurses, and nurse practitioners from the outpatient clinics internal medicine, oncology, gynecology, urology, and breast clinics invited patients who met the inclusion criteria to participate by giving them an information package during a follow-up visit or sending the package to them following review of the patient's files. The information package included: (1) a letter with trial information and a username and password for first login, (2) an informed consent form with return envelope, (3) an information brochure concerning Medical Research, (4) a short manual on how to use the KNW, and (5) a small card with contact details and space where participants could write down their new username and password. A reminder was send after two weeks. Patients who agreed to participate were requested to sign the informed consent form and return it to the Open University of the Netherlands. Patients who participated in the research but did not return the consent form were contacted to do so. If they did not return the informed consent form after several reminders, they were excluded from evaluation.

After online registration, participants were randomly assigned to either the intervention group or the waiting list control group. Both groups had to fill in a questionnaire at four time points: At baseline (T0), after 3 months (T1), after 6 months (T2), and after 12 months (T3). T1 aimed to measure possible mediating variables, while T2 and T3 aimed to measure the short- and long-term effectiveness of the intervention, respectively. The intervention group had 6 months access to the KNW directly after baseline. The waiting list control group had access to the intervention after T3.

Several methods were used to increase the response rate. First, several automated e-mail reminders were sent for each measurement. Second, in the baseline measurement, participants could leave their telephone number so we could contact them concerning the research. When we noted that participants had not reacted to the e-mail reminders, we contacted them through telephone as a final reminder. Third, in the e-mail reminders participants were explained that they would receive a small token of appreciation at the end of the trial. That is, participants received a book voucher with a value of €10 for trial participation.

Measurements

The primary outcomes for the evaluation of the KNW comprise psychosocial well-being and lifestyle outcomes. Measuring psychosocial well-being comprised assessment of quality of life (Aaronson et al., 1993), psychological distress (Bjelland, Dahl, Haug, & Neckelmann, 2002; Zigmond & Snaith, 1983), mental adjustment to cancer (Watson & Homewood, 2008), fatigue (Vercoulen et al., 1994), work limitations (Burton, Chen, Conti, Pransky, & Edington, 2004; Burton, Pransky, Conti, Chen, & Edington, 2004; Lerner et al., 2001), and social support (van Sonderen, 2012). Measuring lifestyle comprised assessment of physical activity (Wendel-Vos et al., 2003), food consumption (van den Brink et al., 2005), and smoking behavior (Mudde et al., 2006). Secondary outcomes included measures that were assumed to moderate or mediate the effects of the primary outcomes, such as resilience (Smith et al., 2008), self-control (Tangney, Baumeister, & Boone, 2004), personal control (Moss-Morris et al., 2002), problem-solving skills (D'Zurilla et al., 2002; Dreer et al., 2009), and several background characteristics (e.g., age, gender, education, employment status, and disease and treatment history). Finally, we measured cancer survivors' unmet needs (Hodgkinson et al., 2007b).

Power calculation

Sample size calculations were based on the outcomes of quality of life and psychological distress, since these were expected to be the most difficult to change. Calculations showed that 144 patients per group were required to compare means for these outcomes between groups with a power greater than .80, one sided with an alpha of 0.10. This was based on an expected effect size of .30 and, since recruitment would be through hospitals, a correction for multilevel analyses (intracluster correlation coefficient = .005, design effect = 1.15). With an expected dropout rate of 20% during the study, this meant that 376 patients in total needed to be included at baseline. With 224 patients included in the intervention group and 218 patients in the waiting list control group at baseline, this target has been achieved.

DISCUSSION

The aim of this paper was to describe the systematic development and the study design for evaluation of the KNW, a web-based computer-tailored intervention aimed at providing psychosocial and lifestyle support during life after cancer. The intervention aims to reduce cancer survivors' experienced problems in seven areas: (1) cancer-related fatigue, (2) difficulties concerning return to work, (3) anxiety and depression, (4) relationships and intimacy issues, (5) a lack of physical activity, (6) a lack of healthy food intake, and (7) difficulties in preparing or maintaining smoking cessation. By reducing the experienced problems in these areas, it is expected that this ultimately will result in a higher quality of life. The intervention was developed using the IM protocol (Bartholomew et al., 2016). This protocol supports health promotion program planners in systematically developing a theory- and evidence-based program, and, as a result, increasing the likelihood of its effectiveness.

Beside the systematic development, the KNW has several other strengths. First, since the KNW concerns a web-based intervention, it can reach many patients at once and is accessible anytime and anywhere (Lustria et al., 2009). Second, by means of tailoring, information is more personally relevant. Therefore, it is more likely that this information increases attention, is more thoughtfully processed, and facilitates behavior change or maintenance (Brug et al., 2003; de Vries & Brug, 1999; Noar et al., 2007; Rimal & Adkins, 2003). Third, the use of video material to accompany the text also increases the likelihood that the information is remembered and recalled (Bol et al., 2013; Idriss et al., 2009). Fourth, as universal methods, the KNW uses the principles of PST (Nezu et al., 1999) and CBT (Gielissen, 2007) to stimulate cancer survivors to learn self-management techniques that they also can apply in other situations. Fifth, elements of the KNW are based on existing interventions that already have been proven effective. Sixth, by evaluating the KNW through an RCT, we will be able to draw conclusions about the intervention's effectiveness.

However, there are also some weaknesses that should be mentioned. First, the intervention contains much written information. Since PST and CBT are quite extensive forms of therapy, it was a challenge to reduce the amount of information while still holding to the theoretical framework of these methods. Much information might particularly be a problem for people with low health literacy (Verkissen et al., 2014), since they might not be able to adequately process all the information given. To avoid an overload of information, participants could freely choose which modules to visit, which steps to follow, and which assignments to make. Participants could stop anytime and continue at the point where they stopped. The use of video material might also be beneficial in the understanding of the information for survivors with low health literacy (Davis, Williams, Marin, Parker, & Glass, 2002; Hart, Blacker, Panjwani, Torbit, & Evans, 2015). Second, although the KNW is based on PST and CBT, there is no real patient-therapist interaction. Except by self-report, it is not possible to investigate whether the learned skills were applied in the right way (Finfgeld, 1999). In addition, it is difficult to anticipate the experienced emotions and non-verbal behavior of the participant or to give further explanation on why a certain advice is given. With computer tailoring, it is only possible to anticipate reactions that are highly expected. Third, while a greater proportion of cancer survivors are elderly (Dutch Cancer Society, 2011), this group in general has fewer computer skills (AGE Platform Europe, 2008) and is less likely to use the Internet as a source of health-related information (Chou et al., 2011) than younger cancer survivors. To address this problem, the KNW was developed in such way that it is relatively easy to use. The invitation for participation was accompanied with a quick guide for using the KNW and the program provides instructional videos explaining how the KNW works. Also, support through telephone and e-mail is provided. It should be noted that this is only a temporary issue, as computer skills and use are increasing rapidly, especially among older adults (Centraal Bureau voor de Statistiek, 2014).

In conclusion, the KNW is a theory- and evidence-based web-based computer-tailored intervention that seems a promising tool to support cancer survivors to cope with cancer-related issues during life after treatment. The results of the RCT, which will be presented in the upcoming chapters, will provide more insight into the effectiveness and working mechanisms of the KNW and its appreciation by its users.

PART II

INTERVENTION PROCESS EVALUATION

Use and appreciation of a tailored self-management eHealth intervention for early cancer survivors: Process evaluation of a randomized controlled trial

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ABSTRACT

Objective: A fully automated computer-tailored web-based self-management intervention, *Kanker Nazorg Wijzer* (Cancer Aftercare Guide), was developed to support early cancer survivors to adequately cope with psychosocial complaints and to promote a healthy lifestyle. The self-management training modules of the intervention target the following topics: return to work, fatigue, anxiety and depression, relationships, physical activity, diet, and smoking cessation. Participants were guided to relevant modules by personalized module referral advice that was based on participants' current complaints and identified needs. The aim of this study was to evaluate the adherence to the module referral advice, examine the intervention module use and its predictors, and describe the appreciation of the intervention and its predictors. Additionally, we explored predictors of personal relevance.

Methods: This process evaluation was conducted as part of a randomized controlled trial. Early cancer survivors with various types of cancer were recruited from 21 Dutch hospitals. Data from online self-report questionnaires and logging data were analyzed from participants allocated to the intervention condition. Chi-square tests were applied to assess the adherence to the module referral advice, negative binominal regression analysis was used to identify predictors of module use, multiple linear regression analysis was applied to identify predictors of the appreciation, and ordered logistic regression analysis was conducted to explore possible predictors of perceived personal relevance.

Results: Of the respondents ($n = 231$; $M_{age} = 55.59$, $SD = 11.46$; 79.2% female), 98.3% were referred to one or more modules ($M = 2.9$, $SD = 1.5$), and 85.7% visited at least one module ($M = 2.1$, $SD = 1.6$). Significant positive associations were found between referral to specific modules (range 1–7) and the use of the corresponding modules. The likelihood of visiting a particular module was higher when respondents were referred to that module by the module referral advice. Predictors of visiting a higher number of modules were a higher number of module referrals ($\beta = .14$, $p = .009$) and a higher perceived personal relevance ($\beta = .15$, $p = .014$), while having a partner was related to a lower number of modules used ($\beta = -.26$, $p = .044$). Overall appreciation was high ($M = 7.5$, $SD = 1.2$; scale 1–10) and was predicted by a higher perceived personal relevance ($\beta = .62$, $p < .001$). None of the demographic and cancer-related characteristics significantly predicted the perceived personal relevance.

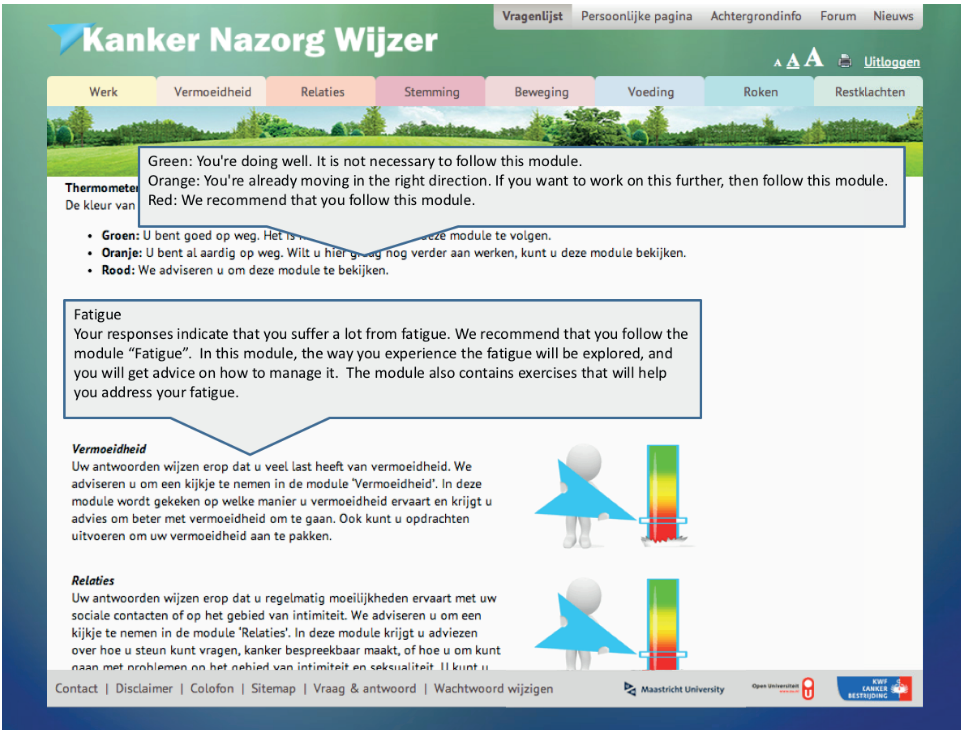
Conclusion: The Cancer Aftercare Guide in general and more specifically its modules were well used and highly appreciated by early cancer survivors. Indications were found that the module referral advice might be a meaningful intervention component to guide the users in following a preferred selection of modules. These results indicate that the fully automated

web-based Cancer Aftercare Guide provides personally relevant and valuable information and support for early cancer survivors. Therefore, this intervention can complement usual cancer aftercare and may serve as a first step in a stepped-care approach.

INTRODUCTION

Recovery from cancer and its treatment can be challenging for cancer survivors. A variety of physical, psychosocial, and lifestyle difficulties might impede the resumption of previous daily life activities (Bluethmann et al., 2015). Cancer aftercare guidelines for oncology professionals recommend paying attention to the early detection and recognition of psychological distress, fatigue, pain, problems with daily activities, lifestyle risks, and also to stimulating self-care within the first year after completing the primary curative cancer treatment (Comprehensive Cancer Centre the Netherlands, 2011b; Runowicz et al., 2016). Further, due to the aging population and improved cancer care, the population of cancer survivors is growing while complaints, needs, and preferences of cancer survivors can vary individually over the different subjects and time (Given & Given, 2013; Kanera et al., 2016a; The Netherlands Cancer Registry, 2017; Willems et al., 2016). For these reasons, fully automated, computer-tailored web-based cancer aftercare interventions may be suitable for providing a large number of cancer survivors with personalized advice at relatively low costs (Kohl, Crutzen, & de Vries, 2013). Moreover, online solutions fit well with the increasing numbers of cancer survivors who search the Internet for health-related information, especially with those survivors who do not seek face-to-face guidance or treatment (Chou et al., 2011; Ritterband & Tate, 2009). Web-based interventions might be appropriate to be integrated as a first step in a stepped-care approach, as it offers a low-intensity intervention first before referring to interventions that are more intensive. Such first-step, low-intensity interventions might be sufficient to meet the personal needs of a large proportion of survivors with relatively mild complaints and are less costly (Krebber et al., 2012). In addition, web-based interventions can comprise relevant information as written text, videos, animations, interactive features, hyperlinks, while personalization of the content is possible by applying computer tailoring (Broekhuizen, Kroeze, van Poppel, Oenema, & Brug, 2012; de Vries & Brug, 1999; Noar et al., 2007).

The web-based intervention *Kanker Nazorg Wijzer* (Cancer Aftercare Guide; KNW) is a fully automated intervention that aims to increase survivors' quality of life by providing psychosocial support as well as promoting positive lifestyle changes, and it targets cancer survivors of any type of cancer (Willems et al., 2015). The KNW consists of seven self-management training modules covering the topics return to work, fatigue, anxiety and depression, social relationship and intimacy issues, physical activity, diet, and smoking cessation (see Figure 3.1), supplemented with one general information module on residual symptoms. Based on the responses to a screening questionnaire, cancer survivors receive personalized advice on which KNW modules are most relevant for them to use. This module referral advice (MRA) is designed in a fashion analogous to traffic lights as displayed in Figure 4.1. This MRA aims to guide participants through the wide-ranging KNW portal, based on experienced complaints and identified needs, as assessed by the screening questionnaire. Six months after baseline (i.e., directly after intervention closure), the KNW has been shown to be effective in reducing fatigue and depressive symptoms and improving several quality of life domains (i.e., emotional and social functioning), (Willems et al., 2017a), and strong indications were found for an increase in moderate physical activity and a higher intake of vegetables, fruits, and fish (Kanera, Bolman, Willems, Mesters, & Lechner, 2016b). Besides assessing the effects of the KNW, it is important to understand how this complex intervention was used and appreciated by the participants, whether use and appreciation was predicted by certain user characteristics, and to evaluate relevant key intervention components (Brouwer et al., 2011; Hulscher, Laurant, & Grol, 2003; Kohl et al., 2013; Linnan & Steckler, 2002). Moreover, it is essential to examine specifically whether the provided information was perceived as personally relevant in order to evaluate the computer tailoring.



Green: You're doing well. It is not necessary to follow this module.
Orange: You're already moving in the right direction. If you want to work on this further, then follow this module.
Red: We recommend that you follow this module.

Thermometer
De kleur van

- **Groen:** U bent goed op weg. Het is deze module te volgen.
- **Oranje:** U bent al aardig op weg. Wilt u hier nog verder aan werken, kunt u deze module bekijken.
- **Rood:** We adviseren u om deze module te bekijken.

Fatigue
Your responses indicate that you suffer a lot from fatigue. We recommend that you follow the module "Fatigue". In this module, the way you experience the fatigue will be explored, and you will get advice on how to manage it. The module also contains exercises that will help you address your fatigue.

Vermoeidheid
Uw antwoorden wijzen erop dat u veel last heeft van vermoeidheid. We adviseren u om een kijkje te nemen in de module 'Vermoeidheid'. In deze module wordt gekeken op welke manier u vermoeidheid ervaart en krijgt u advies om beter met vermoeidheid om te gaan. Ook kunt u opdrachten uitvoeren om uw vermoeidheid aan te pakken.

Relaties
Uw antwoorden wijzen erop dat u regelmatig moeilijkheden ervaart met uw sociale contacten of op het gebied van intimiteit. We adviseren u om een kijkje te nemen in de module 'Relaties'. In deze module krijgt u adviezen over hoe u steun kunt vragen, kanker bespreekbaar maakt, of hoe u om kunt gaan met problemen op het gebied van intimiteit en seksualiteit. U kunt u

Figure 4.1: Module referral advice that encourages participants to follow relevant KNW modules

Previously published web-based interventions in the areas of lifestyle, mental health, and chronic conditions differ with regard to the number of (cancer-related) topics, the composition of the target group, the intervention components, and the delivery mode (Goode, Lawler, Brakenridge, Reeves, & Eakin, 2015; Kim & Park, 2015; Kohl et al., 2013; Kuijpers et al., 2013; McAlpine et al., 2015; van den Berg, Peters, Kraaijeveld, Gielissen, & Prins, 2013). Generally, typical web-based interventions are modular in set-up, are updated weekly, require weekly visits, last for about 10 weeks, and include interaction with the system, peers, or a counselor (Kelders, Kok, Ossebaard, & van Gemert-Pijnen, 2012). The actual use of most interventions was low, or data on the use have been poorly reported (Kelders et al., 2012; Kohl et al., 2013). The extent of use might be influenced by differences in participant and intervention characteristics (Ritterband et al., 2009). Prior studies among cancer survivors have shown that different user characteristics were related to different user patterns: for example, a higher usage was found among those with low levels of self-reported social support and a high illness burden, and among survivors who were working and who received radiotherapy (Berry, Blonquist, Patel, Halpenny, & McReynolds, 2015; Borosund, Cvancarova, Ekstedt, Moore, & Ruland, 2013). Being female, middle aged or older, having mid to high levels of education, a healthy body mass index (BMI), a healthier lifestyle, and having a low quality of life were predictors for a higher use of (multiple behavior) eHealth interventions among the general population (Brouwer et al., 2010; Reinwand, Schulz, Crutzen, Kremers, & de Vries, 2015b). Reported intervention characteristics that might predict usage were peer or counselor support, in-person contact, updates of the intervention, and sending reminders (Brouwer et al., 2011; Kelders et al., 2012; Ritterband et al., 2009). According to previously published studies, mixed results were found on the relationship between intervention usage and outcomes, such as symptom distress, depression, and lifestyle behaviors (Berry et al., 2015; Donkin et al., 2013; Schulz et al., 2012). With regard to appreciation, prior studies reported that web-based interventions were positively evaluated by cancer survivors, and a higher use was associated with a higher appreciation in a generic web-based intervention for breast cancer survivors (de Cocker et al., 2015; Ritterband et al., 2012; van den Berg et al., 2013).

The design of the KNW portal differs from most of the existing web-based interventions for cancer survivors by providing personalized self-management training on seven topics and by allowing users to choose which modules they want to use during an intervention period of 6 months. Previously identified effective intervention characteristics of web-based lifestyle interventions were tailored feedback, the use of theory, interactivity, goal setting, and online or in-person contact (Kelders et al., 2012; Kohl et al., 2013). The KNW comprises all these elements, except for in-person contact. However, the MRA provides automated personalized guidance through the KNW modules. Given the large scope and the varied target group of the KNW portal, it is important to assess how the intervention was used, appreciated, whether the content was sufficiently tailored to be perceived as personally relevant, and what possible factors, including personal relevance, might predict the module use and its appreciation. In addition, the MRA might be a meaningful intervention component. Therefore, the association between the MRA and the KNW module use also needs to be evaluated.

The main objective of this study is threefold: (1) to describe the use of the KNW modules and to identify predictors of a higher number of modules used, (2) to investigate the adherence to the provided MRA, and (3) to describe the appreciation of the KNW and its predictors. Additionally, to explore how well the tailoring worked and whether the perceived personal relevance might be different among subgroups, we explored possible predictors of personal relevance.

METHODS

This process evaluation was conducted as part of a two-armed randomized controlled trial (RCT) that evaluates the effects of the KNW portal. For the purpose of this report, all respondents of the intervention condition were included in the analyses. The details of the trial design, sample size calculation, participant eligibility, recruitment procedures, and the intervention have been published elsewhere (Kanera et al., 2016b; Willems et al., 2015, 2017a) (see also Chapter 3). Ethical approval for this trial (Dutch Trial Register NTR3375) was obtained from the Medical Ethics Committee Zuyderland-Zuyd (NL41445.096.12). All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments of comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Specific intervention elements: MRA and module principles

A comprehensive description of the intervention, including the eight KNW modules, the underlying theoretical frameworks, and technical features are published in detail elsewhere (Kanera et al., 2016b; Willems et al., 2015) (see also Chapter 3). This section describes the details of the MRA that was based on personal scores from the baseline questionnaire and that can refer to the seven self-management modules of the KNW (see Figure 3.1). The classification criteria for green, orange, and red MRA are summarized in Table 4.1. A green MRA signifies that the respondent reported no complaints, or minor complaints or needs, concerning the specific topic. Therefore, following the correspondent module is not a high priority. An orange MRA was provided when the respondents reported elevated but not severe complaints, or when respondents partially adhered to the lifestyle recommendations of the World Cancer Research Fund/American Institute for Cancer

Research and the American Cancer Society (Rock et al., 2012; WCRF/AICR, 2007). The "orange" advice praises respondents' reasonably positive scores, but recommends that they follow the corresponding module for further improvement. This orange category includes a wide coverage of score ranges, allowing for participants with higher, but not severe scores to still receive some positive and encouraging feedback and not lose their motivation to follow a module due to feedback that might be perceived as too stringent. A red MRA was provided only when severe psychosocial complaints, problematic functioning, or low/no adherence to lifestyle recommendations was reported, thus indicating that the respondent might be in high need of support concerning the specific topic. In that case, it was strongly recommended to follow the corresponding module. More detailed information on the underlying measures and cutoff points is included in Appendix B.

Throughout the different KNW intervention modules, principles of problem-solving therapy, cognitive behavioral therapy, social cognitive theories, and self-regulation theories were applied (Baumeister, Heatherton, & Tice, 1994; D'Zurilla & Nezu, 2007; de Vries et al., 2003; Gielissen, 2007). According to the I-Change Model (de Vries et al., 2003), awareness factors such as knowledge, cues to action, and risk perception might be important determinants in the dynamic process of behavior change by influencing motivation and intention. By applying the MRA, participants were made aware of their current psychosocial status and lifestyle behaviors in relation to the norms and guidelines, with the aim of guiding the participants toward the appropriate self-management modules. When using the modules, self-management skills training was provided by encouraging respondents to observe their current behavior in more detail, choose themes to work on, set goals, and to prepare action and coping plans, followed by monitoring their experiences and possible progress in the changed strategies and behaviors. Within the modules, the information and support was tailored to the current emotional status, lifestyle behavior, and motivational determinants (attitude, self-efficacy, intention) by the application of computer tailoring. Furthermore, the feedback was tailored to personal characteristics (gender, age, marital status, children, education level), and cancer-related and medical issues (type of cancer, comorbidities). Thirty days after completing (parts of) one module, the participants were invited to reflect on their behavioral change plans and experiences in a brief personalized evaluation session. They were also encouraged to continue applying the previously recommended self-management skills. Furthermore, valuable generic information about lifestyle and psychosocial issues was accessible when visiting the user forum and the monthly news items.

Table 4.1: Classification of the green, orange, and red MRA

Module	Measurements and classification criteria	MRA categories		
		Green	*Orange*	*Red*
Return to Work	Extended CaSUN (Hodgkinson et al., 2007b; Mesters et al., 2015; Willems et al., 2016). Needs concerning: Help to adjust/find a job (0, 3–5); Help to receive financial support (0, 3–5); Help to carry out work (0, 3–5); Information on rules and legislation (0, 3–5)	No unmet needs (0)	Score on unmet needs 3–12	Score on unmet needs ≥13
Fatigue	CIS, subjective fatigue subscale (1–56) (Vercoulen et al., 1994)	<27	27–35	>35
Relationships	SSL-D (6–24) (van Sonderen, 2012) CaSUN (two items[a]) (Hodgkinson et al., 2007b)	SSL-D ≤7	SSL-D = 8 or 9 & needs CaSUN	SSL-D ≥10 & needs CaSUN
Mood	HADS-A (0–21) and HADS-D (0–21) (Zigmond & Snaith, 1983) MAC: dimension negative adjustment to cancer (16–64) (Watson & Homewood, 2008)	HADS-A <8 and HADS-D <8 and MAC ≤36	HADS-A <8, HADS-D <8 and MAC >36; HADS-A <8 and HADS-D 8–15; HADS-A 8–15 and HADS-D <8 or 8–15	HADS-A <8 or 8–15 and HADS-D >15; HADS-D <8 or 8–15 and HADS-A >15; HADS-A >15 and HADS-D >15
Physical Activity	SQUASH (de Hollander, Zwart, de Vries, & Wendel-Vos, 2012; Wendel-Vos, Schuit, Saris, & Kromhout, 2003): Weekly ≥150 min moderate to vigorous PA Daily ≥30 mins of moderate PA on ≥5 days p/w	Meeting both conditions	Meeting one out of two conditions	Meeting no conditions
Diet	Dutch Standard Questionnaire on Food Consumption (van den Brink, Ocké, Houben, van Nierop, & Droomers, 2005): Daily ≥200g vegetables; Daily ≥2 pieces of fruit; Weekly ≥2 servings of fish; Daily ≥15g whole grains[b]; Daily ≥ 4 servings of potatoes/whole-grain rice/whole-grain pasta	Meeting at least four out of five conditions	Meeting two or three out of five conditions	Meeting one or none out of five conditions
Smoking	Smoking, not smoking, time point of quitting (Mudde, Willemsen, Kremers, & de Vries, 2006)	Not smoking, quit prior to cancer diagnosis	Quit smoking after cancer diagnosis	Current smokers

CaSUN: Cancer Survivors' Unmet Needs questionnaire; CIS: Checklist Individual Strength; PA: physical activity; p/w: per week; HADS: Hospital Anxiety and Depression Scale, HADS-A: Anxiety subscale, HADS-D: Depression subscale; MAC: Mental Adjustment to Cancer scale; SSL-D: Social Support List-Discrepancy; SQUASH: Short Questionnaire to Assess Health Enhancing Physical Activity. [a] Needs related to sexuality and fertility. [b] Whole-grain bread, oatmeal, cereals.

Measurements

All data were derived from online self-report questionnaires and logging details.

Module use

Module use was assessed by using logging data. Actual use was dichotomized (yes/no) for each module separately (in total eight modules). Module use was categorized into "yes" when at least the first three pages of a module were used. These three pages comprised important key information after which participants followed personalized pathways through the modules. The individual pathways were based on the responses to the baseline questionnaire, own preferences and goals, and take into consideration that the amount of needed information and/or support can vary to initiate behavior change (Donkin et al., 2013). Additionally, by assessing login data (last day the separate modules were used), the number of weeks of module engagement was registered.

Appreciation

At 6-month follow-up, the overall rating of the KNW and separate ratings for each of the used module(s) were assessed on a scale ranging from 1 (*very poor*) to 10 (*outstanding*) (e.g., "Overall, how do you rate the KNW?", "How do you rate the Mood module on a scale from 1 to 10"). Further, four separate items were measured on a five-point Likert-scale ranging from 1 (*low*) to 5 (*high*) to evaluate whether the provided information and support was understandable, useful, personally relevant, and recommendable to fellow patients. The perceived personal relevance ("Was the information from the Cancer Aftercare Guide of personal relevance for you?") was included in the analysis of this study to explore whether computer tailoring worked well within the KNW. These items correspond to items that were used in other studies to measure the appreciation of web-based interventions (Stanczyk et al., 2014; van Genugten et al., 2012; Walthouwer, Oenema, Lechner, & de Vries, 2015b).

Demographic and cancer-related variables

Information about demographic and cancer-related characteristics was collected at baseline. Standard questions were used to measure age, gender, and marital status. Marital status was dichotomized into "with partner" (married, cohabiting partners) and "without partner" (single, divorced, widowed). Education level was categorized into "low" (lower vocational education, medium general secondary education), "medium" (secondary vocational education, higher general secondary education), and "high" (higher vocational education, university education). Employment status was dichotomized into "working" (self-employed, in paid employment) and "not working" (unemployed, retired, unable to work). Type of cancer was categorized into "breast", "colorectal", and "other types of cancer" (i.e., bladder, esophageal, gynecologic, hematologic, kidney, liver, lung, prostate, stomach, testicular, and thyroid cancer). Type of treatment was categorized into "surgery, chemotherapy, and radiotherapy", "surgery and chemotherapy", "surgery and radiotherapy", and "other". Further, aftercare (yes/no) and comorbidities (yes/no) were measured, and height and weight were assessed to determine BMI. The time since completion of primary treatment in weeks was based on registry data from the hospitals.

Statistical analyses

The analyses were performed using Stata 13.1. Descriptive statistics were used to describe demographic and cancer-related characteristics of the module (non-)users and the number of weeks of module engagement among all participants of the intervention condition at baseline. To calculate the appreciation outcomes, participants who completed the relevant questions at the 6-month measurement and who used the corresponding modules were included. Chi-square tests were used to determine the relationships between the MRA and the subsequent module use with a two-sided alpha = .05 level of significance. Negative binominal regression analysis was used to identify the predictors of a higher number of modules used (0–8), due to overdispersed count data. Independent variables (hypothesized predictors) were demographic variables (gender, age, marital status, education, employment), cancer-related variables (cancer type, treatment type, number of weeks after completing primary cancer treatment, aftercare used, comorbidities, BMI), the number of red and orange MRA, ranging from 0 to 7, and the perceived personal relevance, ranging from 1 to 5. To examine the predictors of a higher overall appreciation of the KNW, multiple linear regression analysis was applied among participants who completed the follow-up questionnaire after 6 months. The dependent variable was the overall rating of the KNW, measured at 6-month follow-up, ranging from 1 to 10. The same independent variables as described above were counted as predictors. Furthermore, the number of modules used (sum score 0–8) was added to the multiple linear regression model. To explore possible predictors of perceived personal relevance, ordered logistic regression analysis was conducted, taking into consideration that the dependent variable, perceived personal relevance, was an ordinal variable, ranging from 1 to 5. Within this analysis, all demographic and cancer-related characteristics were added as independent variables. Dummy coding was used for categorical variables including more than two categories and the continuous and ordinal variables were standardized in all conducted regression analyses. Since filling out all computer-based questions was required, and respondents were reminded automatically if a question was not answered, there were no missing data at baseline. Missing data at 6-month follow-up due to dropout were not imputed when calculating appreciation outcomes.

RESULTS

Baseline characteristics of the intervention participants are displayed in Table 4.2. The majority of the participants was female (79.2%), mean age was 55.59 (*SD* = 11.46) years, and 70.1% had been treated for breast cancer. A detailed overview of cancer diagnoses among the sample is shown in Appendix C. Mean time since completing primary cancer treatment was 25.06 (*SD* = 13.49) weeks.

Module use

The majority (80-100%) of the module users continued after reading the first three compulsory pages of the different modules. The numbers and percentages of participants who used the separate modules are displayed in Table 4.2. The Diet module (58.0%) was used most often, and the Smoking module was used least often (10.0%). However, from all the smokers at baseline (*n* = 27), 13 (48%) individuals used the Smoking module. Overall, the participants used on average 2.06 (*SD* = 1.57) KNW modules; 14.3% used no modules, 30.3% used one module, 18.2% used two modules, 21.2% used three modules, 8.7% used four modules, 3.9% used five modules, and 3.4% individuals used six or more modules. Module engagement was highest during the first 16 weeks after getting KNW access: around 80% of the users used the modules within this period.

Provided module referral advice

Table 4.3 displays how the red, orange, and green MRA ranged among the participants and how the modules were used. For the modules Fatigue, Diet, and Smoking, more red compared to orange MRA was provided, and for the modules Return to Work, Mood, Relationships, and Physical Activity, more orange compared to red MRA was given. Green MRA was most frequently given with regard to the modules Smoking, Return to Work, Mood, and Relationships. Module use after getting a red or orange MRA was 58.8% and 38.6% for Fatigue module, 55.6% and 52.4% for Return to Work module, 25% and 30.3% for Mood module, and 25.9% and 27.3% for Relationships module. Concerning the lifestyle modules, module use after receiving a red or orange MRA for Physical Activity was 25% and 35%, for Diet 50.4% and 68.7%, and for Smoking 48.2% and 42.9%. From the 231 participants, 173 (74.9%) received at least one red MRA, and 192 (83.1%) received at least one orange MRA. On average, the participants were referred to 2.9 (*SD* = 1.5) relevant modules (either red or orange MRA).

Table 4.2: Overall baseline characteristics of the KNW participants and categorized for module use (*n* = 231)

			Modules of the KNW							
	Overall (*n* = 231)	**No module (*n* = 33) (14.3%)**	**Return to Work (*n* = 53) (22.9%)**	**Fatigue (*n* = 82) (35.5%)**	**Relation-ships (*n* = 38) (16.5%)**	**Mood (*n* = 49) (21.2%)**	**Physical Activity (*n* = 51) (22.1%)**	**Diet (*n* = 134) (58%)**	**Smoking (*n* = 23) (10%)**	**Residual Symptoms (*n* = 47) (20.4%)**
Female, *n* (%)	183 (79.2)	26 (78.8)	46 (86.8)	63 (76.8)	30 (79.0)	41 (83.7)	44 (86.3)	106 (79.1)	17 (73.9)	40 (85.1)
Age, mean (*SD*)	55.6 (11.5)	52.5 (10.7)	52.8 (9.5)	55.1 (11.6)	55.9 (12.1)	54.4 (11.7)	56.3 (9.7)	56.0 (11.1)	51.6 (8.7)	56.2 (9.0)
With partner, *n* (%)	193 (83.6)	27 (81.8)	43 (81.1)	65 (79.3)	31 (81.6)	37 (75.5)	42 (82.4)	109 (81.3)	16 (69.6)	36 (76.6)
BMI, mean (*SD*)	26.0 (5.0)	27.2 (7.3)	25.7 (5.0)	26.2 (4.3)	26.1 (3.5)	25.3 (4.0)	26.1 (3.6)	25.4 (4.7)	24.8 (3.1)	25.4 (3.9)
Education level (%)										
Low	76 (32.9)	13 (39.4)	12 (22.6)	23 (28.1)	12 (31.6)	15 (30.6)	18 (35.3)	42 (31.3)	9 (39.1)	13 (27.7)
Medium	76 (32.9)	12 (36.4)	20 (37.7)	31 (37.8)	13 (34.2)	20 (40.8)	18 (35.3)	44 (32.8)	7 (30.4)	14 (29.8)
High	79 (34.2)	8 (24.2)	21 (39.6)	28 (34.2)	13 (34.2)	14 (28.6)	15 (29.4)	48 (35.8)	7 (30.4)	20 (42.6)
Working at baseline, *n* (%)	122 (52.8)	20 (60.6)	38 (71.7)	40 (48.8)	18 (47.4)	28 (57.1)	27 (52.9)	70 (52.2)	13 (56.5)	26 (55.3)
Cancer type, *n* (%)										
Breast	162 (70.1)	24 (72.7)	40 (75.5)	55 (67.1)	27 (71.1)	36 (73.5)	41 (80.4)	94 (70.2)	18 (78.3)	32 (68.1)
Colon	29 (12.6)	4 (12.1)	4 (7.6)	10 (12.2)	5 (13.2)	6 (12.2)	2 (3.9)	19 (14.2)	3 (13.0)	9 (19.2)
Other	40 (17.3)	5 (15.2)	9 (16.9)	17 (20.7)	6 (15.8)	7 (14.3)	8 (15.7)	21 (15.7)	2 (8.7)	6 (12.8)
Had cancer before, *n* (%)	24 (10.4)	5 (15.2)	3 (5.7)	8 (9.8)	3 (7.9)	4 (8.2)	5 (9.8)	13 (9.7)	2 (8.7)	5 (10.6)
Treatment type, *n* (%)										
Surgery, chemotherapy, and radiotherapy	86 (37.2)	11 (33.3)	20 (37.7)	37 (45.1)	18 (47.4)	20 (40.8)	22 (43.1)	53 (39.6)	11 (47.8)	22 (46.8)
Surgery and chemotherapy	61 (26.4)	11 (33.3)	16 (30.2)	17 (20.7)	9 (23.7)	16 (32.7)	12 (23.5)	35 (26.1)	7 (30.4)	15 (31.9)
Surgery and radiotherapy	46 (19.9)	5 (15.2)	11 (20.8)	15 (18.3)	5 (13.2)	10 (20.4)	11 (21.6)	26 (19.4)	3 (13.0)	8 (17.1)
Other	38 (16.5)	6 (18.2)	6 (11.3)	13 (15.9)	6 (15.8)	3 (6.1)	6 (11.8)	20 (14.9)	2 (8.7)	2 (4.3)
Weeks since completion treatment, mean (*SD*)	25.1 (13.5)	27.1 (15.6)	22.3 (13.7)	24.1 (14.4)	26.5 (12.9)	25.3 (13.6)	23.7 (13.6)	25.0 (13.1)	22.1 (13.2)	25.4 (3.9)
Having comorbidities, *n* (%)	62 (26.8)	10 (30.3)	14 (26.4)	25 (30.5)	10 (26.3)	12 (24.5)	15 (29.4)	34 (25.4)	7 (30.4)	8 (17.0)
Using aftercare, *n* (%)	145 (62.8)	25 (75.8)	38 (71.7)	46 (56.1)	29 (76.3)	32 (65.3)	31 (60.8)	83 (61.9)	12 (52.2)	29 (61.7)

Table 4.3: Provided MRA and subsequent module use

Module	Red			Orange			Green		
	MRA	Followed module (%)		MRA	Followed module (%)		MRA	Followed module (%)	
	%	yes	no	%	yes	no	%	yes	no
Return to Work	3.9	55.6	44.4	18.2	52.4	47.6	77.9	14.4	85.6
Fatigue	34.6	58.8	41.3	19.1	38.6	61.4	46.3	16.8	83.2
Relationships	11.7	25.9	74.1	19.1	27.3	72.7	69.3	11.8	88.1
Mood	1.7	25.0	75.0	28.6	30.3	69.7	69.7	17.4	82.6
Physical Activity	5.2	25.0	75.0	35.9	37.4	62.7	58.9	12.5	87.5
Diet	53.3	50.4	49.6	42.9	68.7	31.3	3.9	44.4	55.6
Smoking	11.7	48.2	51.9	3.1	42.9	57.1	85.3	3.6	96.5

Adherence to the provided module referral advice

The relations between the color of MRA (red, orange, and green, respectively) and module use are shown in Table 4.4. In general, the likelihood that participants actually used a relevant module was higher when the MRA was red or orange compared to green. When comparing module use after receiving a red MRA versus an orange MRA for the modules Return to Work, Mood, Relationships, Physical Activity, and Smoking, the differences were small, meaning that both colors led to comparable module participation. Participants used modules Fatigue ($\chi^2 = 4.60$, $p = .032$, $OR = 2.26$) more often when a red MRA was provided compared to an orange MRA. The Diet module ($\chi^2 = 7.55$, $p = .006$, $OR = 0.46$) was used more often when an orange MRA was provided compared to a red MRA.

Appreciation

From the 231 participants who had access to the KNW intervention, 182 responded to the questions, measured 6 months after baseline, concerning appreciation. The overall appreciation of the KNW was high ($M = 7.5$, $SD = 1.2$) (Table 4.5). In general, the overall KNW was rated more positively among module users compared to non-module users. Ratings of the separate modules ranged from 6.4 (satisfactory) for the Residual Symptoms module to 8 (good) for the Smoking module. Personal relevance ranged from 2.9 to 3.5 (a little bit relevant to relevant). The ratings for comprehensibility, usefulness, and recommendation to other cancer survivors were all positive and very uniform (Table 4.5).

Predictors of a higher number of modules used

Using a higher number of modules was predicted by a higher number of red/orange MRA ($\beta = .14$, $p = .009$) and by a higher perceived personal relevance ($\beta = .15$, $p = .014$). Moreover, having a partner was significantly related with a lower number of modules used ($\beta = -.26$, $p = .044$) (Table 4.6).

Table 4.4: Relationship between the MRA and module use (χ^2-tests; *df* = 1)

	Red compared to orange			Red compared to green			Orange compared to green		
Module	χ^2	*p*	*OR* [95% CI]	χ^2	*p*	*OR* [95% CI]	χ^2	*p*	*OR* [95% CI]
Return to Work	0.03	.863	1.14 [0.21, 6.56]	10.57	**.001**	7.40 [1.46, 39.25]	28.92	**.000**	6.52 [2.92, 14.47]
Fatigue	4.60	**.032**	2.26 [0.99, 5.16]	35.49	**.000**	7.04 [3.12, 14.69]	8.33	**.004**	3.11 [1.30, 7.37]
Relationships	0.02	.901	0.93 [0.26, 3.11]	3.81	.051	2.60 [0.81, 7.49]	6.35	**.012**	2.78 [1.11, 6.73]
Mood	0.05	.822	0.77 [0.01, 10.27]	0.16	.693	1.58 [0.03, 20.50]	4.68	**.031**	2.07 [1.00, 4.21]
Physical Activity	0.70	.404	0.19 [0.00, 1.48]	1.47	.225	2.33 [0.37, 10.57]	18.60	**.000**	4.17 [2.02, 8.74]
Diet	7.55	**.006**	0.46 [0.26, 0.83]	0.12	.730	1.27 [0.26, 6.71]	2.18	.140	2.74 [0.54, 14.67]
Smoking	0.06	.803	1.24 [0.17, 10.06]	58.08	**.000**	25.20 [7.67, 85.09]	22.40	**.000**	20.36 [2.40, 141.94]

Table 4.5: Appreciation of KNW after 6 months

	Overall	No module	Fatigue	Return to Work	Mood	Relation-ships	Physical Activity	Diet	Smoking	Residual Symptoms
Overall KNW (1–10), mean (*SD*)	7.5 (1.2)	7.1 (2.0)	7.6 (1.1)	7.6 (1.1)	7.4 (1.0)	7.4 (1.0)	7.6 (1.1)	7.5 (1.0)	7.8 (1.2)	7.4 (1.1)
Modules (1–10)^a, mean (*SD*)			7.3 (1.3)	7.0 (1.3)	7.5 (1.2)	7.2 (0.8)	7.7 (1.1)	7.6 (1.0)	8 (1.3)	6.4 (1.9)
Subquestions on content (1–5)^b, mean (*SD*)										
Understandable?	4.3 (0.6)	4.1 (1.0)	4.4 (0.5)	4.4 (0.5)	4.3 (0.5)	4.5 (0.5)	4.4 (0.5)	4.4 (0.5)	4.3 (0.5)	4.4 (0.5)
Useful?	3.7 (0.8)	3.7 (1.1)	3.8 (0.8)	3.7 (0.8)	3.7 (0.8)	3.7 (0.8)	3.7 (0.7)	3.7 (0.8)	3.8 (0.9)	3.4 (0.9)
Personally relevant?	3.2 (0.9)	2.9 (1.2)	3.4 (0.8)	3.3 (0.7)	3.2 (0.9)	3.4 (0.9)	3.5 (0.7)	3.2 (0.8)	3.3 (0.9)	3.3 (0.9)
Recommendable to fellow survivors?	3.9 (1.0)	3.6 (1.1)	3.9 (1.0)	3.9 (1.0)	3.8 (1.0)	3.7 (1.0)	4 (1.0)	3.9 (1.0)	4.1 (0.9)	3.8 (1.0)

[a] No module *n*=18; Fatigue *n*=47; Return to Work *n*=27; Mood *n*=13; Relationships *n*=11; Physical Activity *n*=28; Diet *n*=77; Smoking *n*=6; Residual Symptoms *n*=14

[b] No module *n*=18; Fatigue *n*=67; Return to Work *n*=46; Mood *n*=45; Relationships *n*=34; Physical Activity *n*=45; Diet *n*=115, Smoking *n*=18, Residual Symptoms *n*=39

Table 4.6: Predictors of a higher number of followed modules of the KNW (n = 182)

	Higher number of followed modules (0–8)		
Variable	**β**	***SE* β [95% CI]**	***p***
Gender *(ref. male)*	.07	.24 [–.39, .53]	.771
Age	.03	.07 [–.10, .16]	.650
Marital status *(ref. no partner)*	–.26	.13 [–.50, –.01]	**.044**
Being employed *(ref. no)*	.18	.10 [–.08, .41]	.192
Education level *(ref. low)*			
Medium	.14	.12 [–.11, .38]	.274
High	.17	.13 [–.08, .41]	.192
Breast cancer *(ref. other)*	.04	.21 [–.38, .45]	.867
Primary cancer treatment *(ref. other)*			
Surgery and radiotherapy	.15	.18 [–.31, .40]	.797
Surgery and chemotherapy	.27	.18 [–.09, .63]	.163
Surgery, chemotherapy, and radiotherapy	.25	.17 [–.08, .58]	.135
Number of weeks after completing treatment	.02	.05 [–.08, .11]	.730
Participating in aftercare (*ref. no*)	–.08	.11 [–.29, .14]	.481
Having co-morbidities *(ref. no)*	–.05	.12 [–.29, .19]	.657
BMI	–.06	.06 [–.17, .05]	.311
Number of orange/red MRA (0–7)	.14	.05 [.03, .24]	**.009**
Perceived personal relevance (1–5)	.15	.06 [.03, .27]	**.014**
Pseudo R^2	.05		
Wald χ^2 (15)	51.48		.000

Predictors of a higher appreciation of KNW overall

A higher appreciation with the overall KNW was significantly predicted by a higher perceived personal relevance ($\beta = .62$, $p < .001$) (Table 4.7). None of the demographic and cancer-related variables, or the number of red/orange MRA, or number of modules used predicted a higher overall appreciation of the KNW intervention.

Predictors of a higher perceived personal relevance

None of the demographic and cancer-related characteristics significantly predicted the perceived personal relevance of the KNW content, indicating that the KNW content was rated comparably personally relevant among individuals with different demographic and cancer-related characteristics (Table 4.8).

Table 4.7: Predictors of a higher appreciation of the of the KNW (*n* = 182)

	Appreciation (1–10)		
Variable	**β**	***SE* β [95% CI]**	***p***
Gender *(ref. male)*	–.22	.36 [–.92, .48]	.530
Age	.07	.12 [–.16, .30]	.557
Marital status *(ref. no partner)*	.36	.27 [–.17, .88]	.178
Being employed *(ref. no)*	.12	.18 [–.25, .49]	.514
Education level *(ref. low)*			
Medium	–.07	.20 [–.47, .32]	.708
High	.16	.18 [–.20, .52]	.379
Breast cancer *(ref. other)*	.24	.35 [–.44, .93]	.488
Primary cancer treatment *(ref. other)*			
Surgery and radiotherapy	–.01	.34 [–.68, .67]	.987
Surgery and chemotherapy	.01	.27 [–.55, .53]	.967
Surgery, chemotherapy, and radiotherapy	–.41	.28 [–.97, .15]	.152
Number of weeks after completing treatment	.02	.08 [–.14, .17]	.833
Participating in aftercare *(ref. no)*	–.17	.20 [–.55, .22]	.397
Having co-morbidities *(ref. no)*	.36	.18 [–.00, .72]	.051
BMI	–.01	.02 [–.05, .02]	.474
Number of orange/red MRA (0–7)	–.16	.10 [–.36, .04]	.122
Number of followed modules (0–8)	.03	.08 [–.13, .18]	.738
Perceived personal relevance (1–5)	.62	1.00 [.43, .82]	**.000**
R^2	.36		
F	1.01		.000

Table 4.8: Predictors of a higher perceived personal relevance of the KNW content (*n* = 182)

	Perceived personal relevance (1–5)		
Variable	**β**	***SE* β [95% CI]**	***p***
Gender *(ref. male)*	–.03	.61 [–1.23, 1.18]	.964
Age	–.12	.22 [–.56, .31]	.578
Marital status *(ref. no partner)*	.25	.34 [–.54, 1.03]	.538
Being employed *(ref. no)*	–.25	.34 [–.92, .42]	.468
Education level *(ref. low)*			
Medium	–.60	.37 [–1.32, .13]	.106
High	–.70	.37 [–1.42, .02]	.058
Breast cancer *(ref. other)*	–.40	.58 [–1.54, .74]	.488
Primary cancer treatment *(ref. other)*			
Surgery and radiotherapy	–.30	.54 [–1.37, .76]	.576
Surgery and chemotherapy	.60	.46 [–.31, 1.51]	.196
Surgery, chemotherapy, and radiotherapy	.03	.48 [–.91, .97]	.955
Number of weeks after completing treatment	–.11	.14 [–.38, .17]	.439
Participating in aftercare *(ref. no)*	.19	.33 [–.46, .84]	.570
Having co-morbidities *(ref. no)*	–.05	.33 [–.70, .59]	.868
BMI	.01	.15 [–.28, .30]	.933
Pseudo R^2	.03		
χ^2	14.58		.407

DISCUSSION

This process evaluation of the web-based KNW evaluated the automated guidance toward the KNW modules and subsequent module use, and the appreciation of this intervention. Despite the noncommittal nature of the KNW, more than 85% of the participants used one or more of the eight modules, and there was clear interest in all eight modules. These results confirm the need for wide-ranging support among early cancer survivors. Interestingly, automated referrals to specific modules were related to a higher number of modules used. Moreover, the complex KNW was highly appreciated and perceived as personally relevant by early cancer survivors.

The MRA aimed to guide the respondents toward the appropriate modules by giving feedback about current problem areas and needs. Cancer survivors might not have noticed some of these needs, and the MRA may have raised awareness about these topics. The importance of increasing awareness is theoretically grounded as described by Weinstein and Sandman (1992) in their Precaution Adoption Process Model. That model includes a sequence of five stages within behavior change: "unaware of the issue", "aware of the issue but not personally engaged", "engaged and deciding what to do", "planning to act but not yet having acted", and "acting". Prior research confirmed that a considerable number of colorectal cancer survivors were unaware of healthy diet recommendations, and older cancer survivors reported being less aware of the beneficial effects of a healthy lifestyle (Hawkins, Berkowitz, & Rodriguez, 2015; Niu et al., 2015). In addition, research revealed that cancer survivors might be less aware of available psychosocial support and solutions to psychosocial problems, while, for example, addressing maladaptive illness perceptions and adopting more adaptive self-management behaviors may lead to better health outcomes (Mehnert & Koch, 2008; Thong, Kaptein, Vissers, Vreugdenhil, & van de Poll-Franse, 2016). Consequently, curiosity about available self-management support needs to be encouraged (Kohl et al., 2013). In accordance with the I-Change Model, the MRA could increase knowledge about the current level of well-being, psychosocial conditions, and lifestyle behavior. Besides that, the MRA could elevate the risk perception and may serve as a cue to action with regard to the relevant topics, given that the solutions to the problems are provided (relevant self-management module) (de Vries et al., 2003). These awareness/solution triggers might positively influence the motivation and intention to perform desired behavior, which is in line with the findings of Walthouwer, Oenema, Candel, Lechner, and de Vries (2015a), who identified awareness as an important moderator in the relationship between psychosocial determinants and specific dietary behavior (eating in moderation) in the general population. The results in our study illustrate that these awareness/solution triggers are most likely to be followed when a red or orange MRA was provided. Thus, the MRA successfully referred those respondents with elevated as well as severe complaints and/or needs. This especially accounted for fatigue, since highly fatigued respondents (red

MRA) were more likely to use the Fatigue module compared to participants with less fatigue (orange MRA). With regard to diet, the results indicate that especially those who already were more engaged in a healthier diet were more likely to use the Diet module. These results imply that the topic diet could be of general interest to the participants, while the topic fatigue might be most interesting for participants with specific complaints. Consequently, the MRA may be a meaningful intervention component to increase motivation, subsequent module use, and problem-solution, while MRA adherence might be related to the specific behavior. Using topic-specific KNW modules has shown to be effective in decreasing fatigue, depressive feelings, and was beneficial in increasing moderate physical activity and fruit and fish consumption (Kanera et al., 2016b; Willems et al., 2017a).

Within the KNW, participants were referred on average to 2.9 modules, while on average 2.1 modules were used. The appreciation rates were high, and the results showed that a higher number of modules used did not contribute to a higher appreciation. However, a higher perceived personal relevance did contribute to a higher appreciation. This is in line with Wilson et al. (2015) reporting that a moderate number of recommendations in multiple behavior interventions might produce the highest level of change, while engagement with a higher number of recommendations might be too demanding. Within the KNW, respondents were allowed to make their own choices, despite the provided MRA. Prior research confirms that the possibility to choose within multiple behavior interventions may prevent high attrition rates and could improve intervention outcomes (Brouwer et al., 2010; Kwak et al., 2010; Schulz et al., 2012). Offering wide ranging support in combination with personalized referral to relevant topics and the possibility to choose might prevent overload. Donkin et al. (2013) support this suggestion by reporting that a certain level of usage might be needed to obtain benefit from an online intervention for depression. However, after reaching a point of therapy saturation, little or no additional program gains might be expected. This is in line with a web-based study among cancer survivors and with another web-based obesity prevention study among the general population, which reported that more intervention use did not result in better intervention outcomes (Borosund et al., 2013; Walthouwer, Oenema, Lechner, & de Vries, 2015c). Using a higher number of modules may not be necessary for all users to benefit most from the KNW. Our results revealed that having no partner was related to the use of a higher number of modules, and participants who were in greater need of support (higher number of red/orange MRA) indeed used a higher number of modules. This is consistent with the findings of Borosund et al. (2013), who reported that in particular cancer survivors with low levels of social support and a high illness burden used self-management components of a web-based illness management support system. Furthermore, higher perceived personal relevance was related to using a higher number of modules, which might be explained by receiving a higher amount of computer-tailored content within the modules. The overall KNW was highly appreciated with an average grade of 7.5, indicating an appreciation from very satisfactory to good. The low variability (*SD* = 1.2) indicates a considerably unanimous positive rating 6 months after getting access to the KNW. Results from our study indicate that perceived personal relevance might be a key component to explain a higher appreciation. Computer tailoring was applied within the KNW in order to create personally relevant feedback. Since perceived personal relevance could not be predicted by demographic and cancer-related characteristics, we can conclude that the tailoring of information worked well. In comparison, the overall satisfaction of a generic fully automated web-based self-management intervention for breast cancer survivors was 7.0 (*SD* = 1.2) (van den Berg et al., 2013). In addition, the overall appreciation of a web-based weight management intervention for overweight adults was 6.6, and the overall appreciation of a web-based text- and video-tailored intervention for smoking cessation in the general population was 6.5 (*SD* = 1.62; scales ranged from 1–10) (Stanczyk et al., 2014; van Genugten et al., 2012). The overall appreciation ratings of KNW module users were more positive than the ratings of module non-users, although the module non-users were still quite positive in their ratings. In addition to the modules, the KNW has a user forum and participants received monthly emails inviting them to visit generic monthly news items. Filling out the screening questionnaire and follow-up questionnaires, combined with receiving personalized feedback on problem areas (by the MRA), as well as the additional KNW features, might already have raised awareness and provided other valuable information to achieve benefits among module non-users. Overall, the high appreciation rate indicates that the broad design and tailored information of the KNW seem to fit well with the needs of early cancer survivors.

Limitations

Some limitations need to be addressed. First, providing data on completion of the separate themes and specific activities within the modules, and on completion of the evaluation sessions was not possible due to the module design. This information might be interesting for future studies. Therefore, we recommend future interventions to study in more detail participation of intervention modules. Second, within our study, it was not possible to compare the relationships between the MRA and module use to a control group not receiving the MRA. Consequently, the results need to be interpreted with caution, as it is conceivable that without the MRA, similar module choices could have been made. Future experimental research might explore the specific effects of a similar automated referral system on subsequent choices. Third, this eHealth intervention requires respondents to have computer skills and health literacy, such as competence at accessing, understanding, appraising, and applying the health information provided (Sorensen et al., 2012). However, since eHealth literacy was not assessed in this study, it is not possible to estimate the extent to which this might have influenced initial recruitment and the use and appreciation of the KNW. Fourth, mainly middle-aged, female breast cancer survivors who scored fairly well on quality of life and depression participated, which might be a too selective group to represent the general cancer survivor population. During recruitment, mainly breast cancer outpatient clinics participated. Five-year survival rates of breast cancer are relatively high (The Netherlands Cancer Registry, 2017). While, in general, females with higher socioeconomic status are most often reached in web-based interventions (Kohl et al., 2013), interpretations of these findings still should be viewed with caution.

CONCLUSION

The KNW in general and the specific KNW modules were substantially used and highly appreciated by early cancer survivors, confirming the need for wide-ranging support among this target group. Results indicate that the MRA may be seen as a meaningful key component of the fully automated KNW intervention by guiding users to follow a preferred selection of modules, given their current complaints and identified needs. Moreover, the overall intervention and separate modules were highly appreciated, which could be explained by a higher perceived personal relevance. We can conclude that computer tailoring worked well and that the range of topics, design, and personalized information suited the needs of early cancer survivors. This process evaluation adds meaningful information on the use and appreciation of web-based cancer aftercare interventions and confirms that the KNW offers valuable and appropriate support for early cancer survivors to complement usual cancer aftercare, and, therefore, may serve as a first step in a stepped-care approach.

PART III

INTERVENTION EFFECT EVALUATION

5

Short-term effectiveness of a web-based tailored intervention for cancer survivors on quality of life, anxiety, depression, and fatigue: Randomized controlled trial

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ABSTRACT

Objective: The aim of this study was to evaluate the short-term effectiveness of the web-based computer-tailored intervention *Kanker Nazorg Wijzer* (Cancer Aftercare Guide). The intervention aims to support cancer survivors with managing psychosocial and lifestyle-related issues. In this study, the impact on quality of life, anxiety, depression, and fatigue were evaluated.

Methods: Cancer survivors were recruited through 21 Dutch hospitals (November 2013–June 2014). Outcome measures included quality of life (EORTC QLQ-C30), anxiety and depression (HADS), and fatigue (CIS). In a randomized controlled trial with an intervention group ($n = 231$) and a waiting list control group ($n = 231$), the short-term effectiveness was evaluated through multilevel linear regression analyses, controlling for selective dropout, baseline differences, and several demographic and disease-related characteristics.

Results: In total, 188 participants of the intervention group and 221 of the control group completed the 6-month measurement (dropout = 11.5%). The intervention was effective in reducing depression ($B = -0.63$, $p = .007$, $f^2 = .019$, $d = 0.21$) and fatigue ($B = -4.36$, $p = .020$, $f^2 = .013$, $d = 0.21$). In addition, effects were found for emotional ($B = 3.47$, $p = .022$, $f^2 = .013$, $d = 0.15$) and social functioning ($B = 3.95$, $p = .011$, $f^2 = .017$, $d = 0.15$), although this evidence was less strong. There were indications that the effects of fatigue and social functioning were influenced by module use.

Conclusion: While effect sizes were small, they can be considered as clinically relevant. With the Cancer Aftercare Guide being an effective, low-intensity, and easily accessible intervention, it could serve as a first step in stepped care for needs assessment and initial support for psychosocial problems that are present after cancer treatment.

INTRODUCTION

After cancer treatment, many survivors face new challenges that affect their quality of life (Wu & Harden, 2015), in particular anxiety, depression, and fatigue (Brown et al., 2010; Harrington et al., 2010; Prue et al., 2006). In the first two years following diagnosis, approximately one in five survivors show symptoms of anxiety or depression (Mitchell et al., 2013). While the prevalence of fatigue is difficult to determine (Donovan, McGinty, & Jacobsen, 2013), prevalence rates of up to 50% have been found (Husson et al., 2015a; Minton & Stone, 2008).

Cancer survivors are expected to adopt an active role in managing their health and well-being. However, many express low self-efficacy in managing distress and fatigue (Foster et al., 2015). This is not surprising, as these are complex and interrelated problems (Brown & Kroenke, 2009). To improve self-management skills, problem-solving therapy (PST) and cognitive behavioral therapy (CBT) have been shown to be effective approaches (Willems et al., 2015). PST focuses on learning problem-solving techniques to address a problem, including understanding the problem, finding a solution, trying out the solution, and evaluating the result. While CBT also has a problem-focused and action-oriented approach, it primarily focuses on addressing inaccurate or negative thinking.

While PST and CBT are primarily provided through face-to-face contact, this mode of delivery is limited in its reach. The Internet has become a key source of health-related information (Chou et al., 2011), and cancer survivors indicate feeling positive about self-management eHealth interventions (Jansen et al., 2015). A great advantage of such interventions is that they can have a great reach and are easily accessible (Lustria et al., 2009). Through computer tailoring, information on reaching the desired health outcome can be provided based on the survivor's personal characteristics (Lustria et al., 2009). By personalizing information, behavior change or maintenance is better facilitated (Brug et al., 2003).

In the general population, internet-based interventions using PST or CBT have shown promising results in addressing psychological distress and fatigue (Spek et al., 2007; van Straten et al., 2008). However, evidence on the benefits of eHealth interventions for cancer survivors is limited (McAlpine et al., 2015). A few well-powered studies of stand-alone web-based interventions for cancer survivors were found effective in reducing psychological distress (van den Berg et al., 2015; Yun et al., 2012) and fatigue (van den Berg et al., 2015; Yun et al., 2012) and improving quality of life (Yun et al., 2012) and self-efficacy skills (Carpenter et al., 2014). Only one of these interventions was developed for multiple cancer types and provided tailored information (Yun et al., 2012). More research is therefore needed.

To provide cancer survivors personalized information and support on psychosocial and lifestyle issues, we developed the web-based computer-tailored *Kanker Nazorg Wijzer* intervention (Cancer Aftercare Guide; KNW) (Willems et al., 2015). Through problem identification, goal selection, psychoeducation, action planning, and evaluation, survivors are encouraged to effectively manage life after cancer. This study presents the short-term effects of the KNW on quality of life, anxiety, depression, and fatigue. In addition, we explore how intervention use influenced the intervention effects.

METHODS

A randomized controlled trial (RCT) comparing an intervention group with a waiting list control group was conducted. The RCT was registered in the Dutch Trial Register (NTR3375) and approved by the Medical Ethics Committee Zuyderland-Zuyd (NL41445.096.12).

The intervention

The KNW (http://www.kankernazorgwijzer.nl) was systematically developed using the Intervention Mapping protocol (Willems et al., 2015). This protocol consists of six steps: needs assessment, specification of objectives, selecting theories and applications, producing materials, program implementation, and evaluation. The KNW consists of eight modules, of which seven are self-management training modules. The training modules cover the topics return to work, fatigue, anxiety and depression, social relationship and intimacy issues, physical activity, diet, and smoking cessation. The eighth module provides general information on the most common residual symptoms. For an overview of the scope and sequence of all modules, see Figure 3.1. A detailed description of the modules is described in Chapter 3.

The program is developed as a stand-alone intervention that aims to increase cancer survivors' quality of life by providing psychosocial support and promoting positive lifestyle changes. Participants start by filling in a baseline questionnaire that enables tailoring. Participants then receive personalized advice on which of the modules deserve their attention. Within a module, the information is tailored further, eventually resulting in a personalized action plan.

The structure and content of the training modules are based on the principles of PST and CBT (Willems et al., 2015). For PST, the modules consist of four components divided over two sessions. In the first session, participants (1) identify their problem, (2) select a goal and receive psychoeducation and assignments on how to deal with their problem, and (3) personalize their goal through action plans. (4) After 30 days, participants are invited for a second session in which they can evaluate the progress of their goal. Basic CBT principles are covered by providing psychoeducation and assignments, such as monitoring behavior or thoughts, challenging dysfunctional cognitions, and encouraging patients to set new goals. The KNW is programmed to be an open and unrestrictive program: users can choose which modules they want to visit and can skip assignments.

Participants and procedure

Patients were eligible for participation if they were 18 years or older; had been diagnosed with any type of cancer; primary treatment (surgery, chemotherapy, and/or radiotherapy) had been completed successfully for at least 4 weeks, but for no more than 56 weeks[1]; there was no sign of recurrence in the latest follow-up visit; they were able to speak and read Dutch; and there was no serious medical, psychiatric, or cognitive illness that would interfere participation. As the KNW is developed for the general population of cancer survivors, there was no preselection on baseline levels of intervention outcomes.

Representatives of 45 hospitals in the Netherlands (e.g., department heads, oncologists, research nurses, nurse practitioners) of outpatient clinics internal medicine, oncology, gynecology, urology, and the breast clinic were contacted for assistance in recruitment. Professionals of 21 hospitals recruited patients between November 2013 and June 2014. Eligible patients were invited to participate by giving them an information package during a follow-up visit or sending the package following review of the patient's files. The information package included: (1) a letter with trial information and a username and password for first login, (2) an informed consent form with return envelope, (3) an information brochure concerning Medical Research, (4) an instruction manual on how to use the KNW, and (5) a card with contact details. A reminder was sent after two weeks. Patients who agreed to participate were requested to return the signed consent form to the Open University of the Netherlands. Those who participated in the research but did not return the informed consent form after several reminders were excluded from the analyses. Sample size calculations were based on the outcomes quality of life, anxiety, and depression and showed that, after correction for multilevel analyses and an expected dropout of 20%, 188 patients per group were required ($\alpha = .10$, $\beta = .20$, $d = .30$).

After online registration, the computer randomly assigned participants to either the intervention or the waiting list control group (allocation ratio 1:1). Both groups had to fill in a questionnaire at four time points: at baseline and after 3, 6, and 12 months from baseline. The 3-month measurement measured possible mediating variables, while the 6- and 12-month measurement aimed to measure the short- and long-term effectiveness of the intervention, respectively. The intervention group had access to the KNW for 6 months directly after baseline. The waiting list control group had access to the intervention after the last measurement. During the waiting period, this group received care as usual.

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[1] Originally, this criterion was set to 6–52 weeks (see Chapter 3). After recruitment, we noted that participants were included outside this criterion. The lower limit of 6 weeks was set so participants had had a sufficient recovery period after treatment before participating in the study; the upper limit of one year was set to include participants highest in their distress. Because participants voluntarily participated and could decide whether they were able to participate and levels of distress are still high 56 weeks after treatment (Hinnen et al., 2008), we adjusted this criterion to 4–56 weeks. This led to an additional 13 participants in the control condition and 7 in the intervention condition.

Measurements

Demographic characteristics included gender, age, relationship status, educational level, income level, and employment status. *Disease-related characteristics* included Body Mass Index (BMI), cancer type, having had cancer before, treatment type, time since last treatment, participation in support program after treatment, and comorbidity. As the majority of participants had breast cancer, cancer type was dichotomized into "breast" and "other" (i.e., bladder, colorectal, esophageal, gynecologic, hematologic, kidney, liver, lung, prostate, stomach, testicular, and thyroid cancer).

*Quality of life w*as measured with the global health status scale and the functional scales of the EORTC Quality of Life Questionnaire (EORTC QLQ-C30) (Aaronson et al., 1993). Global health status ($\alpha = .89$) was measured with two items on a seven-point scale[2]. Items for physical (five items, $\alpha = .74$), role (two items, $\alpha = .86$), emotional (four items, $\alpha = .88$), cognitive (two items, $\alpha = .72$), and social functioning (two items, $\alpha = .77$) were measured on a four-point scale. Total scale scores ranged from 0 to 100. A high score on global health status represents a high quality of life; a high score on the functional scales represents a high/healthy level of functioning.

Anxiety and depression was measured with the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). Items for anxiety (seven items, $\alpha = .83$) and depression (seven items, $\alpha = .82$) were measured on a four-point scale. Scale scores ranged from 0 to 21, with a score of 8 or higher being an indication for anxiety or depression.

Fatigue was measured with the total score of the Checklist Individual Strength (CIS) (Vercoulen, Alberts, & Bleijenberg, 1999). The 20-item CIS comprises four scales measuring subjective fatigue, concentration, motivation, and activity. All items range from 1 to 7. The total score (range 20–140, $\alpha = .94$) is an overall indication of fatigue, with a score higher than 76 indicating a problematic level of fatigue (Bultmann et al., 2000).

Statistical analyses

Baseline differences in demographic, disease-related, and psychosocial characteristics between participants in the intervention and control condition were determined using independent *t*-tests, analysis of variance, and chi-square tests. To determine selective dropout between baseline and 6-month measurement, logistic regression analysis was used with dropout (0 = no, 1 = yes) as outcome and group assignment and demographic, disease-related, and psychosocial characteristics as independent variables.

It was possible that there was interdependence between participants from the same hospital. Therefore, we conducted multilevel linear regression analyses with hospital as random intercept and condition and the baseline value of the outcome variable as random

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[2] All Chronbach's alphas reported in this study are based on the baseline data of the study sample ($n = 462$).

slopes. The models were adjusted for the demographic and disease-related characteristics described in the "Measurements" section. Variables with more than two categories were dummy coded. In addition, the models were adjusted for dropout effects and baseline differences between both groups. For the multilevel analyses, an independent covariance structure was chosen and the models were fit using the maximum likelihood procedure. To correct for multiple testing, we applied the false discovery rate (fdr) method (Benjamini & Yekutieli, 2001). Next, we conducted intention-to-treat analyses by imputing data for participants who did not fill in the 6-month questionnaire by means of multiple imputation. Missing data was imputed 20 times and based on the same predictors used in the mixed models (Enders, 2010).

Then, we tested whether module use influenced the intervention's effectiveness. A module was considered used when participants continued after visiting the introduction page of the module. Because quality of life was considered to be a global measure of intervention effectiveness, we tested whether the number of modules used influenced the effects on quality of life. For this, intervention condition was split up in participants who used a low number of modules (0–1) versus a high number of modules (2–8). While the intervention as whole is expected to have an effect on anxiety, depression, and fatigue (Willems et al., 2015), the modules Mood and Fatigue more directly address these issues by focusing on dealing with negative thoughts or feelings and making practical changes in daily life. Therefore, we tested whether the use of the Mood module influenced the effects on anxiety and depression, and whether the use of the Fatigue module influenced the effect on fatigue.

Cohen's *d* was calculated for insight into the effect sizes of the intervention effects, with effect sizes of .20, .50, and .80 indicating small, medium, and large effects, respectively (Cohen, 1992). For the overall intervention effectiveness, Cohen's *d* was based on the difference between the intervention and control group at the 6-month measurement. Cohen's *d* for the influence of module use on intervention effectiveness was based on change over time of the intervention subgroup corrected for the change over time of the control group (Feingold, 2009). Further, Cohen's *d* does not take into account the covariates and random effects included in the multilevel analyses. Therefore, Cohen's f^2 as a measure of local effect size was additionally calculated (Selya, Rose, Dierker, Hedeker, & Mermelstein, 2012), with effect sizes of .02, .15, and .35 considered as small, medium, and large effects, respectively (Cohen, 1992). All analyses were conducted using Stata 13.1, except for the correction for multiple testing, which was calculated using R 3.2.3.

RESULTS

An overview of the number of patients enrolled in the intervention and lost to follow-up is provided in Figure 5.1. Table 5.1 shows that, except for treatment type ($\chi^2(3) = 9.39$, $p = .024$), the intervention and control group were comparable. Further, participants in the control group ($B = 1.93$, $SE = 0.67$, $p = .019$) and women ($B = -1.51$, $SE = 0.66$, $p = .023$) were more likely to fill in the 6-month questionnaire, while participants with higher social functioning ($B = 0.02$, $SE = 0.01$, $p = .042$) were less likely to do so. Therefore, the effect analyses were also adjusted for social functioning. According to the cutoff scores, 22.3% had a clinical indication for anxiety, 13.4% for depression, and 34.9% for fatigue at baseline.

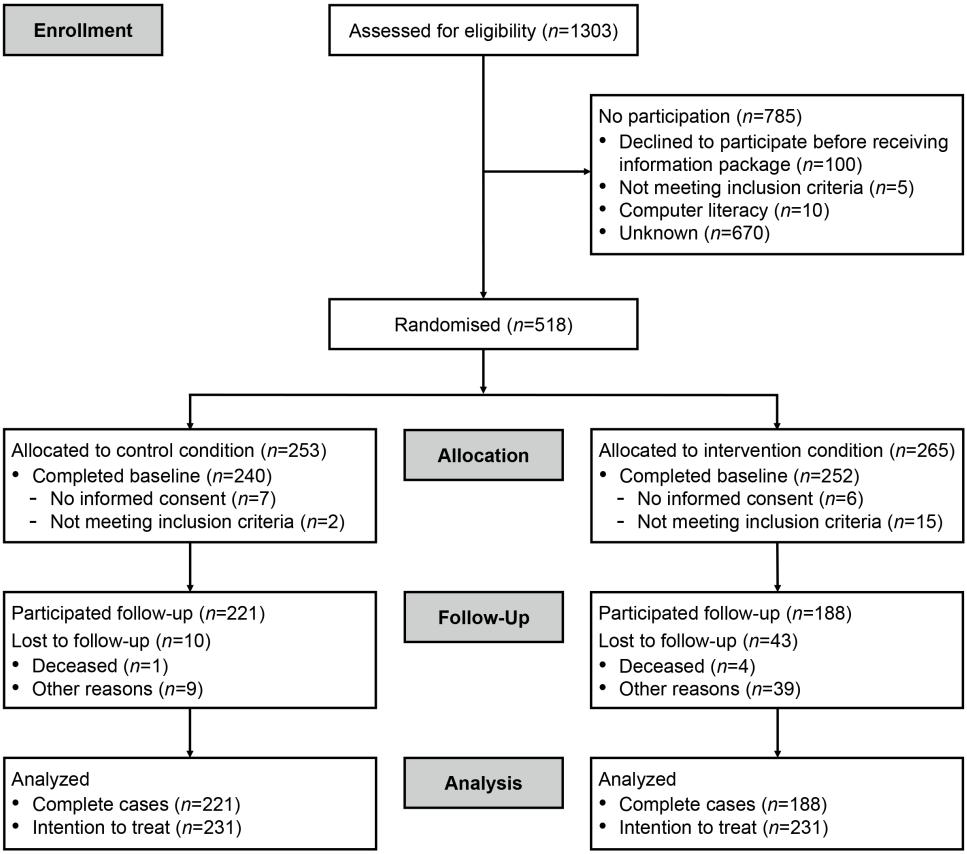

Figure 5.1: Flow diagram of study

Table 5.1: Baseline demographic, disease-related, and psychosocial characteristics of the participants who completed the 6-month measurement (*n* = 409)

	Control (*n* = 221)	Intervention (*n* = 188)	*p*
Demographic characteristics			
Gender (% women)	81.00	80.85	.971
Age (years), mean (*SD*)	56.28 (11.45)	56.26 (10.84)	.982
Relationship status (% partner)	81.00	85.11	.269
Education level[a] (%)			.205
Low	42.08	33.51	
Medium	29.41	34.04	
High	28.51	32.45	
Modal income (%)			.267
Below modal income	16.74	11.17	
Approximately modal income	34.39	37.77	
Above modal income	48.87	51.06	
Employment status (% employed)	47.96	50.00	.681
Disease-related characteristics			
BMI, mean (*SD*)	26.46 (4.91)	26.06 (5.03)	.419
Cancer type (% breast cancer)	71.04	71.28	.958
Had cancer before (% yes)	9.95	9.04	.754
Treatment type (%)			**.024**
Surgery, chemotherapy, and radiotherapy	46.15	35.64	
Surgery and chemotherapy	21.72	25.53	
Surgery and radiotherapy	12.67	22.34	
Other	19.46	16.49	
Time since last treatment (weeks), mean (*SD*)	23.38 (12.78)	25.28 (13.46)	.143
Participation in support program (% yes)	60.63	62.77	.659
Comorbid condition (% yes)	26.70	29.26	.565
Psychosocial characteristics			
Global health status (0–100), mean (*SD*)	73.04 (19.13)	73.94 (16.72)	.617
Physical functioning (0–100), mean (*SD*)	83.08 (15.91)	85.53 (14.53)	.106
Role functioning (0–100), mean (*SD*)	74.13 (27.08)	75.71 (23.84)	.536
Emotional functioning (0–100), mean (*SD*)	79.94 (21.52)	78.99 (22.14)	.661
Cognitive functioning (0–100), mean (*SD*)	78.66 (22.66)	79.61 (20.34)	.657
Social functioning (0–100), mean (*SD*)	82.05 (22.63)	79.88 (21.42)	.321
Anxiety (0–21), mean (*SD*)	4.49 (3.74)	4.80 (3.70)	.402
Depression (0–21), mean (*SD*)	3.43 (3.41)	3.45 (2.99)	.933
Fatigue (20–140), mean (*SD*)	64.57 (27.86)	62.75 (25.62)	.491

[a] Low: lower vocational education, medium general secondary education; Medium: secondary vocational education, higher general secondary education; High: higher vocational education, university education.

Module use

The participants in the intervention group who completed the 6-month measurement on average used 2.22 (*SD* = 1.58) modules. Of those using at least one module (89.4%), the average time between first login and last use of a module was 10.67 weeks (*SD* = 6.78), with 83.9% using a module for the last time within 18 weeks since first login. Seventy participants (37.2%) used the Fatigue module, with 75.7% using the module for the last time within 18 weeks since first login. Forty-six participants (24.5%) used the Mood module, with 71.7% using the module for the last time within 18 weeks since first login.

Intervention effects

The KNW intervention had a significant effect on increasing emotional ($B = 3.47$, $p = .022$, $f^2 = .013$, $d = 0.15$) and social functioning ($B = 3.95$, $p = .011$, $f^2 = .017$, $d = 0.15$), and decreasing depression ($B = –0.63$, $p = .007$, $f^2 = .019$, $d = 0.21$) and fatigue ($B = –4.36$, $p = .020$, $f^2 = .013$, $d = 0.21$) 6 months after baseline (see Table 5.2). These effects remained significant after correction for multiple testing. Intention-to-treat analyses showed that the found effects for depression ($B = –0.49$, $p = .039$) and fatigue ($B = –4.31$, $p = .019$) remained significant.

Influence of module use

For a detailed overview of the results of the module use analyses, see Table 5.3. The analyses showed that the effectiveness on emotional functioning was only significant for participants who used 0 to 1 modules ($B = 4.21$, $p = .038$, $f^2 = .011$, $d = 0.18$) and the effectiveness on social functioning only for participants who used 2 to 8 modules ($B = 4.14$, $p = .022$, $f^2 = .015$, $d = 0.28$). For depression, there was a significant effect for participants who did not use the Mood module ($B = –0.60$, $p = .017$, $f^2 = .014$, $d = 0.27$). While the *B* coefficient for the effect on depression for participants using the Mood module was larger than for participants not using this module, it failed to reach significance ($B = –0.71$, $p = .060$, $f^2 = .011$, $d = 0.35$). For fatigue, only an effect was found for participants who used the module Fatigue ($B = –6.78$, $p = .009$, $f^2 = .019$, $d = 0.37$). After correction for multiple testing, all effects failed to reach significance.

Table 5.2: Results of the multilevel analyses of the effect of the intervention on quality of life, anxiety, depression, and fatigue

	M (*SD*) at 6 months		Complete case (*n* = 409)							Imputed data (*n* = 462)			
	Control	Intervention	*B*	*SE B*	95% CI	*p*	p_{fdr}	f^2	*d* [95% CI]	*B*	*SE B*	95% CI	*p*
Global health status	75.90 (20.58)	77.44 (18.17)	0.60	1.65	[−2.64, 3.84]	.716	.716	.000	−0.08 [−0.27, 0.12]	−0.03	1.50	[−2.97, 2.91]	.985
Physical functioning	85.88 (15.25)	88.83 (13.42)	1.13	1.02	[−0.87, 3.13]	.268	.344	.004	−0.20 [−0.40, −0.01]	0.40	1.06	[−1.68, 2.49]	.704
Role functioning	79.86 (24.32)	82.80 (22.07)	2.70	1.96	[−1.15, 6.55]	.170	.255	.005	−0.13 [−0.32, 0.07]	1.61	1.94	[−3.65, 3.97]	.934
Emotional functioning	81.00 (20.31)	83.78 (17.76)	3.47	1.51	[0.51, 6.43]	**.022**	**.050**	.013	−0.15 [−0.34, 0.05]	2.57	1.54	[−0.45, 5.58]	.095
Cognitive functioning	80.24 (21.65)	81.91 (21.06)	1.04	1.65	[−2.20, 4.28]	.528	.594	.002	−0.08 [−0.27, 0.12]	−0.56	1.68	[−3.86, 2.75]	.742
Social functioning	87.25 (19.45)	90.07 (16.86)	3.95	1.56	[0.89, 7.00]	**.011**	**.050**	.017	−0.15 [−0.35, 0.04]	1.60	1.57	[−1.49, 4.68]	.310
Anxiety	4.66 (3.97)	4.39 (3.89)	−0.43	0.27	[−0.96, 0.93]	.106	.191	.006	0.07 [−0.13, 0.26]	−0.38	0.27	[−0.92, 0.16]	.167
Depression	3.53 (3.68)	2.82 (3.06)	−0.63	0.23	[−1.08, −0.17]	**.007**	**.050**	.019	0.21 [0.01, 0.40]	−0.49	0.24	[−0.95, −0.02]	**.039**
Fatigue	61.77 (28.15)	55.90 (26.72)	−4.36	1.87	[−8.03, −0.67]	**.020**	**.050**	.013	0.21 [0.02, 0.41]	−4.31	1.84	[−7.92, −0.70]	**.019**

The intraclass correlation coefficient (ICC) of the multilevel linear regression models ranged from .000 to .023.

Table 5.3: Results of the multilevel analyses of the effect of module use on quality of life, anxiety, depression, and fatigue

		M (*SD*)		Complete case (*n* = 409)						
	n	Baseline	6 months	*B*	SE *B*	95% CI	*p*	p_{fdr}	f^2	d_{change}
Global health status										
Control (ref.)	231	73.04 (19.13)	75.90 (20.58)							
0–1 modules	76	76.86 (16.64)	78.29 (18.05)	−0.23	2.15	[−4.46, 3.99]	.913	.913	.000	0.06
2–8 modules	112	71.95 (16.55)[b]	76.86 (18.30)	1.09	1.89	[−2.61, 4.78]	.564	.634	.000	0.09
Physical functioning										
Control (ref.)	231	83.08 (15.91)	85.88 (15.25)							
0–1 modules	76	87.11 (13.91)	89.74 (12.95)	1.53	1.37	[−1.16, 4.22]	.265	.341	.004	0.09
2–8 modules	112	84.46 (14.90)	88.21 (13.75)	0.87	1.18	[−1.44, 3.19]	.460	.591	.002	0.10
Role functioning										
Control (ref.)	231	74.13 (27.08)	79.86 (24.32)							
0–1 modules	76	80.92 (21.55)[a]	85.09 (21.01)	3.93	2.64	[−1.24, 9.11]	.137	.247	.005	0.01
2–8 modules	112	72.17 (24.75)[b]	81.25 (22.72)	1.89	2.28	[−2.57, 6.36]	.406	.591	.002	0.13
Emotional functioning										
Control (ref.)	231	79.94 (21.52)	81.00 (20.31)							
0–1 modules	76	80.48 (23.55)	85.31 (17.63)	4.21	2.03	[0.24, 8.18]	**.038**	.171	.011	0.18
2–8 modules	112	77.98 (21.19)	82.74 (17.85)	2.98	1.76	[−0.46, 6.42]	.090	.203	.007	0.23
Cognitive functioning										
Control (ref.)	231	78.66 (22.66)	80.24 (21.65)							
0–1 modules	76	82.02 (20.69)	80.92 (21.03)	−1.38	2.21	[−5.70, 2.95]	.532	.599	.000	0.14
2–8 modules	112	77.98 (20.04)	82.59 (21.15)	2.65	1.91	[−1.10, 6.40]	.166	.299	.006	0.17
Social functioning										
Control (ref.)	231	82.05 (22.63)	87.25 (19.45)							
0–1 modules	76	82.24 (20.61)	90.35 (16.84)	3.66	2.09	[−0.43, 7.76]	.080	.182	.008	0.21
2–8 modules	112	78.27 (21.90)	89.88 (16.94)	4.14	1.81	[0.58, 7.69]	**.022**	.099	.015	0.28
Anxiety										
Control (ref.)	231	4.49 (3.74)	4.66 (3.97)							
Not used Mood module	142	4.46 (3.63)	4.04 (3.78)	−0.51	0.29	[−1.07, 0.06]	.081	.182	.007	0.20
Used Mood module	46	5.87 (3.76)[a, b]	5.50 (4.03)	−0.20	0.44	[−1.07, 0.67]	.648	.648	.001	0.17
Depression										
Control (ref.)	231	3.43 (3.41)	3.53 (3.68)							
Not used Mood module	142	3.30 (3.02)	2.74 (3.06)	−0.60	0.25	[−1.09, −0.11]	**.017**	.153	.014	0.27
Used Mood module	46	3.91 (2.88)	3.09 (3.08)	−0.71	0.38	[−1.47, 0.03]	.060	.180	.011	0.35
Fatigue										
Control (ref.)	231	64.57 (27.86)	61.77 (28.15)							
Not used Fatigue module	118	55.81 (25.03)[a]	52.09 (26.87)	−2.90	2.16	[−7.13, 1.34]	.180	.270	.003	0.03
Used Fatigue module	70	74.46 (22.26)[a, b]	62.33 (25.38)	−6.78	2.60	[−11.88, −1.67]	**.009**	.081	.019	0.37

Baseline differences in outcomes were tested with independent samples *t*-tests: [a] Intervention subgroup score differs significantly from control group score; [b] Intervention subgroup score differs significantly from other intervention subgroup score. Correction for multiple testing was carried out in two sets. In the first set, the *p*-values of 0–1 modules used, not used Mood module, and not used Fatigue module were corrected for each other. In the second set, the *p*-values of 2–8 modules used, used Mood module, and used Fatigue module were corrected for each other. Cohen's *d* was based on the change over time within the intervention subgroup (I), corrected for the change over time of the control group (C): $d_{change} = (M_{change\text{-}I}/SD_{change\text{-}I}) - (M_{change\text{-}C}/SD_{change\text{-}C})$.

DISCUSSION

In this study, the short-term effectiveness of the web-based computer-tailored KNW intervention on quality of life, anxiety, depression, and fatigue was evaluated. The dropout rate was low (Christensen, Griffiths, & Farrer, 2009). The intervention was effective in increasing emotional and social functioning and reducing depression and fatigue. The effect sizes were considered small (range $d = 0.15–0.21$, range $f^2 = .013–.019$). The intention-to-treat analyses confirmed the results for depression and fatigue, but failed to show significant effects for emotional and social functioning. However, these results should be taken with caution: as the mean score for emotional and social functioning were relatively close to the upper boundary, a greater proportion of the imputed values were imputed below the original means of the outcomes. This might have caused biased results, making it inconclusive whether there is an effect for emotional and social functioning.

Additionally, we conducted analyses for differences in module use. Because the effects failed to reach significance after correction for multiple testing, the evidence is less convincing. Still, the results provide useful information. First, while the effect on emotional functioning was only significant for participants using 0 to 1 modules, this effect was very weak: the change over time between the intervention subgroups was equal and the Cohen's *d* for participants using 2 to 8 modules was stronger. Second, the results for social functioning indicated that the effect was stronger for those using 2 to 8 modules. Third, there was a significant effect on depression for those not using the Mood module. This indicates that the information outside the Mood module, such as information from other modules and a non-tailored newsletter on depression, was sufficient to reduce depression. The effect on depression for those using the Mood module was not significant. However, the *B* coefficient was larger than the coefficient for non-users of the Mood module. This indicates that the non-significance could result from lack of power. Fourth, the results for fatigue indicate that the effect is only significant for those using the Fatigue module. It should be noted that there were baseline differences in fatigue between the subgroups, with users of the Fatigue module being more fatigued. This self-selection indicates that the tailored advice worked and the module was used by those who needed it most (see also Chapter 4). For the analyses this means that, although the analyses were corrected for baseline differences, the groups were not equal and the results should be interpreted cautiously.

Our results are comparable with the results of two similar interventions. A non-tailored CBT-based intervention for breast cancer survivors aimed at increasing empowerment and decreasing distress was, amongst others, effective in decreasing distress ($d = 0.33$), anxiety and depression (HADS total score; $d = 0.37$), and fatigue ($d = 0.33$) (van den Berg et al., 2015). A tailored education program for survivors with cancer-related fatigue was found to be effective in, amongst others, reducing fatigue ($d = 0.29$), anxiety ($d = 0.33$), and quality of life (*d* = 0.26) (Yun et al., 2012). Further, a meta-analytic review found that CBT-based eHealth interventions for patients with somatic conditions were effective in reducing psychological distress (range *d* = 0.17–0.21) (van Beugen et al., 2014). However, the interventions in this review where not fully automated and offered contact with a therapist. For face-to-face psychosocial interventions, meta-analyses demonstrated small to medium effect sizes for interventions addressing (former) cancer patients' quality of life (*d* = 0.26), anxiety (*d* = 0.38), depression (*d* = 0.33), and fatigue (*d* = 0.31) (Faller et al., 2013; Kangas et al., 2008), with more intensive therapies having greater effects. While the effects of face-to-face interventions seem to be greater than eHealth interventions, eHealth interventions are better accessible, have greater reach, and are considered to be a less-intensive and more cost-effective way to deliver validated treatments (Lustria et al., 2009; Newman, Szkodny, Llera, & Przeworski, 2011). Therefore, the effectiveness of the KNW can be considered clinically relevant.

In comparison to other studies, our study sample showed a relative good overall quality of life, but scored (slightly) lower on cognitive and social functioning (Husson, Mols, van de Poll-Franse, & Thong, 2015b; Scott et al., 2008), they had relative low levels of depression (Mitchell et al., 2013), and relatively high levels of fatigue (Vercoulen et al., 1999). Because the effectiveness of an intervention seems to be influenced by the level distress at the start of the intervention, with greater distress resulting in greater effects (Faller et al., 2013; Schneider et al., 2010), it could be expected that the found effects for emotional functioning and depression would have greater magnitude if participants were doing less well on these areas.

The KNW was effective in reducing depression, yet no effects were found for anxiety. Both anxiety and depression were addressed by challenging intrusive thoughts, dealing with rumination, planning pleasant activities, and relaxation exercises. Possibly, the Mood module was set up too broad to effectively address anxiety and should have focused on a more specific type of anxiety, such as fear of recurrence. In line with this, possibly the measurement used to assess anxiety (HADS) was not specific enough to detect a difference in the specific anxiety aspects that were addressed in the KNW.

Limitations

The study is subject to some limitations. First, selective dropout might have influenced the results. However, with a low dropout rate and correction for the differences between completers and non-completers in the analyses, minimal influences of dropout effects may be expected. The results of the intention-to-treat analyses gave support for this. Second, while we put much effort in recruiting a diverse group of cancer survivors, women with breast cancer and survivors who scored fairly well on quality of life and depression were overrepresented. In general, females and low-risk individuals are more prone to participate in online interventions (Kohl et al., 2013). However, this makes it difficult to generalize the findings to survivors of other cancer types and survivors with lower psychosocial well-being. Further, the intervention to a lesser extent reached the older population, which can be expected for internet-based interventions (Chou et al., 2011). Finally, the measurements were self-administered questionnaires. Although only validated questionnaires were used, the results could be influenced because of social desirability.

CONCLUSION

The KNW is a theory-based web-based computer-tailored intervention effective in reducing depression and fatigue. In addition, the KNW is effective in improving the quality of life domains emotional and social functioning, although this evidence is less strong. The effects can be considered as clinically relevant. With these results, new evidence is provided for the benefits of eHealth interventions for cancer survivors. Future research should investigate possible moderators or mediators of these effects (see Chapters 6 & 7). Further, use of and satisfaction with the intervention should be evaluated (see Chapter 4). The KNW can be considered as an effective, low-intensity, and easily accessible intervention. Therefore, it could serve as a first step in stepped care for needs assessment and initial support for psychosocial problems that are present after cancer treatment.

6

Long-term effectiveness and moderators of a web-based tailored intervention for cancer survivors on social and emotional functioning, depression, and fatigue: Randomized controlled trial

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ABSTRACT

Objective: The web-based computer-tailored *Kanker Nazorg Wijzer* (Cancer Aftercare Guide) supports cancer survivors with psychosocial issues during cancer recovery. The current study investigates whether the 6-month effects in increasing emotional and social functioning and reducing depression and fatigue hold at 12 months from baseline. Moreover, it explores whether patient characteristics moderate the 6- and 12-month intervention effectiveness.

Methods: Cancer survivors from 21 Dutch hospitals (November 2013–June 2014) were randomized to an intervention ($n = 231$) or a waiting list control group ($n = 231$). Intervention effects on emotional and social functioning (EORTC QLQ-C30), depression (HADS), and fatigue (CIS) were evaluated through multilevel linear regression analyses.

Results: At 12 months from baseline, the intervention group no longer differed from the control group in emotional and social functioning, depression, and fatigue. Moderator analyses indicated that, at 6 months from baseline, the intervention was effective in improving social functioning for men ($d = 0.34$), reducing fatigue for participants ≤56 years ($d = 0.44$), and reducing depression for participants who received chemotherapy ($d = 0.36$). At 12 months from baseline, participants with a medium educational level reported higher social functioning ($d = 0.19$), while participants with a low educational level reported lower social functioning ($d = 0.22$) than participants with a similar educational level in the control group.

Conclusion: The intervention gave cancer patients a head start to psychological recovery after the end of cancer treatment. The control group caught up in the long run. Therefore, it is suggested that the Cancer Aftercare Guide expedites recovery after cancer treatment. Being a low-intensity, easily accessible, and relatively low-cost intervention, it could serve as a relevant step in recovery and stepped care.

INTRODUCTION

After treatment, many cancer survivors face a variety of difficulties and challenges affecting their quality of life (Harrington et al., 2010; Wu & Harden, 2015), of which anxiety, depression, and fatigue are prominent issues (Brown et al., 2010; Mitchell et al., 2013; Prue et al., 2006; Simard et al., 2013). Ideally, cancer survivors should have an active role in managing their health and well-being (Fenlon & Foster, 2009). However, they often feel neither confident (Foster & Fenlon, 2011) nor prepared by health professionals to effectively manage life after cancer treatment, resulting in prominent information needs (Stanton, 2012). Since the number of cancer survivors will only increase over the years (Hewitt et al., 2006; The Netherlands Cancer Registry, 2017), effective support in self-management is crucial.

The Internet has become an important source of health-management information for cancer survivors (Chou et al., 2011; van de Poll-Franse & van Eenbergen, 2008). Survivors indicate feeling positive about self-management eHealth interventions (Jansen et al., 2015). A great advantage of such interventions is their potentially wide reach, easy accessibility, 24/7 availability, and anonymity (Lustria et al., 2009). In addition, personalized information on reaching the desired health outcome can be provided by means of computer tailoring (Lustria et al., 2009), facilitating behavior change and/or maintenance (Brug et al., 2003). eHealth interventions can be valuable to serve as a relevant step in stepped oncology care, since, in general, they are low in intensity and sufficient to meet the needs of a large proportion of survivors with relatively mild complaints. They can also easily be used for some patients to become aware of their need for more intensive interventions (e.g., therapist treatment or medication) (Krebber et al., 2016; Krebber et al., 2012).

There is little evidence on the benefits of eHealth interventions for cancer survivors (McAlpine et al., 2015). A few studies evaluated the effectiveness of stand-alone (i.e., not combined with face-to-face support) web-based psychosocial interventions (Beatty et al., 2016; Carpenter et al., 2014; Duffecy et al., 2013; Owen et al., 2005; Ritterband et al., 2012; van den Berg et al., 2015; Wootten et al., 2015; Yun et al., 2012), often only reporting preliminary results (Beatty et al., 2016; Duffecy et al., 2013; Owen et al., 2005; Ritterband et al., 2012; Wootten et al., 2015). Three sufficiently powered randomized controlled trials found eHealth interventions for cancer survivors to be effective in reducing psychological distress (van den Berg et al., 2015; Yun et al., 2012) and fatigue (van den Berg et al., 2015; Yun et al., 2012), and improving quality of life (Yun et al., 2012) and self-efficacy skills (Carpenter et al., 2014). Only one of these three interventions was developed for multiple cancer types and provided tailored information (Yun et al., 2012). Carpenter et al. (2014) and van den Berg et al. (2015) found effects directly after intervention completion (10 weeks and 4 months after baseline, respectively), but not at any follow-up measures (20 weeks and 6 and 10 months after baseline, respectively). The follow-up effects for the intervention group of the study by Carpenter et al. (2014) are, however, difficult to interpret, since the control group received access to the intervention before the last measurement. Yun et al. (2012) also found effects directly after intervention completion (12 weeks after baseline), but they did not conduct any follow-up measures. More research on the long-term effectiveness of web-based interventions for cancer survivors is therefore needed (McAlpine et al., 2015).

Since effective self-management interventions for cancer survivors are highly needed, we developed the web-based computer-tailored *Kanker Nazorg Wijzer* (Cancer Aftercare Guide; KNW). The KNW provides cancer survivors personalized information and support on psychosocial and lifestyle issues (Kanera et al., 2016b; Willems et al., 2015, 2017a). Through problem identification, goal selection, psychoeducation, action planning, and evaluation, survivors are encouraged to effectively manage life after cancer. The effectiveness of the KNW on quality of life, anxiety, depression, and fatigue was assessed 6 months after baseline in a randomized controlled trial (RCT) comparing an intervention group to a waiting list control group (Willems et al., 2017a). Participants had access for 6 months and were free to use the KNW whenever they wanted. In practice, 84% only used the KNW modules in the first 18 weeks following first login. The KNW was found to be effective in improving the quality of life components emotional and social functioning, and reducing depression and fatigue.

For future implementation of the KNW and evaluation of the impact of the intervention, further insight is needed into the extent to which the effects are sustained in the longer-term. The main purpose of the current study is therefore to evaluate whether the effects on emotional and social functioning, depression, and fatigue at 6 months after baseline are sustained in the long term (i.e., 12 months after baseline). Since there is little evidence on the long-term effectiveness of web-based self-management interventions for cancer survivors, the current study contributes to the knowledge on this area. Second, intervention effectiveness might differ among patient subgroups (Tamagawa et al., 2012). While there is some evidence that demographic and treatment-related characteristics may influence effectiveness of psycho-oncological interventions (Kalter et al., 2015; Tamagawa et al., 2012), there is, to our knowledge, no specific evidence whether these factors influence the effectiveness of web-based self-management interventions for cancer survivors specifically. This information is important, since this provides directions for further development of the tailored content used within the KNW. If the KNW is only effective for particular subgroups, then providing additional subgroup specific information might improve intervention effectiveness. In the current study, we explore whether gender, age, educational level, and treatment type moderated intervention effectiveness in the short term (i.e., 6 months after baseline), as well as in the long term (i.e., 12 months after baseline).

METHODS

The long-term effects were evaluated in an RCT comparing an intervention group with a waiting list control group. The RCT was registered in the Dutch Trial Register (NTR3375) and approved by the Medical Ethics Committee Zuyderland-Zuyd (NL41445.096.12).

Intervention

The KNW (http://www.kankernazorgwijzer.nl) was systematically developed using the Intervention Mapping protocol (Bartholomew et al., 2016). This protocol consists of six steps: needs assessment, specification of objectives, selecting theories and applications, producing materials, program implementation, and evaluation. The KNW was developed as a stand-alone web-based intervention that aims to increase cancer survivors' quality of life by providing psychosocial support and promoting positive lifestyle changes. The intervention consists of eight modules, of which seven are self-management training modules. The training modules cover the topics returning to work, fatigue, anxiety and depression, social relationship and intimacy issues, physical activity, diet, and smoking cessation. The eighth module provides general information on the most common residual symptoms. For an overview of the scope and sequence of all modules, see Figure 3.1. A detailed description of the study protocol and intervention components is published elsewhere (Willems et al., 2015) (see also Chapter 3).

The KNW is fully automated and computer tailored. Prior to using the program, participants fill in a baseline questionnaire that enables tailoring. Participants then receive personalized advice on which of the modules deserve their attention (Kanera et al., 2016c). Within a module, the refinement of information is continued, eventually resulting in a personalized action plan. Further, the KNW is programmed to be an open and unrestrictive program: users can choose which modules they want to visit or which assignments they want to make.

The structure and the content of the training modules are based on the principles of problem-solving therapy (PST) (D'Zurilla & Nezu, 2007) and cognitive behavioral therapy (CBT) (Beck, 2011). For PST, the modules consist of four components, divided over two sessions. In the first session, participants (1) identify their problem, (2) select a goal and receive psychoeducation and assignments on how to deal with their problem, and (3) personalize their goal through action plans. (4) After 30 days, participants are invited for a second session in which they can evaluate the progress of their goal. Basic CBT principles are covered by providing psychoeducation, several assignments (e.g., monitoring behavior or thoughts, challenging dysfunctional cognitions, planning pleasant activities, setting new goals), and relaxation exercises. CBT-based assignments are mainly implemented in modules discussing issues with large psychosocial and cognitive components (i.e., return to work, fatigue, anxiety and depression, and social relationships and intimacy issues). The information provided in the modules is supported by videos of fellow survivors and professionals from different fields discussing recovery after cancer and dealing with problems and daily troubles.

Participants and procedure

Patients were eligible for participation if they were 18 years or older; they had been diagnosed with any type of cancer; their primary treatment (surgery, chemotherapy, and/or radiotherapy) had been completed successfully for at least 4 weeks, but for no more than 56 weeks; there was no sign of recurrence in the latest follow-up visit; they were able to speak and read Dutch; there was no serious medical, psychiatric, or cognitive illness that would interfere participation; and they returned a signed informed consent form.

Representatives of 45 hospitals in the Netherlands (e.g., department heads, oncologists, research nurses, nurse practitioners) from outpatient clinics internal medicine, oncology, gynecology, urology, and the breast clinic were contacted for assistance in recruitment. Professionals of 21 hospitals recruited patients between November 2013 and June 2014. The professionals had access to patient files and often knew the patients personally and thus were able to determine whether a particular patient met the inclusion criteria and was physically or mentally able to participate in the study. Eligible patients were invited to participate by giving them an information package during a follow-up visit or sending the package following review of the patient's files. The information package included (1) a letter with trial information and a username and password for first login, (2) an informed consent form with return envelope, (3) an information brochure concerning Medical Research, (4) an instruction manual on how to use the KNW, and (5) a card with contact details. A reminder was sent after 2 weeks. Patients who agreed to participate were requested to return the signed consent form to the Open University of the Netherlands. Sample size calculations were based on the outcomes quality of life, anxiety, and depression and showed that, after correction for multilevel analyses and an expected dropout of 20%, 188 patients per group were required ($\alpha = .10$, $\beta = .20$, $d = 0.30$).

After online registration, the computer randomly assigned participants to either the intervention or the waiting list control group (allocation ratio 1:1). Participants were not stratified before group assignment. Both groups had to fill in a questionnaire at baseline and after 3, 6, and 12 months from baseline. The 3-month measurement measured possible mediating variables (Willems et al., 2017b), while the 6- and 12-month measurement aimed to measure the short- and long-term effectiveness of the intervention, respectively. The intervention group had access to the KNW for 6 months directly after baseline. Access to the intervention was postponed for the waiting list control group until after the 12-month measurement.

Measurements

Demographic characteristics included gender, age, relationship status, educational level, income level, and employment status. Educational level was categorized as "low" (lower vocational education, medium general secondary education), "medium" (secondary vocational education, higher general secondary education) and "high" (higher vocational education, university education), according to the Dutch educational system. *Disease-related characteristics* included body mass index (BMI), cancer type, having had cancer before, treatment type, time since last treatment, participation in support program after treatment, and comorbidity. As the majority of participants had breast cancer, cancer type was dichotomized into "breast" and "other" (i.e., bladder, colorectal, esophageal, gynecologic, hematologic, kidney, liver, lung, prostate, stomach, testicular, and thyroid cancer). Treatment type was categorized as "surgery and chemotherapy", "surgery and radiotherapy", "surgery, chemotherapy, and radiotherapy", and "other" (see Table 6.1).

Emotional and social functioning were measured with the EORTC Quality of Life Questionnaire (EORTC QLQ-C30) (Aaronson et al., 1993). The emotional functioning scale (four items, α = .88) assessed whether participants felt tense, irritable, depressed, or were worried. The social functioning scale (two items, α = .77) assessed whether the participants' physical condition or treatment had interfered with their family life or social activities. Items in both scales were measured on a four-point scale. Total scale scores ranged from 0 to 100. A high score represents a high level of functioning.

Depression was measured with the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). Items (seven items, α = .82) were measured on a four-point scale. Scale score ranged from 0 to 21, with a score of 8 or higher being an indication for depression.

Fatigue was measured with the total score of the Checklist Individual Strength (CIS) (Vercoulen et al., 1999). The 20-item CIS comprises four scales measuring subjective fatigue, concentration, motivation, and activity. All items range from 1 to 7. The total score (range 20–140, α = .94) is an overall indication of fatigue, with a score higher than 76 indicating a problematic level of fatigue (Bultmann et al., 2000).

Statistical analyses

Analyses were conducted using Stata 13.1, except for correction for multiple testing, which was calculated in R 3.3.2. Selective dropout between baseline and the 12-month measurement was tested using the same procedure as in the evaluation of the short-term effectiveness (Willems et al., 2017a). A logistic regression analysis was conducted with dropout (0 = no, 1 = yes) as outcome and research condition, demographic and disease-related characteristics, and baseline values of the health outcomes (i.e., functional scales of the EORTC QLQ-C30, anxiety and depression scales of the HADS, and total fatigue scale of the CIS) as independent variables.

Main outcome analyses

To evaluate the long-term effectiveness of the KNW on emotional functioning, social functioning, depression, and fatigue, we conducted multilevel linear regression analyses (mixed models) with a random intercept for three levels (1: time; 2: individual; 3: hospital), and research condition and the baseline value of the outcome variable as random slopes within the hospital level. The models were kept similar to the models used to evaluate the short-term effectiveness of the KNW (Willems et al., 2017a), except that time was added as an additional level. By including an interaction term between condition (0 = control, 1 = intervention) and time (0 = 6 months, 1 = 12 months) it could be evaluated whether the effects at 6 months from baseline remained at 12 months from baseline (with a non-significant interaction indicating that the intervention effects do not change over time). The condition variable in this model reflects the intervention's effectiveness at 6 months from baseline (Twisk, 2006). By recoding the time variable (0 = 12 months, 1 = 6 months), the condition variable in the model reflects intervention effectiveness at 12 months from baseline. Recoding the time variable is a more efficient way to determine the intervention's effectiveness at particular time points than conducting simple slope analyses, while providing exactly the same results (Dawson, 2013; Twisk, 2006).

Results are provided for the crude models (unadjusted models with only the variables condition, time, and condition*time included in the model) as well as the adjusted models (Twisk, 2006). The adjusted models were corrected for gender, age, relationship status, educational level, income level, employment status, BMI, cancer type, having had cancer before, treatment type, time since last treatment, participation in support program after treatment, comorbidity, and dropout characteristics. Categorical variables with more than two categories were dummy coded. The multilevel models were fit using the maximum likelihood procedure. To correct for multiple testing, we applied the false discovery rate (fdr) method (Benjamini & Yekutieli, 2001). Cohen's *d* was provided for insight into the effect sizes of the intervention effects (Cohen, 1992). Intention-to-treat analyses were conducted by imputing data for participants who did not fill in the 6-month or 12-month questionnaire by means of multiple imputation. Missing data was imputed 20 times and based on the same predictors used in the mixed models (Enders, 2010).

Further, we evaluated whether module use influenced the long-term intervention effects using the same procedure as in the evaluation of the short-term effectiveness (Willems et al., 2017a). A module was considered used when participants continued after visiting the introduction page of the module. With quality of life being considered as a global measure of intervention effectiveness (Willems et al., 2015), we tested whether the number of modules used influenced the effects on emotional and social functioning. This was done by categorizing the condition variable into three categories: control group, participants who made little use of the KNW (i.e., visited 0–1 modules), and participants who made more intensive use of the KNW (i.e., visited 2–8 modules).[1] For depression and fatigue, we tested whether the effects differed among participants who visited the modules addressing depression and fatigue, respectively. This was done by recategorizing the condition variable into: control group, Mood/Fatigue module used, Mood/Fatigue module not used. For the analyses on the effects of module use only the data of baseline and 12-month follow-up was used.

Moderator analyses

In order to explore whether the short- and long-term intervention effects differed among specific subgroups of participants, moderator analyses were conducted. In the moderator analyses for the short-term effects, only the 6-month follow-up data was included, and for the long-term effects moderator analyses, only the data of the 12-month follow-up was included. Interaction terms between intervention condition and age, gender, educational level, and treatment type were assessed. To get better insight into the influence of different treatment modalities on the intervention's effectiveness, treatment type was recategorized into "surgery alone", "chemotherapy with or without surgery", "radiotherapy with or without surgery", and "chemotherapy and radiotherapy with or without surgery" (see Table 6.1), with "surgery alone" used as reference category. Since interaction terms have less power, the significance levels of the interaction terms were set to $p < .10$ (Twisk, 2006). When an interaction term was significant, the subgroup effects for gender, educational level (dummy coded), and treatment type (dummy coded) were determined according to the same procedure as the subgroup effects for the interaction between time and condition were determined in the longitudinal mixed models. For example, when entering the interaction between condition (0 = control, 1 = intervention) and gender (0 = male, 1 = female), the coefficient for condition indicates the intervention's effectiveness for men. By recoding the gender variable, the coefficient for condition indicates the intervention's effectiveness for women. Age was entered as a continuous variable. When the interaction between age and condition was significant, margins were plotted to determine the cutoff point for which age group the intervention was effective (UCLA Statistical Consulting Group, 2016). Then, age was dichotomized and the effectiveness for the different age groups was determined using the same procedure as the other binary moderators.

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[1] Since a small percentage of participants used four or more modules (see the "Results" section), number of modules used was not suitable for use as a continuous variable and, therefore, was dichotomized using a median split.

RESULTS

An overview of the number of patients enrolled in the intervention and lost to follow-up is provided in Figure 6.1. Patient characteristics are displayed in Table 6.1. Dropout analyses showed that participants in the control group ($B = 1.73$, $SE = 0.32$, $p < .001$) and participants with approximately modal income (in comparison to below modal income) ($B = -0.82$, $SE = 0.41$, $p = .046$) were more likely to fill in the 12-month questionnaire, while participants with higher social functioning were less likely to do so ($B = 0.02$, $SE = 0.01$, $p = .032$). Of the overall sample at baseline, 13.4% had a clinical indication for depression and 34.9% for fatigue according to the manual instructed cutoff scores.

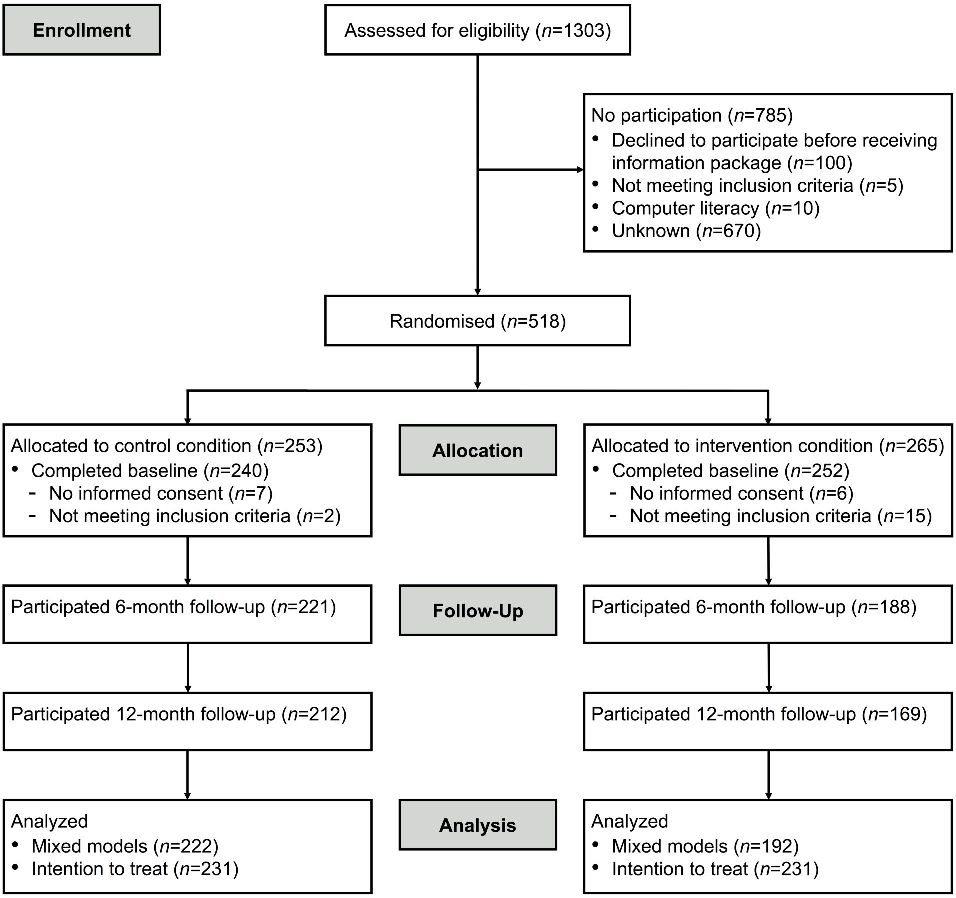

Figure 6.1: Flow diagram of study

Table 6.1: Baseline demographic and disease-related characteristics (*n* = 462)

	Control (*n* = 231)	**Intervention (*n* = 231)**
Demographic characteristics		
Gender (% women)	80.5%	79.2%
Age (years), mean (*SD*)	56.16 (11.33)	55.59 (11.46)
Relationship status (% partner)	79.7%	83.5%
Education level (%)		
Low	42.0%	32.9%
Medium	30.3%	32.9%
High	27.7%	34.2%
Modal income (%)		
Below modal income	18.2%	12.1%
Approximately modal income	33.8%	36.4%
Above modal income	48.1%	51.5%
Employment status (% employed)	48.1%	52.8%
Disease-related characteristics		
BMI, mean (*SD*)	26.45 (4.86)	25.96 (4.96)
Cancer type		
Breast	71.0%	70.1%
Bladder	0.4%	0.4%
Colorectal	15.6%	12.6%
Esophageal	1.3%	1.3%
Gynecologic	2.6%	3.9%
Hematologic	6.1%	5.2%
Kidney	0.4%	1.3%
Liver	0.4%	0%
Lung	0%	2.2%
Prostate	0.9%	1.3%
Stomach	0.9%	0.4%
Testicular	0.4%	0.9%
Thyroid	0%	0.4%
Had cancer before (% yes)	10.0%	10.4%
Treatment Type		
Surgery	13.4%	12.1%
Chemotherapy	4.3%	3.5%
Radiotherapy	1.3%	0.4%
Chemotherapy & radiotherapy	0.4%	0.4%
Surgery & chemotherapy	20.8%	26.4%
Surgery & radiotherapy	12.3%	19.9%
Surgery, chemotherapy & radiotherapy	46.8%	37.2%
Time since last treatment (weeks), mean (*SD*)	23.44 (12.90)	25.06 (13.49)
Participation in support program (% yes)	61.0%	62.8%
Comorbid condition (% yes)	27.3%	26.8%

Intervention use and appreciation

The participants in the intervention group who completed the 6- or 12-month measurement (*n* = 192) on average used 2.20 modules (*SD* = 1.58). Of those using at least one module (89.1%), the average time between first login and last use of a module was 10.63 weeks (*SD* = 6.78), with 84.8% using a module for the last time within 18 weeks since first login. In total, 30.2% used one module, 18.8% used two modules, 21.9% used three modules, 9.9% used four modules, and 8.3% used five or more modules. Visitor rate per module is: Diet 60.9%, Fatigue 37.0%, Return to Work 24.5%, Mood (anxiety and depression) 24.0%, Physical Activity 24.0%, Residual Symptoms 20.8%, Relationships 18.8%, and Smoking 9.9%. The overall appreciation of the KNW, on a scale from 1 to 10, was considered high (*M* = 7.48, *SD* = 1.20) (Kanera et al., 2016c).

Intervention effects

Table 6.2 and Figure 6.2 show the mean scores of the outcomes at baseline and at 6 and 12 months after baseline (see Appendix D for a more detailed overview of the data distribution). The interaction terms between time and condition for emotional functioning (*B* = −0.39, *SE* = 1.66, *p* = .814), social functioning (*B* = −2.20, *SE* = 2.02, *p* = .276), depression (*B* = 0.21, *SE* = 0.24, *p* = .376), and fatigue (*B* = 3.03, *SE* = 1.93, *p* = .117) were non-significant, indicating that the intervention effects remain over time. However, the directions of the interaction coefficients indicate that the differences in the outcomes between the intervention and control group are smaller at 12 months from baseline than they were at 6 months from baseline.

Table 6.2: Means (*SD*s) of outcomes at baseline, 6 months, and 12 months

	Baseline (*n* = 462)	**6 months (*n* = 409)**	**12 months (*n* = 379)**
Emotional functioning			
Control	79.83 (21.49)	81.00 (20.31)	81.90 (19.61)
Intervention	77.78 (22.60)	83.78 (17.76)	83.58 (20.58)
Social functioning			
Control	82.03 (22.53)	87.25 (19.45)	87.86 (19.00)
Intervention	79.80 (21.04)	90.07 (16.86)	88.29 (19.52)
Depression			
Control	3.44 (3.45)	3.53 (3.67)	3.21 (3.47)
Intervention	3.65 (3.26)	2.82 (3.06)	2.90 (2.99)
Fatigue			
Control	65.20 (28.25)	61.77 (28.15)	59.87 (27.51)
Intervention	64.55 (26.46)	55.90 (26.72)	58.83 (29.14)

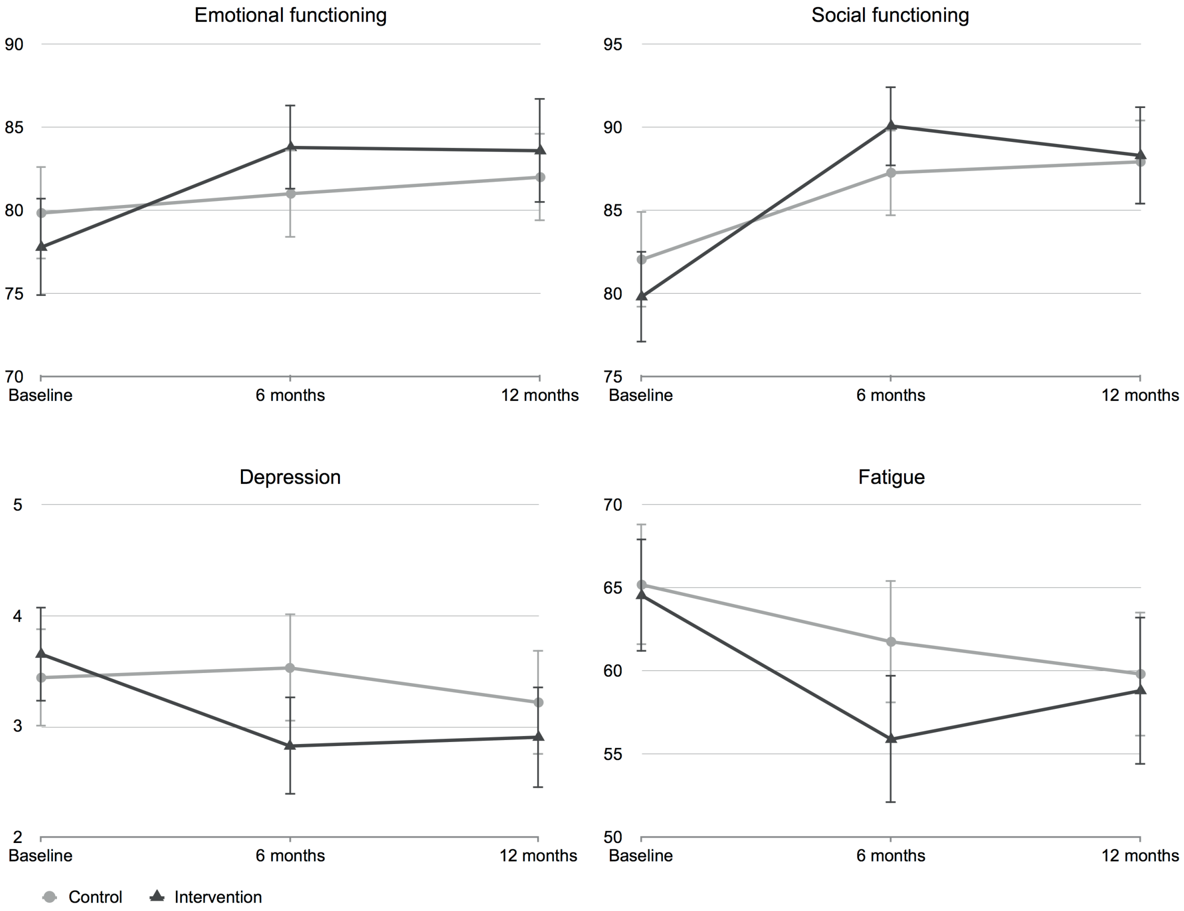

Figure 6.2: Line graphs of the outcome scores at baseline and 6 and 12 months after baseline. Vertical bars represent the 95% CI of the mean.

As a result, between-group differences at 12 months from baseline on emotional ($B = 2.65$, $SE = 1.60$, $p = .096$, $d = 0.08$) and social functioning ($B = 1.31$, $SE = 1.67$, $p = .435$, $d = 0.02$), depression ($B = -0.25$, $SE = 0.21$, $p = .227$, $d = 0.10$), and fatigue ($B = -1.01$, $SE = 1.98$, $p = .611$, $d = 0.04$) were all non-significant (Table 6.3). The mean scores on the outcomes suggest that the intervention group remained fairly stable in emotional and social functioning, depression and fatigue between 6 and 12 months from baseline, but that the control group slightly improved over time, leading to non-significant group differences at 12 months from baseline. Furthermore, no effects were found for the influence of module use on the 12-month intervention effects.

Moderators

Gender moderated the 6-month effectiveness of social functioning ($p = .098$), with the KNW being effective in improving social functioning for men ($B = 9.14$, $SE = 3.51$, $p = .009$, $d = 0.34$), but not for women ($B = 2.65$, $SE = 1.74$, $p = .129$, $d = 0.11$). Age moderated the 6-month effect of fatigue ($p = .036$), with the KNW being effective in decreasing fatigue for participants aged 56 or younger ($B = -10.48$, $SE = 2.63$, $p < .000$, $d = 0.44$), but not for participants aged 57 or older ($B = 1.86$, $SE = 2.64$, $p = .480$, $d = 0.02$) (see Appendix E, Figure E.1). There was also an indication that age moderated the 12-month effect of social functioning ($p = .098$). However, the margin plot showed no significant difference at different values of age (see Appendix E, Figure E.2). Educational level moderated the 12-month effect of social functioning ($p_{\text{medium}} = .004$, $p_{\text{high}} = .053$).[2] Participants with low educational level reported lower social functioning ($B = -5.84$, $SE = 2.89$, $p = .043$, $d = .22$) and participants with medium educational level reported higher social functioning ($B = 6.13$, $SE = 2.91$, $p = .035$, $d = .19$) than participants with a similar educational level in the control group, while there was no effect for participants with a high educational level ($B = 2.22$, $SE = 3.02$, $p = .464$, $d = .05$). While there was an indication that educational level moderated the 12-month effect of fatigue ($p_{\text{medium}} = .057$), no subgroup effects were found. Finally, treatment type moderated the 6-month effect of depression ($p_{cs} = .027$, $p_{crs} = .083$),[3] with the KNW being effective in decreasing depression for participants who received chemotherapy with or without surgery ($B = -1.16$, $SE = 0.43$, $p = .008$, $d = 0.36$), but not for participants who received surgery only ($B = 0.58$, $SE = 0.65$, $p = .370$, $d = 0.16$), radiotherapy with or without surgery ($B = -0.47$, $SE = 0.55$, $p = .389$, $d = 0.15$), or chemotherapy and radiotherapy with or without surgery ($B = -0.71$, $SE = 0.36$, $p = .052$, $d = 0.13$). For an overview of the means and *SD*s of the health outcomes by moderators, see Table 6.4.

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[2] p_{medium} indicates the significance level of the interaction term between condition and medium educational level. p_{high} indicates the significance level of the interaction term between condition and high educational level.

[3] p_{cs} indicates the significance level of the interaction term between condition and the treatment type category "chemotherapy with or without surgery". p_{crs} indicates the significance level of the interaction term between condition and the treatment type category "chemotherapy and radiotherapy with or without surgery".

Table 6.3: Results of the multilevel analyses testing the effectiveness of the KNW on emotional and social functioning, depression, and fatigue at 6 and 12 months from baseline

		Mixed models ($n = 414$)						Imputed data ($n = 462$)			
		B	*SE B*	95% CI	*p*	p_{fdr}	*d* [95% CI]	*B*	*SE B*	95% CI	*p*
Emotional functioning											
6 months	*Crude*	3.21	1.55	[0.18, 6.25]	**.038**	**.038**	−0.15 [−0.34, 0.05]	2.35	1.59	[−0.77, 5.48]	.139
	Adjusted	3.04	1.54	[0.02, 6.07]	**.049**	**.049**		1.92	1.57	[−1.15, 5.00]	.221
12 months	*Crude*	2.79	1.60	[−0.35, 5.93]	.081	.661	−0.08 [−0.28, 0.12]	0.27	1.67	[−3.01, 3.56]	.871
	Adjusted	2.65	1.60	[−0.47, 5.78]	.096	.384		−0.16	1.66	[−3.43, 3.11]	.923
Social functioning											
6 months	*Crude*	3.64	1.65	[0.41, 6.87]	**.027**	**.037**	−0.15 [−0.35, 0.04]	1.37	1.83	[−2.22, 4.96]	.453
	Adjusted	3.50	1.61	[0.35, 6.66]	**.030**	**.048**		1.03	1.78	[−2.45, 4.53]	.562
12 months	*Crude*	1.38	1.71	[−1.97, 4.73]	.421	.661	−0.02 [−0.22, 0.18]	−3.01	1.81	[−6.57, 0.54]	.096
	Adjusted	1.31	1.67	[−1.97, 4.59]	.435	.580		−3.36	1.76	[−6.80, 0.10]	.057
Depression											
6 months	*Crude*	−0.51	0.20	[−0.90, −0.11]	**.011**	**.037**	0.21 [0.01, 0.40]	−0.51	0.21	[−0.93, −0.10]	**.014**
	Adjusted	−0.46	0.20	[−0.86, −0.07]	**.021**	**.048**		−0.41	0.21	[−0.82, −0.00]	**.049**
12 months	*Crude*	−0.30	0.21	[−0.70, 0.10]	.145	.661	0.10 [−0.11, 0.30]	−0.19	0.21	[−0.60, 0.23]	.375
	Adjusted	−0.25	0.21	[−0.66, 0.16]	.227	.454		−0.09	0.21	[−0.50, 0.33]	.684
Fatigue											
6 months	*Crude*	−4.36	1.98	[−8.23, −0.48]	**.028**	**.037**	0.21 [0.02, 0.41]	−4.84	1.96	[−8.68, −1.00]	**.014**
	Adjusted	−4.04	1.92	[−7.82, −0.26]	**.036**	**.048**		−4.12	1.91	[−7.87, −0.39]	**.030**
12 months	*Crude*	−1.42	2.03	[−5.41, 2.56]	.482	.661	0.04 [−0.17, 0.24]	−0.71	2.02	[−4.68, 3.26]	.725
	Adjusted	−1.01	1.98	[−4.90, 2.88]	.611	.661		−0.00	1.98	[−3.88, 3.88]	1.000

p_{fdr} gives the *p*-values corrected for multiple testing using false discovery rate (Benjamini & Yekutieli, 2001). Correction for multiple testing was carried out in four sets: (1) crude analyses at 6 months, (2) adjusted analyses at 6 months, (3) crude analyses at 12 months, and (4) adjusted analyses at 12 months.

Table 6.4: Means (*SD*s) for fatigue, depression, and social functioning by moderators

		Control		Intervention	
		n	*M (SD)*	*n*	*M (SD)*
Fatigue by age					
≤56 years	T0	107	69.86 (27.33)	125	68.38 (25.39)
	T2	101	66.40 (29.45)	97	54.43 (25.17)
	T3	96	62.53 (27.82)	88	60.38 (30.11)
≥57 years	T0	124	61.18 (28.52)	106	60.05 (27.10)
	T2	120	57.88 (26.52)	91	57.47 (28.34)
	T3	115	57.57 (27.06)	80	57.14 (28.12)
Depression by treatment type					
Surgery only	T0	31	4.32 (4.04)	28	3.14 (3.08)
	T2	29	3.90 (3.76)	25	3.32 (3.66)
	T3	26	3.54 (4.15)	21	3.19 (3.74)
Chemotherapy ± surgery	T0	58	3.43 (3.19)	69	3.52 (2.95)
	T2	58	3.81 (3.94)	53	2.55 (3.03)
	T3	54	3.43 (3.73)	44	2.84 (2.84)
Radiotherapy ± surgery	T0	33	3.91 (3.67)	47	3.91 (3.63)
	T2	31	3.19 (3.43)	43	2.67 (3.31)
	T3	30	3.20 (3.31)	39	2.21 (2.69)
Chemotherapy and radiotherapy ± surgery	T0	109	3.06 (3.32)	87	3.78 (3.37)
	T2	103	3.37 (3.61)	67	2.96 (2.71)
	T3	101	3.03 (3.21)	64	3.28 (2.99)
Social functioning by gender					
Men	T0	45	85.19 (21.97)	48	81.94 (18.78)
	T2	42	88.10 (21.87)	36	94.44 (14.36)
	T3	41	90.24 (19.36)	29	90.80 (18.68)
Women	T0	186	81.27 (22.67)	183	79.23 (21.61)
	T2	179	87.06 (18.91)	152	89.04 (17.27)
	T3	170	81.35 (18.89)	139	87.77 (19.72)
Social functioning by educational level					
Low	T0	97	77.66 (24.87)	76	78.95 (19.12)
	T2	93	86.38 (19.50)	63	88.36 (17.87)
	T3	87	87.55 (18.19)	52	83.33 (20.87)
Medium	T0	70	86.19 (18.16)	76	80.26 (20.85)
	T2	65	84.36 (20.60)	64	89.58 (17.44)
	T3	61	85.79 (21.48)	62	89.78 (20.99)
High	T0	64	84.11 (22.31)	79	80.17 (23.12)
	T2	63	91.53 (17.68)	61	92.35 (15.08)
	T3	63	90.48 (17.38)	54	91.36 (15.44)

T0: baseline; T2: 6 months from baseline; T3: 12 months from baseline.

DISCUSSION

The current study investigated whether the short-term effects (i.e., 6 months from baseline) of the web-based computer-tailored KNW intervention on emotional and social functioning, depression, and fatigue remained in the long term (i.e., 12 months from baseline). In addition, subgroup differences in intervention effectiveness in the short term and long term were explored. The significant increase in emotional and social functioning and decrease in depression and fatigue at 6 months from baseline within the intervention group (see also Willems et al., 2017a) remained fairly stable between 6 and 12 months after baseline, which can be considered as a positive outcome. The control group illustrated a different course, with well-being slowly increasing over the trial period, leading to non-significant differences between the intervention and control group in the long term. Intention-to-treat analyses supported these results. Thus, while the health outcomes of the intervention and control group in the long term are similar, the results suggest that the intervention group benefitted from an extra, earlier period of improved quality of life.

Other eHealth applications for cancer survivors also found that the additional health effects of eHealth interventions did not remain significant in comparison to the control condition after the trial period had ended (Osei, Lee, Modest, & Pothier, 2013; van den Berg et al., 2015; van den Brink et al., 2007). In a comparable intervention by van den Berg et al. (2015), who evaluated the effectiveness of a non-tailored web-based CBT-based intervention aimed at reducing distress and improving empowerment among breast cancer survivors, the intervention was found to be effective in reducing psychological distress directly after intervention closure, but the intervention and control group did not differ at long-term follow-up. Likewise, the natural recovery of the control group led to non-significant between-group differences at long-term follow-up. For face-to-face interventions, long-term effects, albeit often reduced in part, more frequently sustain (Faller et al., 2013; Kangas et al., 2008). This suggests that face-to-face interventions seem to be more effective in sustaining effects in the long term than eHealth intervention do. However, since there is little evidence on the long-term effects of eHealth interventions for cancers survivors, more research is needed to verify this idea.

The KNW was developed for the general population of cancer survivors as a tool to provide personalized information on what to expect after cancer treatment and how to effectively address the survivors' most prominent needs and problems. As the KNW was available to all cancer survivors, there was no preselection on baseline values of the outcomes quality of life, depression, and fatigue. As a consequence, a minority of the participants experienced strong problems on these issues. The fact that, in the long term, no further improvement in emotional and social functioning and no further decrease in depression occurred in the intervention group might therefore be explained by the study sample scoring fairly well on these outcomes. The 6-month scores were already quite good and hard to further improve, and maintenance of these scores should be considered as being very positive. It could be expected that the intervention might be more effective for participants scoring less well on baseline quality of life and depression, since they would have greater opportunity for improvement than those who functioned better at the start of the intervention (Faller et al., 2013; Schneider et al., 2010; Tamagawa et al., 2012). Since there was little variation in the baseline score of these health outcomes within the current study, moderation analyses would provide unreliable results. Therefore, future research should investigate how the effects of the KNW differ between groups with more or less experienced problems.

For fatigue, further improvement would have been possible, but the intervention group showed no further decrease in fatigue after the 6-month measurement. The restricted time period that the intervention was available for use might be a possible explanation for this effect (van den Berg et al., 2015). Fatigue is a multidimensional and complex problem, which can be treated from different angles, such as CBT for fatigue, depression, or sleep; psychoeducation; regulating activities; physical exercise; and relaxation exercises (Berger, Mitchell, Jacobsen, & Pirl, 2015; Prue et al., 2006). While most of these aspects were discussed within the KNW, the amount of information and assignments might be too extensive for this restricted time period. On the other hand, user statistics of the KNW showed that the majority of the participants (>80%) stopped using any of the modules 18 weeks following first use (Willems et al., 2017a). This long-term discontinuation of eHealth application usage is a widely recognized phenomenon (Eysenbach, 2005; Kohl et al., 2013). It is therefore suggested that new techniques can be added to the intervention that may improve the provided feedback and advice and facilitate participant engagement in the intervention. They subsequently need to be tested for their added value. One suggestion could be to add face-to-face support to the intervention, changing the intervention into a blended approach (Brouwer et al., 2011; Kangas et al., 2008; Kohl et al., 2013). However, the downside of adding face-to-face support is that, because of therapist burden, it could undermine the high reach of the intervention (Kohl et al., 2013), while costs would increase significantly. Another option is to provide more additional long-term tailored feedback on the participants' change of their behavior and health status over time (Krebs et al., 2010). While the KNW provided direct feedback after assignment completion and several e-mail reminders to complete the module were sent, no updates were given on the progress over time in comparison to the baseline outcome. By providing such feedback on the survivors' well-being and behavioral changes at multiple moments, long-term effectiveness can be enhanced (Krebs et al., 2010).

Nonetheless, the results are highly relevant, as they suggest that the KNW expedites recovery after cancer. In practice, this means that an easily accessible, low-intensity, and fairly inexpensive intervention can offer several extra months of increased quality of life for a large group of early cancer survivors. This might imply that the health benefits gained from the KNW may lead to lower psychological comorbidity or mortality (Brown & Kroenke, 2009; Cairns & Hotopf, 2005; Mols, Husson, Roukema, & van de Poll-Franse, 2013), which might result in better adherence to follow-up treatment (Arrieta et al., 2013), or better or earlier integration in daily life (e.g., social relations, return to work) (Duijts et al., 2014; Jorgensen, 2008). Therefore, the KNW can serve as a relevant step in a stepped-care approach in cancer aftercare (Krebber et al., 2016; Krebber et al., 2012; Ritterband & Tate, 2009). For patients with mild problems who are able to manage these problems themselves with personalized information and guidance, the KNW can offer sufficient and adequate support to increase and accelerate their recovery process. For patients with more severe problems who might need more intensive support (e.g., face-to-face therapy, or medication), the KNW can recommend seeking out this additional support.

Moderators

The results of the moderator analyses indicate that the KNW was more effective for specific subgroups. In the short term, the KNW was primarily effective in improving social functioning for men ($d = 0.34$), decreasing fatigue for those aged 56 and younger ($d = 0.44$), and decreasing depression for those who received chemotherapy with or without surgery ($d = 0.36$). The effect sizes for these subgroups were substantially higher in comparison to the effect sizes of the complete sample. In the long term, participants with a medium educational level reported higher social functioning ($d = 0.19$), while participants with a low educational level reported lower social functioning ($d = 0.22$) than participants with a similar educational level in the control group. These effect sizes were relatively small.

Concerning the moderating effect of age on fatigue, another study exploring moderators of a guided self-instruction intervention for chronic fatigue syndrome also found the intervention to be more effective for younger patients (Tummers, Knoop, van Dam, & Bleijenberg, 2013). A possible explanation could be that the prognosis for older patients experiencing fatigue is worse than for younger patients and, therefore, the KNW could not offer sufficient support for the older population. While some studies support this relation between older age and worse prognosis, this evidence is mixed (Cairns & Hotopf, 2005). Another explanation could be that younger patients might be more proactive to address their experienced problems, while older patients tend to be more accepting of their physical decline (Derks, Leeuw, Hordijk, & Winnubst, 2005).

The finding that the KNW was more effective for participants who received chemotherapy might be explained by the finding that patients who have received chemotherapy might be more at risk of developing depressive symptoms (de Jong et al., 2002; Fann et al., 2008). It is possible that the sections within the KNW that discussed depressive feelings addressed the needs of this subgroup better. It should be noted that, while almost significant, an intervention effect for depression was not found for the participants who received both chemotherapy and radiotherapy with or without surgery. Possibly, a light intervention as KNW might not be powerful enough to effectively address stronger feelings of depression in some of those who received the heaviest and most intrusive cancer treatment.

Concerning social functioning, results suggest that, in the short term, the intervention had a greater effect on men than women in feeling that their physical condition or treatment did not interfere with their family life or social activities. One explanation could be that women in general rely on a broader social support network of family, friends, and their partner when dealing with cancer-related distress, while men primarily find support in their partner (Harrison, Maguire, & Pitceathly, 1995). Possibly, the advice provided within the KNW on dealing with social relationships focusses less on support in dealing with more complex social relationship structures.

The differences in effect on social functioning within educational level in the long term were unexpected, since the moderator analyses at the short term showed no difference in direction of intervention effects. Investigation of the mean scores of social functioning by educational level suggest that people with a low educational level in the control group show a natural recovery over time. The participants in the intervention group with a low educational level also increase in social functioning 6 months from baseline, but show a small drop at 12 months from baseline. Thus, it is not the case that participants with a low educational level in the intervention group report worse social functioning in the long term in comparison to baseline. Instead, the control group improves more in social functioning than the intervention group does. Therefore, the intervention is not considered effective in increasing social functioning for participants with a low educational level. For participants with a medium educational level, the mean scores suggest that the intervention group improved in social functioning at 6 months from baseline and this effect remained in the long term. Therefore, the intervention is considered effective in improving social functioning for participants with a medium educational level.

The moderator analyses were exploratory and, therefore, the results need to be interpreted with caution. They do, however, provide useful insight into directions in which the intervention and the tailored advice within the intervention could be improved. For example, further development of the intervention could focus on how to address the needs of elderly users better or how to adjust the advice so they match better to the issues associated with the received treatment type.

Limitations

There are some limitations that should be mentioned. First, selective dropout might have influenced the results, in particular the higher dropout in the intervention group. This differential dropout is not uncommon in health behavioral change trials, and might be explained by the intervention being too time intensive, or by the intervention not meeting the participant's expectations (Crutzen, Viechtbauer, Spigt, & Kotz, 2015). Fortunately, the dropout rate at 6 and 12 months from baseline was very low (11.5 and 17.5%, respectively). With this low dropout rate and correction for the differences between completers and non-completers in the analyses, minimal influences of dropout effects may be expected. In addition, the intention-to-treat analyses supported the findings of the long-term effectiveness. Second, while the study aimed to recruit a diverse group of cancer survivors, women with breast cancer and survivors who scored fairly well on quality of life and depression were over-represented. Furthermore, the intervention reached the older population to a lesser extent. In general, female, younger, and low-risk individuals are more prone to participate in online interventions (Brouwer et al., 2010; Kohl et al., 2013). Nonetheless, this selection bias makes it more difficult to generalize the findings to the general population of cancer survivors. Third, while the sensitivity to change for both the CIS and the EORTC QLQ-C30 seems to be adequate (Gielissen et al., 2007; Osoba et al., 1994; Uwer et al., 2011), evidence on the sensitivity to change for the HADS is mixed (Costantini et al., 1999; Kenn, Wood, Kucyj, Wattis, & Cunane, 1987). Thus, the finding that there were no long-term effects on depression could be attributable to the scale not being responsive enough. However, because of little evidence, no strong conclusions can be made on this point. Finally, the online questionnaires were self-administered. While only validated questionnaires were used, the results could be influenced by social desirability.

CONCLUSION

The results of the current study add new insights into the scarce evidence of the (long-term) effectiveness of eHealth interventions for cancer survivors (McAlpine et al., 2015). These results support the notion that web-based interventions can speed up the recovery process of cancer survivors. It is expected that the KNW in particular will be effective for survivors without medical indication, who are experiencing milder complaints that they can manage themselves with the right personalized information (Krebber et al., 2016). With the KNW being a relatively low-intensity, easily accessible, and low-cost tool, which has the potential to reach a large group of cancer survivors, it is believed that it could adequately serve as a relevant step in stepped care for the larger population of cancer survivors, helping them to more quickly deal with their experienced problems and therefore accelerate their recovery.

Working mechanisms of a web-based self-management intervention for cancer survivors: A randomized controlled trial

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ABSTRACT

Objective: The aim of this study was to investigate whether problem-solving skills and perceived personal control over cancer recovery mediated the intervention effects on depression and fatigue of a web-based computer-tailored intervention for cancer survivors – the *Kanker Nazorg Wijzer* (Cancer Aftercare Guide).

Methods: Patients were recruited through 21 Dutch hospitals (November 2013 – June 2014). The mediation model was tested in a randomized controlled trial with an intervention group ($n = 231$) and a waiting list control group ($n = 231$). Hypothesized mediators problem-solving skills (SPSI-R) and personal control (IPQ-R) were measured at baseline and 3 months from baseline. Outcomes depression (HADS) and fatigue (CIS) were measured at baseline and 6 months from baseline.

Results: The intervention effects in decreasing depression and fatigue were mediated by personal control. Problem-solving skills did not mediate the intervention effects on depression and fatigue.

Conclusion: While personal control in the control group decreased in the first 3 months after baseline, levels of personal control within the intervention group were maintained. This effect partially explained the intervention effects on depression and fatigue. The results provide evidence for the relevance of addressing personal control in web-based interventions in order to improve psychosocial well-being in early cancer survivors.

INTRODUCTION

Despite great advances in cancer detection and treatment, many cancer survivors face a variety of difficulties and challenges affecting their quality of life (Wu & Harden, 2015). In particular, depression and fatigue are prominent issues (Irwin et al., 2013; Prue et al., 2006). Approximately one in five survivors shows symptoms of depression within the first two years following diagnosis (Mitchell et al., 2013) and 30–40% experience fatigue within five years after diagnosis (Husson et al., 2015a; Jones et al., 2016). Current guidelines suggest that the patient is mainly held responsible for managing their health and well-being and healthcare professionals should encourage and support them in self-management (Comprehensive Cancer Centre the Netherlands, 2011b; Davies & Batehup, 2011; Fenlon & Foster, 2009). This means that survivors should have an active role in their recovery and rehabilitation, in which the cancer survivor manages the consequences of cancer and its treatment in his or her daily life, understands how and when to seek support, and (if needed) makes lifestyle changes to promote health and well-being (Department of Health et al., 2010; Foster et al., 2015). However, many survivors do not always feel confident in managing life after cancer treatment, in particular in dealing with depression and fatigue (Foster et al., 2015; Foster & Fenlon, 2011). This is not surprising, since these are complex and interrelated issues (Brown & Kroenke, 2009; Moss-Morris & Petrie, 2001). Moreover, cancer survivors often are poorly prepared by health professionals to effectively manage such problems during life after cancer treatment, resulting in prominent information needs (Stanton, 2012).

Cancer survivors use the Internet as a primary source of health-related information (Chou et al., 2011) and in general are positive about self-management eHealth programs (Jansen et al., 2015). A great advantage of such interventions is that they can have an extensive reach and are easily accessible (Lustria et al., 2009; Willems et al., 2015). eHealth programs can incorporate computer tailoring, through which information and guidance can be personalized based on the survivor's personal characteristics (Lustria et al., 2009). By personalizing information, behavior change and maintenance is better facilitated (Brug et al., 2003).

To provide cancer survivors with personalized information and support on psychosocial and lifestyle issues, the web-based computer-tailored *Kanker Nazorg Wijzer* intervention (Cancer Aftercare Guide; KNW) was developed (Willems et al., 2015). In a randomized controlled trial (RCT) comparing an intervention group with a waiting list control group, the effectiveness of the KNW at 6 months after baseline (i.e., after closing access to the KNW) on quality of life, anxiety, depression, and fatigue was evaluated (Willems et al., 2017a). The study showed convincing evidence that the KNW was effective in reducing depression and fatigue.

With the KNW being developed as a fully automated self-management tool, the current study investigates the intervention working mechanisms that might be responsible for reducing fatigue and depression. It is hypothesized that two processes in particular might lead to changes in these outcomes (see Figure 7.1). First, it is expected that the KNW improves participants' problem-solving skills as the KNW was structured according to the principles of Problem-Solving Therapy (PST) (D'Zurilla & Nezu, 2007). During the intervention, cancer survivors were provided with options to learn and apply problem-solving techniques to effectively address their problems (Willems et al., 2015). More specifically, participants identified their problem, selected solutions to this problem, were guided in how to implement the solution in daily life, and were requested to evaluate the result. In general, PST is considered to be an effective approach in treating depression and other cognitive and physical health problems in the general population (Malouff, Thorsteinsson, & Schutte, 2007). Moreover, several interventions for cancer patients based on PST have been shown as effective in improving mental health (Allen et al., 2002), symptom management (Mishel et al., 2002), and reducing psychological distress (Nezu et al., 2003). However, none of these were eHealth interventions. One PST-based eHealth intervention for the general population was found to be effective in reducing depression (Warmerdam, van Straten, Twisk, Riper, & Cuijpers, 2008). However, this eHealth intervention was not fully automated but used a blended approach with therapist support.

Second, it is expected that the KNW increases participants' personal control or self-efficacy in managing their illness (i.e., beliefs about personal abilities to control the illness). Higher personal control has been shown to be related to patients' psychosocial and physical well-being (Ashley, Marti, Jones, Velikova, & Wright, 2015; Hagger & Orbell, 2003; Tamagawa et al., 2012). Personal control is one of the components of illness perceptions in Leventhal's Common Sense Model (Leventhal, Nerenz, & Steele, 1984). The model proposes that patients create illness perceptions based on the information they receive about their disease. These perceptions in turn form the first step in managing the disease (Hagger & Orbell, 2003). The information can be derived from bodily experience, information from the external social environment (e.g., healthcare providers, family, peers), and past experiences with the disease (Leventhal et al., 1980). Providing patients with more disease-specific information has been shown to be related with more feelings of personal control (Husson et al., 2013; Noar et al., 2007). In the KNW, several techniques were used to increase personal control. First, disease-specific information was provided by tailoring the information to the patient's characteristics. Second, principles of cognitive behavioral therapy (CBT) were implemented (Beck, 2011; Goldin et al., 2012), such as monitoring behavior or thoughts, challenging dysfunctional cognitions, planning pleasant activities, setting new goals, and using relaxation exercises. Finally, the information is supported by videos of fellow survivors and professionals from different fields (e.g., clinical psychologist, sexologist, and physiotherapist). The interviewees in these videos served as models (Kok et al., 2016) by informing participants about what they can expect after cancer treatment and how they can deal with their problems and daily troubles.

In sum, the current study investigates to what extent problem-solving skills and personal control mediate the KNW's effect in reducing depression and fatigue. It is expected that the KNW increases problem-solving skills and personal control, which results in a decrease in depressive feelings and fatigue.

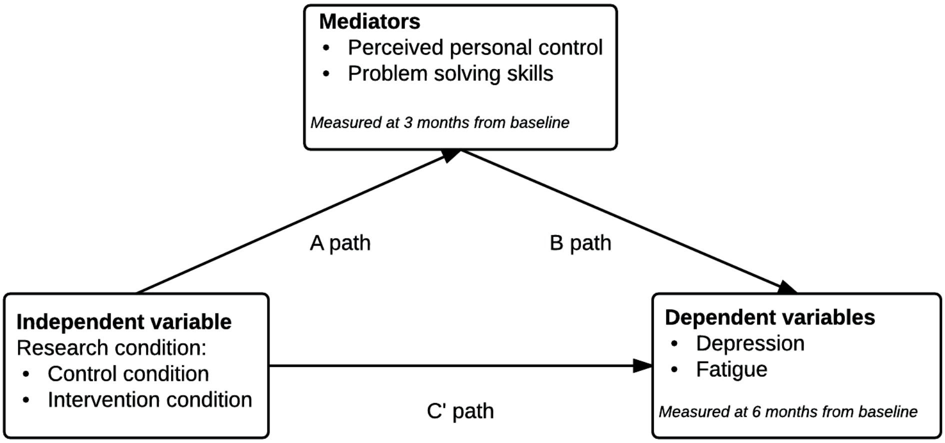

Figure 7.1: Hypothesized mediation model

METHODS

An RCT comparing an intervention group with a waiting list control group was conducted. The RCT was registered in the Dutch Trial Register (NTR3375) and approved by the Medical Ethics Committee Zuyderland-Zuyd (NL41445.096.12).

The intervention

The KNW (http://www.kankernazorgwijzer.nl) was systematically developed using the Intervention Mapping protocol (Bartholomew et al., 2016). This protocol consists of six steps: needs assessment, specification of objectives, selecting behavioral change theories and practical applications, producing program materials, program adoption and implementation, and evaluation. The KNW consists of eight modules (see Figure 3.1), of which seven are self-management training modules. The training modules cover the topics return to work, fatigue, anxiety and depression, social relationships and intimacy issues, physical activity, diet, and smoking cessation. The eighth module provides general information on the most common residual symptoms. Detailed information of the theoretical foundations of the intervention and a description of the modules are described in Chapter 3.

The program is developed as a stand-alone intervention (i.e., there is no therapist support) that aims to increase cancer survivors' quality of life by providing psychosocial support and promoting positive lifestyle changes. It is programmed to be an open and unrestrictive program. Participants start by filling in a baseline questionnaire that enables tailoring. They then receive personalized advice on whether following a particular module would benefit them (Kanera et al., 2016c). Participants are however free to choose whether or not to follow the advice. There is no order in which the modules have to be followed and participants are not obliged finish a particular module before gaining access to another module. Participants were also able to follow multiple modules simultaneously.

Within a module, the information is tailored further, resulting in personalized goals and action plans. The information is primarily tailored on (the determinants of) the health outcomes. For example, the advice within the Fatigue module is based on the answers of the Checklist Individual Strength (Vercoulen et al., 1999), a validated questionnaire to assess the type and severity of fatigue that was included in the baseline screening questionnaire. Questions on the determinants of fatigue are assessed within the Fatigue module itself. The sequence is then the following: when participants have a high fatigue score on the baseline screening questionnaire, they are referred to the Fatigue module. Within the Fatigue module, some additional questions on the determinants of fatigue are asked and participants are referred to the theme that is most relevant for them (e.g., dysregulation of daily activities, thoughts about fatigue, or sleep hygiene measures). Within a theme, different topics are discussed and participants can select the topic that best suits their interests or needs, followed by specific information and assignments related to the topic of interest. At the end of the module, participants make specific action plans to address their most prominent issues.

To address participants' problem-solving skills, the training modules are structured based on the principles of PST (see Figure 3.1). First, participants further specify what determines their problem. Second, participants determine the goal they want to reach and receive psychoeducation and assignments to better understand how to manage their problem. Third, participants personalize their goal by making specific action plans and are encouraged to try out this personal plan in the forthcoming month. Fourth, 30 days after making the action plan, participants are invited to evaluate the progress of reaching their goal and make a new goal if necessary. During the "try out phase" (the period between step 3 and 4), participants still have access to the whole intervention.

Further, basic principles of CBT are addressed within the modules, including psychoeducation, several assignments (e.g., monitoring behavior or thoughts, challenging dysfunctional cognitions, planning pleasant activities, setting new goals), and relaxation exercises. The information in the modules is supported by videos of professionals and fellow survivors, explaining how to deal with problems. The expert videos are mainly focused on mastery learning (i.e., how problems should be addressed); the fellow survivors function as a coping model, in which they acknowledge the difficulties, but also explain that things will be better (Bandura, 1986; Kok et al., 2016).

Participants and procedure

Patients were eligible for participation if they were 18 years or older; had been diagnosed with any type of cancer; primary treatment (surgery, chemotherapy, and/or radiotherapy) had been completed successfully for at least 4 weeks, but for no more than 56 weeks; there was no sign of recurrence at the latest follow-up visit; they were able to speak and read Dutch; and there was no serious medical, psychiatric, or cognitive illness that would interfere with participation.

Representatives of 45 hospitals in the Netherlands (e.g., department heads, oncologists, research nurses, nurse practitioners) of outpatient clinics in internal medicine, oncology, gynecology, urology, and the breast clinic were contacted for assistance in recruitment. Professionals from 21 hospitals recruited patients between November 2013 and June 2014. Eligible patients were invited to participate by giving them an information package during a follow-up visit or sending the package following review of the patient's files. The information package included: (1) a letter with trial information and a username and password for first login, (2) an informed consent form with return envelope, (3) an information brochure concerning Medical Research, (4) an instruction manual on how to use the KNW, and (5) a card with contact details. A reminder was sent after 2 weeks. Patients who agreed to participate were requested to return the signed consent form to the Open University of the Netherlands. Those who participated in the program but did not return the informed consent form after several reminders were excluded from the analyses. Sample size calculations were based on the outcomes quality of life, anxiety, and depression and showed that, after correction for multilevel analyses and an expected dropout of 20%, 188 patients per group had to be included ($\alpha = .10$, $\beta = .20$, $d = .30$).

After online registration, the computer randomly assigned participants to either the intervention or the waiting list control group (allocation ratio 1:1). The intervention group had access to the KNW for 6 months directly after baseline. Within this 6-month period, there were no restrictions in the use of the program. The waiting list control group had access to the intervention after the last measurement (12 months from baseline). During the waiting period, this group received care as usual. This means that the control group, as well as the intervention group, were not restricted in the use of other forms of cancer aftercare.[1]

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[1] Allowing both groups to use any other type of cancer aftercare (e.g., general practitioner, [oncological] physiotherapy, dietitian, and psychological support) during the trial period did not led to any difference in use of aftercare between the groups. At baseline, the control group on average used 1.00 ($SD = 1.04$) types of aftercare and the intervention group 1.08 ($SD = 1.07$) ($t(460) = -0.84$, $p = .402$). At 6 months from baseline, these numbers were 1.17 ($SD = 1.35$) and 1.38 ($SD = 1.34$), respectively ($t(400) = -1.54$, $p = .123$).

Both groups had to fill in a questionnaire at four time points: at baseline and after 3, 6, and 12 months from baseline. The 3-month measurement measured possible mediating variables, while the 6- and 12-month measurements aimed to measure the short- and long-term effectiveness of the intervention, respectively. The current study is thus part of a larger RCT evaluating the effectiveness of the KNW on psychosocial well-being (Willems et al., 2017a; Willems, Mesters, Lechner, Kanera, & Bolman, 2017c). In the current study, the data collected at baseline and 3 and 6 months from baseline were used to evaluate whether problem-solving skills and personal control at 3 months from baseline mediate the effects of depression and fatigue found at 6 months from baseline.

Measurements

Demographic and disease-related characteristics

Demographic characteristics included gender, age, educational level, and relationship status. Educational level was categorized into "low" (lower vocational education, medium general secondary education), "medium" (secondary vocational education, higher general secondary education), and "high" (higher vocational education, university education), according to the Dutch educational system. *Disease-related characteristics* included cancer type, treatment type, and time since last treatment. As the majority of participants had breast cancer, cancer type was dichotomized into "breast" and "other" (i.e., bladder, colorectal, esophageal, gynecologic, hematologic, kidney, liver, lung, prostate, stomach, testicular, and thyroid cancer). Demographic and disease-related characteristics were included in the mediation analyses as covariates.

Outcomes: depression and fatigue

Depression was measured with the depression subscale of the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). The subscale consists of seven items ($\alpha = .82$) and was measured on a four-point scale. Scale scores range from 0 to 21, with a score of 8 or higher being an indication for (clinical) depression.

Fatigue was measured with the total score of the Checklist Individual Strength (CIS) (Vercoulen et al., 1999). The 20-item CIS comprises four scales measuring subjective fatigue, concentration, motivation, and activity. Items range from 1 to 7. The total score (range 20–140, $\alpha = .94$) is an overall indication of fatigue, with a score of higher than 76 indicating a problematic fatigue level (Bultmann et al., 2000).

Mediators: problem-solving skills and personal control

Problem-solving skills were measured using the 10-item version of the Social Problem-Solving Inventory–Revised (SPSI-R) (D'Zurilla et al., 2002; Dreer et al., 2009). The SPSI-R measures two problem-solving orientations (positive and negative orientation) and three problem-solving styles (rational problem-solving, impulsivity/carelessness, and avoidance). Items range from 0 to 4. Total scores range from 0 to 40 (α = .74), with a higher score indicating greater effective social problem-solving abilities.

Personal control was measured with the personal control subscale of the Illness Perception Questionnaire–Revised (IPQ-R) (Moss-Morris et al., 2002). This six-item subscale measures beliefs about personal abilities to control one's illness. The items were slightly adjusted to ask about the beliefs of personal control to manage recovery after cancer treatment (e.g., "What I do can determine whether my cancer recovery gets better or worse"). Items range from 1 to 5. Total scores range from 6 to 30 (α = .80), with higher scores representing more positive beliefs about the controllability of cancer recovery.

Statistical analyses

Statistical analyses were conducted using SPSS 23.0. Baseline differences between the intervention and control condition were determined using independent *t*-tests, analysis of variance, and chi-square tests. To determine selective dropout between baseline and 6-month measurement, logistic regression analysis was used with dropout (0 = no, 1 = yes) as the outcome and research condition and the baseline values of the variables as described in the measurements section as independent variables. Pearson correlations were calculated between the outcomes (depression and fatigue) at baseline and 6 months from baseline and the hypothesized mediators (problem-solving skills and personal control) at baseline and 3 months from baseline.

Mediation analyses

Mediation was tested using the product-of-coefficients approach (MacKinnon, 2008; Preacher & Hayes, 2008). Since there was no clear evidence the data had a multilevel structure (i.e., that there was interdependence between participants from the same hospitals) (Willems et al., 2017a), mediation analyses were based on linear regression models. Depression and fatigue were the dependent variables in the mediation model and were measured at 6 months from baseline. Problem-solving skills and personal control were the hypothesized mediators and were measured at 3 months from baseline. Research condition was the independent variable (0 = control group; 1 = intervention group). Covariates included in the model were gender, age, educational level, relationship status, cancer type, treatment type, time since last treatment, and baseline values of the outcomes and the mediators. Categorical covariates with more than two categories were dummy coded.

The mediation models were conducted with the PROCESS macro (version 2.15) for SPSS (Hayes, 2013). For each outcome (depression or fatigue), separate mediation models were calculated. Mediation was evaluated using the following steps (see Figure 7.1).

First, the intervention effect on depression and fatigue was estimated (C-path). Second, the intervention effect on the hypothesized mediators was estimated (A-path). Third, the effect of the hypothesized mediators on depression and fatigue (B-path) and the effect of the intervention on depression and fatigue, controlling for the hypothesized mediators, was estimated (C'-path). Fourth, the significance of the mediated effect was evaluated by computing the bias-corrected bootstrap 95% confidence intervals (CI) (bootstrap = 5000). The criteria for mediation were met when the 95% CI did not include zero. The proportion of the total effect that was mediated was calculated by dividing the coefficient of the mediated effect by the coefficient of the total effect: $(a \times b) \div (c' + (a \times b))$, as this measure of effect size is preferred for basic mediation models (Wen & Fan, 2015). In addition, simple mediation analyses were conducted to assess the influence of each hypothesized mediator on fatigue and depression separately. Cohen's *d* (Cohen, 1992) was calculated for insight into the effect sizes of the intervention effects (A-path and C-path). Finally, to get better insight into the change in means over time in the intervention and control condition with regard to the intervention effects (A-path and C-path), dependent *t*-tests were used.

RESULTS

Participant characteristics are described in Table 7.1. In total, 231 patients in the control and 231 in the intervention condition returned the informed consent form and completed the baseline measurement; 221 patients in the control and 188 in the intervention group completed the 6-month measurement (dropout = 11.5%) (see Figure 7.2). Table 7.1 shows that, except for treatment type ($\chi^2(3) = 9.39$, $p = .024$), the intervention and control group were comparable. Dropout analyses showed that participants in the control group ($B = 1.80$, $SE = 0.39$, $p = .000$) and women ($B = -1.25$, $SE = 0.62$, $p = .044$) were more likely to fill in the 6-month questionnaire.

Use and appreciation

The participants in the intervention group who completed the 6-month measurement ($n = 188$) on average used 2.22 modules ($SD = 1.58$). Of those using at least one module (89.4%), the average time between first login and last use of a module was 10.67 weeks ($SD = 6.78$), with 83.9% using a module for the last time within 18 weeks since first login (Willems et al., 2017a). In total, 29.8% used one module, 18.6% used two modules, 22.3% used 3 modules, 10.1% used four modules, and 8.5% used five or more modules. Visitor rate per module is: Diet 61.7%, Fatigue 37.2%, Mood (anxiety and depression) 24.5%, Return to Work 24.5%, Physical Activity 23.9%, Residual Symptoms 21.3%, Relationships 19.2%, and Smoking 10.1%. The overall appreciation of the KNW, on a scale from 1 to 10, was considered high ($M = 7.5$, $SD = 1.2$) (Kanera et al., 2016c).

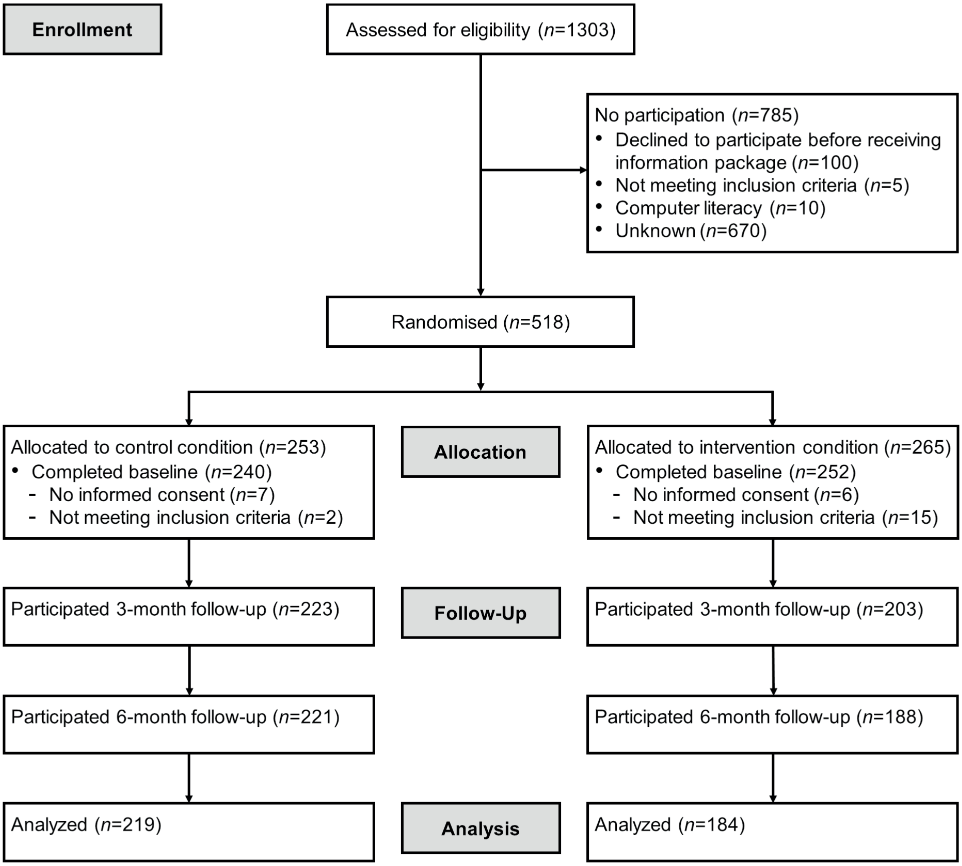

Figure 7.2: Flow diagram of the study

Mediation analyses

All correlations between problem-solving skills, personal control, depression, and fatigue were significant (see Table 7.2). Depression and fatigue were strongly correlated ($r = .67$ at baseline and $r = .76$ at 6 months from baseline). Problem-solving skills and personal control were weakly correlated ($r = .23$ at baseline and $r = .25$ at 6 months from baseline). Table 7.3 shows the results of the mediation analyses. These will be discussed in more detail in the following paragraphs.

Intervention effects on depression and fatigue (C-path)

Six months after baseline, the intervention was effective in reducing depression ($B = -0.62$, $SE = 0.24$, $p = .012$, $d = 0.21$) and fatigue ($B = -3.90$, $SE = 1.98$, $p = .048$, $d = 0.21$) (C-path) (see also Table 7.4).

Table 7.1: Baseline demographic, disease-related, and psychosocial characteristics of the participants who completed the 6-month measurement ($n = 409$)

	Control ($n = 221$)	**Intervention ($n = 188$)**	***p***
Gender (% women)	81.00	80.85	.971
Age (years), mean (*SD*)	56.28 (11.45)	56.26 (10.84)	.982
Relationship status (% partner)	81.00	85.11	.269
Education level (%)			.206
Low	42.08	33.51	
Medium	29.41	34.04	
High	28.51	32.45	
Cancer type (% breast cancer)	71.04	71.28	.958
Treatment type (%)			**.024**
Surgery, chemotherapy, and radiotherapy	46.15	35.64	
Surgery and chemotherapy	21.72	25.53	
Surgery and radiotherapy	12.67	22.34	
Other	19.46	16.49	
Time since last treatment (weeks), mean (*SD*)	23.38 (12.78)	25.28 (13.46)	.143
Problem-solving skills (0–40), mean (*SD*)	26.15 (5.57)	26.52 (4.90)	.483
Personal control (6–30), mean (*SD*)	22.95 (4.04)	23.16 (3.65)	.576
Depression (0–21), mean (*SD*)	3.43 (3.41)	3.45 (2.99)	.933
Fatigue (20–140), mean (*SD*)	64.57 (27.86)	62.75 (25.62)	.491

Table 7.2: Correlation matrix

	1.	**2.**	**3.**	**4.**	**5.**	**6.**	**7.**	**8.**
1. Problem-solving skills (T0)	1	.233***	−.248***	−.212***	.656***	.148**	−.206***	−.228***
2. Personal control (T0)		1	−.300***	−.255***	.235***	.529***	−.272***	−.287***
3. Depression (T0)			1	.671***	−.258***	−.283***	.700***	.617***
4. Fatigue (T0)				1	−.262***	−.307***	.522***	.695***
5. Problem-solving skills (T1)					1	.245***	−.301***	−.276***
6. Personal control (T1)						1	−.359***	−.404***
7. Depression (T2)							1	.756***
8. Fatigue (T2)								1

T0: baseline measurement; T1: measurement at 3 months from baseline; T2: measurement at 6 months from baseline.
** $p < 0.01$; *** $p < 0.001$

Intervention effects on problem-solving skills and personal control (A-path)

Three months after baseline, the intervention and control condition significantly differed in personal control ($B = 1.21$, $SE = 0.33$, $p < .001$, $d = 0.34$), but not in problem-solving skills ($B = 0.56$, $SE = 0.39$, $p = .149$, $d = 0.15$). More specifically, while the intervention condition remained stable in personal control at 3 months from baseline ($t(201) = -0.31$, $p = .756$), the control condition showed a significant decrease in personal control ($t(222) = 3.86$, $p = .000$) (see Table 7.4).

Table 7.3: Results of the mediation analyses for depression and fatigue comparing the intervention group to the control group ($n = 403$)

Outcome	Mediators	A path		B path		Total effects		Mediated effect		Proportion (%)
		A (*SE*)	*p*	B (*SE*)	*p*	C′ + AB (*SE*)	*p*	AB (*SE*)	95% CI	AB/(C′ + AB)
Depression	Problem-solving skills	0.56 (0.39)	.149	−0.10 (0.03)	**.001**			−0.06 (0.05)	[−0.18, 0.01]	9%
	Personal control	1.21 (0.33)	**<.001**	−0.12 (0.04)	**.001**			−0.15 (0.07)	[−0.31, −0.05]	24%
	Total					−0.62 (0.24)	**.012**	−0.20 (0.08)	[−0.41, −0.07]	33%
Fatigue	Problem-solving skills	0.54 (0.39)	.160	−0.24 (0.26)	.346			−0.13 (0.19)	[−0.78, 0.09]	3%
	Personal control	1.18 (0.33)	**<.001**	−1.30 (0.30)	**<.001**			−1.54 (0.56)	[−2.87, −0.64]	40%
	Total					−3.90 (1.98)	**.048**	−1.67 (0.60)	[−3.04, −0.70]	43%

Covariates: gender, age, educational level, relationship status, cancer type, treatment type, and time since last treatment, and baseline values for depression, fatigue, problem-solving skills, and personal control.

Effects of the hypothesized mediators on depression and fatigue (B-path)

Problem-solving skills ($B = -0.10$, $SE = 0.03$, $p = .001$) and personal control ($B = -0.12$, $SE = 0.04$, $p = .001$) at 3 months from baseline were negatively related to depression at 6 months from baseline. While personal control at 3 months from baseline was also negatively related to fatigue at 6 months from baseline ($B = -1.30$, $SE = 0.30$, $p < .001$), there was no association between problem-solving skills and fatigue ($B = -0.24$, $SE = 0.26$, $p = .346$). The simple mediation analyses showed similar results: both problem-solving skills ($B = -0.12$, $SE = 0.03$, $p < .001$) and personal control ($B = -0.14$, $SE = 0.04$, $p < .001$) were significantly related to depression. For fatigue, the relation with personal control was significant ($B = -1.37$, $SE = 0.30$, $p < .001$), while the relation with problem-solving skills was not ($B = -0.42$, $SE = 0.26$, $p = .105$).

Table 7.4: Mean scores of the mediators and outcomes over time

	Score range	*n*	Baseline *M* (*SD*)	3 months *M* (*SD*)	6 months *M* (*SD*)	*t**	*p*
Control group							
Problem-solving skills	0–40	223	26.22 (5.56)	26.35 (5.27)	-	–0.44	.660
Personal control	6–30	223	22.91 (4.04)	21.92 (4.16)	-	3.86	**.000**
Depression	0–21	221	3.43 (3.41)	-	3.53 (3.68)	2.05	**.042**
Fatigue	20–140	221	64.57 (27.86)	-	61.77 (28.15)	–0.59	.559
Intervention group							
Problem-solving skills	0–40	201	26.56 (4.85)	27.10 (4.93)	-	–1.78	.077
Personal control	6–30	202	23.17 (3.64)	23.25 (3.46)	-	–0.31	.756
Depression	0–21	188	3.45 (2.99)	-	2.82 (3.06)	4.22	**.000**
Fatigue	20–140	188	62.75 (25.62)	-	55.90 (26.72)	3.51	**.001**

* Mean difference tested using dependent *t*-test.

Mediated effects (AB)

When controlling for problem-solving skills and personal control, the direct effect (C’-path) of the intervention on depression decreased and was no longer statistically significant ($B = -0.39$, $SE = 0.24$, $p = .115$). The mediation model showed that 33% of the total effect of the intervention on depression was mediated ($B = -0.20$, $SE = 0.08$, 95% CI [–0.41, –0.07]). More specifically, 24% of the intervention effect on depression was mediated by personal control and 9% by problem-solving skills. The mediated effect of personal control was statistically significant ($B = -0.15$, $SE = 0.07$, 95% CI [–0.31, –0.05]); the mediated effect of problem-solving skills not ($B = -0.06$, $SE = 0.05$, 95% CI [–0.18, 0.01]).

Similar results occurred for the mediation model with fatigue as outcome. When controlling for problem-solving skills and personal control, the direct effect (C’-path) of the intervention on fatigue decreased and was no longer statistically significant ($B = -2.06$, $SE =$

1.96, $p = .291$). The mediation model showed that 43% of the total effect of the intervention on fatigue was mediated ($B = -1.67$, $SE = 0.60$, 95% CI [−3.04, −0.70]). More specifically, 40% of the intervention effect on fatigue was mediated by personal control and 3% by problem-solving skills. The mediated effect of personal control was statistically significant ($B = -1.54$, $SE = 0.56$, 95% CI [−2.87, −0.64]); the mediated effect of problem-solving skills not ($B = -0.13$, $SE = 0.19$, 95% CI [−0.78, 0.09]).

DISCUSSION

The current study investigated the mediating effects of problem-solving skills and personal control on depression and fatigue within a web-based computer-tailored intervention for cancer survivors. The results provide insight into what extent the effects of the KNW on depression and fatigue can be explained by changes in problem-solving skills and personal control. The results of the C-path showed that the intervention was effective in reducing depression and fatigue among cancer survivors. These results were similar as the results of the effect evaluation of the intervention on quality of life, depression, anxiety, and fatigue (Willems et al., 2017a) (see also Chapter 5). The results of the mediated effects will now be discussed in more detail.

Mediating effect of problem-solving skills

The results indicate that problem-solving skills did not mediate the intervention effects on depression and fatigue. The intervention was not effective in increasing problem-solving skills at 3 months after baseline (A-path). Further, while problem-solving skills at 3 months from baseline was negatively related to depression at 6 months from baseline, there was no association between problem-solving skills and fatigue at these time points (B-paths). As a result, only 9% of the intervention effect on depression and 3% of the intervention effect on fatigue was mediated by problem-solving skills.

That problem-solving skills did not mediate the intervention's effectiveness on depression and fatigue was unexpected. In particular, it was not expected that the KNW would not be effective in increasing problem-solving skills (A-path). Several therapist-guided interventions based on the principles of PST have been shown to be effective in increasing problem-solving skills in cancer patients (Mishel et al., 2002; Nezu et al., 2003). Warmerdam, van Straten, Jongsma, Twisk, and Cuijpers (2010) investigated whether the effect of depression reduction of a PST-based eHealth intervention with therapist support was mediated by problem-solving skills. The researchers found that only a negative problem orientation and avoidance style, both components of problem-solving skills, mediated the intervention's effectiveness.

There are several explanations why the current study found no mediating effect of problem-solving skills. First, problem-solving skills were measured with a 10-item version of the SPSI-R (Dreer et al., 2009). The reason for this was that, during pilot testing, we noticed that the 25-item version of the scale was fairly long and participants had difficulties getting through all of the questions. With the 10-item version being a more efficient way to measure problem-solving skills, it might be less sensitive in detecting changes in problem-solving skills over time (Dreer et al., 2009). Thus, while problem-solving skills might have been a significant mediator, the measurement instrument may have failed to detect this. Second, it is also conceivable that the intervention was not effective in changing problem-solving skills. A reason might be that the KNW was fully automated and there was no patient-therapist interaction. As a consequence, PST in the KNW was fairly directive. Participants could not define their own problems; the problem definition was based on their answers on the baseline questionnaire. Also, participants had to choose from a list of predefined goals and solutions. Participants were, however, able to personalize their selected goals and solutions. Thus, the personalized messages that can be provided with computer tailoring are limited to reactions that are highly expected (e.g., based on responses to multiple choice questions) (Willems et al., 2015). Another reason is that PST in the KNW was less intensive in comparison to face-to-face therapy. Participants were free to choose how much time whey would like to spend on the KNW. The developers of PST recommend that clients receive multiple sessions each focusing on one step of PST (D'Zurilla & Nezu, 2007). Within the KNW, participants were guided through the PST steps fairly quickly, and there was less room for participants to reflect on each step.

Mediating effect of personal control

In contrast to the results on problem-solving skills, personal control mediated both intervention effects of depression and fatigue. While personal control in the control group significantly decreased in the first 3 months after baseline, personal control within the intervention group did not change (A-path). Higher levels of personal control at 3 months from baseline were associated with lower levels of depression and fatigue at 6 months from baseline (B-paths). As a result, 24% of the effect on depression and 40% of the effect on fatigue was mediated by personal control. The results seem to indicate that the intervention contributes to maintaining perceived personal control over managing life after cancer.

These results support Leventhal's Common Sense Model (Hagger & Orbell, 2003; Leventhal et al., 1984) and provide new evidence of the importance of the mediating role of personal control. The importance of illness perceptions as mediators in interventions for cancer patients has been highlighted earlier (Stanton, Luecken, MacKinnon, & Thompson, 2013). While Traeger et al. (2013) found that several illness perceptions (i.e., treatment control and illness coherence) mediated the effect of improving emotional well-being in a CBT-based group intervention for cancer survivors, no mediating effect for personal control was found. The authors argue that this might be explained by their intervention mainly addressing distorted health beliefs and not explicitly targeting specific illness perceptions. Concerning interventions for other populations, Warmerdam et al. (2010) found that personal control was an important mediator in explaining the effect of both a CBT-based and PST-based eHealth intervention with therapist support in reducing depressive symptoms in the general population. Wiborg et al. (2012) found that personal control was an important mediator of the effectiveness of a CBT-based intervention aimed at reducing chronic fatigue in patients with chronic fatigue syndrome. One major limitation of the studies of Warmerdam et al. (2010) and Wiborg et al. (2012) was that the mediators and outcomes were measured at the same time-point, making it more difficult to make inferences about causality. Our current study replicated the importance of personal control in a longitudinal design, thereby strengthening the previous findings.

While the evidence of the mediating role of personal control in explaining intervention effectiveness is limited, the results suggest that targeting personal control in a stand-alone web-based self-management intervention is an important mechanism to increase health outcomes. More specifically, focusing on personal control might be particularly important for stand-alone (eHealth) interventions, which rely on the participant's level of control much more than therapist-led interventions do. It is, therefore, recommended that future research on the effectiveness of stand-alone self-management eHealth interventions also focus the working mechanisms of their intervention, in order to increase knowledge on this area.

Limitations

There are some limitations that should be noted. First, selective dropout might have influenced the results, in particular the higher dropout in the intervention group at 3 months (control 3.5%; intervention 12.1%) as well as 6 months (control 4.3%; intervention 18.6%) from baseline. This differential dropout is, however, common in trials for health behavioral change interventions, and might be explained by the intervention being experienced as too time intensive by some participants, or by the intervention not meeting the participant's expectations (Crutzen et al., 2015). Another explanation might be that the control group was more motivated to continue in the research, since they would receive access to the intervention after the last measurement. Fortunately, the dropout rates were low. With this low dropout rate and correction for the differences between completers and non-completers in the analyses, minimal influences of dropout effects may be expected. Second, since the KNW was developed to address the general population of cancer survivors, there was no preselection on the baseline levels of the intervention outcomes (Willems et al., 2015). As a result, participants at baseline scored relatively low on depression (Mitchell et al., 2013). Since the baseline level of distress influences intervention effectiveness (Schneider et al., 2010), greater effects could be expected when participants were doing less well in this area. This might also have had influence on the mediating effect of personal control on depression: there was more variation in experienced levels of fatigue than there was in depression, which was generally low. The mediating effect of personal control on fatigue was stronger than it was for depression (40% and 24%, respectively). It could, therefore, be expected that the mediating effect of personal control on depression might have been stronger when participants would have had, to some extent, higher baseline scores for depression. Third, women with breast cancer were overrepresented in the RCT and the intervention reached the older population to a lesser extent. This makes it more difficult to generalize the findings. This self-selection is, however, not uncommon: in general, females and low-risk individuals are more prone to participate in online interventions (Kohl et al., 2013) and younger cancer survivors are more likely to use the Internet for health-related information (Chou et al., 2011). Finally, as mentioned earlier, we used an adapted version of the SPSI-R (Dreer et al., 2009), while a more extensive measure of problem-solving skills would be preferred.

CONCLUSION

The KNW is developed as a self-management tool for initial support for psychosocial problems that are present after cancer treatment. While previous research showed that the KNW was effective in increasing psychosocial well-being (Willems et al., 2017a), the current study further supports this by showing that perceived personal control in managing recovery after cancer is an important mediator in explaining the intervention effects on depression and fatigue. The role of problem-solving skills serving as mediator is unclear. The results support the function of the KNW as being developed as a self-management tool and provide evidence for the importance of addressing personal control in (web-based) self-management interventions.

General discussion

8

The aim of this thesis was to systematically develop and evaluate a theory- and evidence-based self-management intervention for cancer survivors within the first year after cancer treatment – the *Kanker Nazorg Wijzer* (Cancer Aftercare Guide; KNW). The first part of the thesis comprised the development of the intervention, in which information and support needs among cancer survivors within the first year after cancer treatment were investigated, and a detailed description of the systematic development of the intervention was provided. In the second part, the use and appreciation of the intervention was described. In the third part, the evaluation of the effectiveness of the intervention on quality of life, anxiety, depression, and fatigue was described, and the working mechanisms of the intervention were investigated. In this general discussion, an overview of the previous chapters is provided, in which (a) the main findings of the research project are discussed, (b) the strengths and limitations are considered, and (c) recommendations are given for research and practice. The chapter ends with a general conclusion.

MAIN FINDINGS AND DISCUSSION

Development of the intervention

Before developing an online self-management intervention to provide cancer survivors with tailored information and support, it is important to investigate what kind of information and support needs cancer survivors have. In a survey, we explored cancer survivors' unmet needs by investigating (a) to what extent cancer survivors experience unmet needs (the necessity of developing the intervention), (b) what the most prominent needs are (determining the content of the intervention), and (c) to what extent these needs differ among patient characteristics (determining the extent to which information needs to be tailored) (**Chapter 2**). The results showed that the majority of cancer survivors experience one or more unmet needs. The most frequently reported unmet needs comprised of receiving emotional and social support, managing side effects or complications, dealing with fear of recurrence, receiving adequate cancer care and up-to-date information, and carrying out work. These results substantiate the relevance of developing an intervention providing cancer survivors with information and support to address their needs. In addition, the results showed that the experienced needs varied greatly among cancer survivors, indicating that tailoring can serve as a relevant method for information provision.

The Intervention Mapping protocol (Bartholomew et al., 2016) was used to develop the KNW and is considered to be a very useful tool for intervention development (**Chapter 3**). By means of a needs assessment, consisting of focus groups and a survey study, cancer survivors' most prominent health problems and their impact on quality of life were investigated. The health issues revealed from the needs assessment were translated into seven self-management training modules, discussing the topics fatigue, return to work, anxiety and depression, social relationship and intimacy issues, physical activity, diet, and smoking cessation. In an eighth module, general information on the most common residual symptoms was provided. While multiple methods for behavioral change were used in the intervention, two methods formed the core of the KNW: *skills training for self-management* and *tailoring* of information. To effectively train self-management skills, several evidence-based approaches were integrated into the intervention. First, all modules were structured according to the principles of problem-solving therapy (PST) (D'Zurilla & Nezu, 2007). Second, elements of cognitive behavioral therapy (CBT) (Beck, 2011) were implemented in the modules covering problems which have strong psychosocial components (i.e., fatigue, anxiety and depression, return to work, and social relationships). The modules covering lifestyle behaviors (i.e., physical activity, diet, and smoking) made use of several social cognitive theories and self-regulation theories to change the behavioral determinants (Baumeister et al., 1994; de Vries et al., 2003). With the intervention covering such a wide range of topics, we considered a tailored approach to be an essential method for information provision, as it omits redundant information and facilitates behavioral change (Brug et al., 2003; de Vries & Brug, 1999; Noar et al., 2007; Rimal & Adkins, 2003).

Evaluation of the intervention

To evaluate the process (i.e., program use and appreciation) and effectiveness of the KNW, we conducted a randomized controlled trial (RCT), in which the intervention group was compared with a waiting list control group (**Chapters 4–6**). This thesis focused on the evaluation of the intervention's effectiveness in improving psychosocial well-being. More specifically, it was investigated whether the KNW was effective in increasing quality of life and reducing anxiety, depression, and fatigue. Intervention effectiveness on lifestyle-related outcomes has been published elsewhere (Kanera et al., 2016b; Kanera et al., 2017).

Use and appreciation

One of the main components of the intervention was the tailored advice referring participants to the intervention modules that best suited the participants' needs (**Chapter 4**). The results showed that 74.9% of the participants received at least one "red" and 83.1% at least one "orange" module referral advice, with an average of three module referrals. Participants visited two modules on average, with 85.7% percent of the participants visiting at least one module. Visitor rate per module was: Diet 58.0%, Fatigue 35.5%, Return to Work 22.9%, Physical Activity 22.1%, Mood (anxiety and depression) 21.2%, Residual Symptoms 20.4%, Relationships 16.5%, and Smoking 10.0%. Participants were more likely to visit a module when they were advised to visit that module. That is, 41.3% and 42.5% of the participants visited a module after having received a "red" or "orange" advice, respectively, while 17.3% visited a module after having received a "green" advice. These results indicate that, in general, the referral advice worked well and might be a meaningful intervention component to guide users in selecting the modules that are most personally relevant. It is suggested from theory that the inclusion of a module referral advice within a self-management intervention might increase knowledge, motivation, awareness, and risk perception, facilitating behavioral change (de Vries et al., 2003; Walthouwer et al., 2015a; Weinstein & Sandman, 1992).

The KNW in general, as well as the individual modules, were highly appreciated. Greater perceived personal relevance of the KNW was associated with a higher appreciation of the KNW. While participants visited two modules on average, using more modules did not lead to higher appreciation of the intervention. Possibly, using a high number of modules could make the intervention too demanding or could lead to therapy saturation and, therefore, might not lead to better health outcomes and intervention appreciation (Donkin et al., 2013; Wilson et al., 2015). Further, the KNW was programmed as an open and unrestricted program, in which participants were (despite the provided module referral advice) free to visit all the modules they pleased. It is suggested that providing such an open structure might have led to higher user satisfaction and might have prevented high attrition rates (Brouwer et al., 2010; Kwak et al., 2010; Schulz et al., 2012). For the participants who did not visit any modules (14%), providing only an indication of risk areas (as was done by the module referral advice) might already have been beneficial for them by making them more aware of their situation and providing cues to action. This suggestion might be reflected by the fact that even among the non-module users the appreciation of the KNW was high.

Effectiveness in changing quality of life, anxiety, depression, and fatigue

The effectiveness of the KNW was evaluated by means of an RCT, comparing an intervention group with a waiting list control group. The evaluation of the short-term effectiveness of the intervention on quality of life, anxiety, depression, and fatigue (**Chapter 5**), showed that, at 6 months from baseline (directly after intervention closure), the intervention group scored significantly higher on emotional functioning ($d = 0.15$) and social functioning ($d = 0.15$) and lower on depression ($d = 0.21$) and fatigue ($d = 0.21$) than the control group. Intention-to-treat analyses confirmed the results for the effects on depression and fatigue, but not for the effects on emotional and social functioning. In addition, it was investigated how module use influenced these results. The most important finding was that that the effect size for fatigue was much higher for participants who used the Fatigue module ($d_{change} = 0.37$) than those who did not use this module ($d_{change} = 0.03$). It should be noted that the participants who used the Fatigue module experienced significantly higher levels of fatigue than participants who did not use this module. This is not surprising, since those who were referred to the Fatigue module were more likely to visit this module (58.8% and 38.6% of those who received a "red" and "orange" advice, respectively) than those who did not receive a referral advice (16.8%) (see **Chapter 4**). These findings suggest that the Fatigue module was used by those who needed it most and was effective in reducing fatigue.

Then, it was evaluated whether the significant short-term effects of emotional and social functioning, depression, and fatigue remained in the long term (i.e., 12 months after baseline) (**Chapter 6**). The significant increase in emotional and social functioning and decrease in depression and fatigue at 6 months from baseline within the intervention group remained fairly stable between 6 and 12 months after baseline. This is considered as a positive outcome, since the intervention group had not fallen back to their baseline levels of these health outcomes 6 months after the intervention's closure. The control group, however, slowly improved over the trial period, leading to non-significant differences in the health outcomes between the intervention and control group in the long term. Intention-to-treat analyses confirmed these results. Thus, while in the long term, levels of emotional and social functioning, depression, and fatigue between the intervention group and control group did not differ significantly anymore, the results suggest that the intervention group benefitted from an extra, earlier period of improved health. Concerning differences in effects among the participant subgroups, evidence was found that the short-term effects on depression and fatigue were moderated by participants' characteristics.

With little evidence on the benefits of eHealth interventions for cancer survivors being available (McAlpine et al., 2015), the results of the evaluation of the KNW contribute to this field of research by suggesting that a web-based computer-tailored self-management intervention for cancer survivors has beneficial effects in improving well-being in the short term and gives cancer survivors a head start in cancer recovery. Effect sizes for the short-term effects were small, but comparable to other eHealth interventions addressing depression without therapist support in the general population (d = 0.22) (Spek et al., 2007) or with therapist support for patients with somatic conditions (d = 0.21) (van Beugen et al., 2014), and comparable to educational interventions addressing cancer-related fatigue (d = 0.27) (Bennett et al., 2016; Du et al., 2015). The results are also similar to two eHealth interventions specifically developed for cancer survivors. A fully automated non-tailored CBT-based intervention for breast cancer developed by van den Berg et al. (2015) was, amongst others, effective in reducing psychological distress (combined anxiety and depression score; d = 0.37) and fatigue (d = 0.33) directly after intervention closure (i.e., 4 months after baseline); a tailored education program for survivors with cancer-related fatigue developed by Yun et al. (2012) was effective in, amongst others, reducing fatigue (d = 0.29) and anxiety (d = 0.33), and improving quality of life (d = 0.26) after intervention closure (i.e., 12 weeks after baseline). The difference in effect size between these interventions and the KNW can be explained by these interventions being developed for specific populations of cancer survivors: van den Berg et al. (2015) focused on problems specific to breast cancer patients, while Yun et al. (2012) preselected participants on a moderate to high baseline level of fatigue. Since the KNW was developed for the general population of cancer survivors, there was no preselection based on patient characteristics. However, as discussed earlier, we found that the effect size for fatigue was almost twice as high for those who used the Fatigue module ($d_{change} = 0.37$) in comparison to the complete sample ($d = 0.21$). This is partly attributable to the finding that this (self-selected) group was significantly more fatigued and therefore had more room for improvement. This effect might therefore be better comparable with the intervention effect on fatigue found by Yun et al. (2012). Further, only the study by van den Berg et al. (2015) investigated the long-term effectiveness of their intervention (i.e., 6 months after intervention closure). In general, the pattern of results was similar to the results of the KNW: the control group showed a natural recovery in the health outcomes, which resulted in non-significant differences between both groups in the long term.

That we found both an effect for depression and fatigue is in line with our expectations, since these two concepts are highly interrelated (Brown & Kroenke, 2009; Moss-Morris & Petrie, 2001). In fact, methods used for the treatment of fatigue, such as CBT for insomnia, are often also used to treat depression (Smith, Huang, & Manber, 2005). Next to fatigue, lack of physical activity and an unhealthy diet might also explain feelings of depression (Lopresti, Hood, & Drummond, 2013). Thus, the effects on depression might also be influenced by the modules addressing cancer-related fatigue, physical activity, and diet. This idea is supported by the results of the evaluation of the short-term effectiveness showing that the effect on depression was significant for those who did not use the Mood module. While the KNW was effective in reducing depression, no effects were found for anxiety, which was unexpected. Both anxiety and depression were addressed in the Mood module by challenging intrusive thoughts, dealing with rumination, planning pleasant activities, and relaxation exercises. Participants had to write down their own anxious or depressing thoughts and then received structured advice on how to change these unhelpful thoughts into helpful thoughts or how to avoid ruminating. This approach most likely worked for addressing depression, but might not have been sufficient to address anxiety. A first reason might be that anxiety disorders take several forms, such as generalized anxiety disorder, specific phobias, panic disorder, or adjustment disorder (Brown et al., 2010; Stark et al., 2002). The Mood module might not have distinguished well enough between these different types of anxiety, and, therefore, the provided advice might not have been specific enough to change anxiety levels. A suggestion for future development would be to not discuss anxiety in general, but to provide specific information and support to a highly prevalent perceived threat, such as fear of cancer recurrence. Second, an important aspect of treating anxiety is to improve the risk assessment of situations the patient fears (Beck, 2011). The KNW did not provide any information on risk assessment, since it is challenging to provide reliable information through a fully automated intervention on whether a particular perceived risk is functional or not.

While we found that the KNW was effective in increasing emotional and social functioning, both components of quality of life, we found no intervention effect of the KNW in improving overall quality of life (i.e., global health status). This absence of an overall effect might be explained by a response shift among participants, which involves changing internal standards, values, and the conceptualization of quality of life as a consequence of being confronted with a life-threatening disease (Schwartz & Sprangers, 1999; Sprangers & Schwartz, 1999). Thus, cancer survivors may, as a consequence of their illness, have downgraded their life goals to more attainable goals (von Blanckenburg et al., 2014). By doing so, experienced quality of life remains stable. A second explanation might be that participants in our study sample scored fairly well on overall quality of life (see "Strengths and limitations" in this chapter). Thus, there might have been too little room for improvement within the study sample to find an effect on overall quality of life.

Effect of the intervention in subgroups

To gain insight into whether patient characteristics influenced the intervention effects, moderator analyses were conducted (**Chapter 6**). More specifically, it was investigated whether gender, age, educational level, and treatment type moderated the intervention effects of emotional and social functioning, depression, and fatigue at the short and the long term. The results of these complete case analyses indicated that, at 6 months from baseline, the intervention was effective in improving social functioning for men ($d = 0.34$), reducing fatigue for those aged 56 and younger ($d = 0.44$), and reducing depression for participants who received chemotherapy ($d = 0.36$). At 12 months, participants with a medium educational level reported higher social functioning ($d = 0.19$), while participants with a low educational level reported lower social functioning ($d = 0.22$) than participants with a similar educational level in the control group.

A first explanation for the subgroup effect concerning fatigue might be that the prognosis for older patients experiencing fatigue is worse than for younger patients, and the KNW could not offer sufficient support for the older population. However, evidence for this suggestion is mixed (Cairns & Hotopf, 2005). A second explanation could concern differences in coping strategies among older and younger cancer survivors. That is, younger survivors might be more proactive in addressing their experienced problems, while older survivors might be more accepting of their physical decline (Derks et al., 2005; Mao et al., 2007). Finally, it could also be that older patients have fewer computer skills (AGE Platform Europe, 2008) and therefore were less active in the KNW. However, if that was the case, we then would have expected that age would also be a moderator for the other intervention effects, but no clear evidence was found for this suggestion. In addition, age was not associated with the number of modules used, perceived personal relevance, or appreciation of the intervention (see **Chapter 4**). Concerning the finding that the KNW was more effective in reducing depression for participants who received chemotherapy, previous research suggests that patients who have received chemotherapy might be more at risk of developing depressive symptoms (de Jong et al., 2002; Fann et al., 2008). Thus, survivors who had received chemotherapy might have had stronger needs in receiving advice on how to address depressive feelings, and the KNW thus better supported this group in this area. It should be noted that, while almost significant, no intervention effect for depression was found for participants who received both chemotherapy and radiotherapy with or without surgery. Possibly, a light intervention as KNW might not be powerful enough to adequately address stronger feelings of depression in some of those who received the heaviest and most intrusive cancer treatment. An explanation for the finding that the KNW was more effective in improving social functioning amongst men could be that men, in general, primarily find support in their partner when dealing with cancer-related distress, while women often rely on a broader social support network of family, friends, and their partner (Harrison et al., 1995). Possibly, the advice provided within the KNW on dealing with social relationships was less suitable for dealing with more complex social relationship structures (in which more people are involved) and, therefore, had a better fit with men's needs.

The finding that, in the long term, participants with a medium educational level reported higher social functioning and participants with a low educational level reported lower social functioning than participants with a similar educational level in the control group might be explained as follows: detailed data-inspection showed a natural recovery over time for participants with a low educational level in the control group; the participants in the intervention group with a low educational level also increased in social functioning 6 months from baseline, but showed a small drop at 12 months from baseline. Thus, participants with a low educational level in the intervention group did not score lower on social functioning in the long term in comparison to baseline. Instead, the control group improved more in social functioning than the intervention group did. Therefore, the intervention is not considered effective in increasing (or decreasing) social functioning for participants with a low educational level. For participants with a medium educational level, the mean scores suggest that the intervention group improved in social functioning at 6 months from baseline and that this effect remained in the long term. The control group did not improve over time. Therefore, the intervention is considered effective in improving social functioning for participants with a medium educational level.

Working mechanisms of the intervention

Finally, the mechanisms hypothesized to explain the short-term effects of the KNW on depression and fatigue were investigated (**Chapter 7**). With the KNW being a self-management tool based on principles of PST and CBT, we expected that the intervention would increase problem-solving skills and perceived personal control in cancer recovery (measured at 3 months from baseline), which in turn would decrease depression and fatigue (measured at 6 months from baseline). The results of the mediation analyses showed that personal control partially mediated the intervention effects of depression (24%) and fatigue (40%); no mediating effects of problem-solving skills were found.

The finding that problem-solving skills did not mediate the intervention effect on depression and fatigue was not in line with our hypothesis. There are, however, several possible reasons why there was no mediating effect. First, we used the 10-item version of the Social Problem-Solving Inventory–Revised (SPSI-R) (Dreer et al., 2009). To our knowledge, no other studies have used this version of the SPSI-R to evaluate the mediating intervention effects. The reason for our choice was that, during pilot testing, we noticed that the 25-item version of the scale was too demanding for participants, especially since this scale was part of a much larger battery of tests. While the 10-item version of the questionnaire might be more efficient to use, it might also be less sensitive in detecting changes in problem-solving skills (Dreer et al., 2009). Second, problem-solving skills consists of five components, which are positive problem orientation, rational problem solving, negative problem orientation, impulsivity/carelessness, and avoidance. In our study, we measured problem-solving skills with a total score. It could be that some of the components of problem-solving skills would mediate the intervention's effectiveness, but that these effects were not found due to the choice of measure. For example, in a study by Warmerdam et al. (2010), the researchers found that the effectiveness of a PST-based eHealth intervention with therapist support in reducing depression was partially explained by a reduction in negative problem orientation and avoidance style. A third reason might be that the KNW simply was not effective in changing problem-solving skills. The KNW was fully automated and there was no patient-therapist interaction. As a consequence, the use of PST in the KNW was fairly directive. Participants could not define their own problems; the problem definition was based on their answers on the baseline questionnaire. Also, participants had to choose from a list of predefined goals and solutions. Participants were, however, able to personalize their selected goals and solutions. The feedback messages were thus limited to responses to fixed answers or reactions and emotions that were highly expected, which is a consequence of providing automated tailored feedback. In addition, the KNW was also less intensive in comparison to face-to-face therapy. While the developers of PST recommend that clients receive multiple sessions, each focusing on one step of PST (D'Zurilla & Nezu, 2007), participants of the KNW were free to choose when and for how long they wanted to use the intervention. Thus, for the KNW to be effective in increasing problem-solving skills, a more in-depth or intensive approach might be necessary (e.g., a blended eHealth intervention with therapist support). A disadvantage of such an approach would be that the intervention would be less flexible and costlier.

An important finding was that the effects of depression and fatigue were partly mediated by perceived personal control in managing cancer recovery. More specifically, this mediating effect of personal control on depression and fatigue was not explained by a significant increase of personal control in the intervention group, but by a decrease of personal control in the control group, suggesting that the intervention helped to prevent a naturally occurring decline in personal control in managing cancer recovery. These results provide new evidence of the importance of supporting patients in maintaining or increasing personal control in eHealth interventions (Stanton et al., 2013). Mediation analyses of two other self-management interventions, an eHealth intervention for the general population aimed at reducing depression (Warmerdam et al., 2010), and a guided self-instruction intervention for patients with chronic fatigue syndrome (Knoop, van der Meer, & Bleijenberg, 2008; Wiborg et al., 2012) also found that personal control was an important mediator in explaining intervention effectiveness. A major limitation of both studies is that the mediators and outcomes were measured at the same time-point, making it more difficult to make inferences about causality. The study in **Chapter 7** provided new evidence for the importance of personal control in a longitudinal design, thereby strengthening the previous findings. The results suggest that targeting personal control in a stand-alone web-based self-management intervention may be an important mechanism to increase health-related outcomes. Moreover, the results support the function of the KNW as being developed as a self-management tool for initial support for the psychosocial problems that are present after cancer treatment.

STRENGTHS AND LIMITATIONS

The results of the studies conducted within this thesis should be interpreted bearing in mind the strengths and limitations of these studies. The current section discusses these strong and weak points concerning the intervention, study design, study population, and measurements, with a primary focus on studies describing the RCT (**Chapters 4–7**).

Intervention

The innovative nature of the KNW is considered to be an important strength of the intervention. To our knowledge, the KNW is the first web-based intervention specifically designed for early cancer survivors that addresses multiple psychosocial as well as lifestyle-related problems. While this broad approach was chosen, implementing computer-tailored advice ensured that only personally relevant information, aimed at targeting the participants' specific needs, was provided. It is suggested that providing such tailored information improves information processing and facilitates behavior change (Brug et al., 2003; de Vries & Brug, 1999; Noar et al., 2007; Rimal & Adkins, 2003). In addition, the video material that accompanied the tailored information might also increase the likelihood that the information is remembered and recalled (Bol et al., 2013; Idriss et al., 2009). Next, the KNW was systematically developed using the Intervention Mapping protocol (Bartholomew et al., 2016). Using such an theory- and evidence-based approach for intervention development increases the likelihood of intervention effectiveness (Bartholomew et al., 2016). The protocol helps to select evidence-based methods that best fit the goal of the specific intervention being developed. For the KNW, PST (D'Zurilla & Nezu, 2007; Nezu et al., 1999) and CBT (Beck, 2011; Gielissen, 2007) were selected as the primary methods for improving self-management skills among cancer survivors in order to deal more effectively with their cancer-related problems. Finally, since the intervention is a fully automated stand-alone intervention (i.e., there is no face-to-face support), a strong point is that standardized care can be more effectively implemented (Patrick & Canevello, 2011; Tate & Zabinski, 2004). The KNW is easy to implement at low costs, can reach many patients at once, and is accessible anytime and anywhere (Leykin et al., 2012; Lustria et al., 2009; Tate & Zabinski, 2004).

However, there are also some limitations in the intervention design. First, while not including face-to-face support has advantages in the implementation and dissemination of the intervention, it also has its disadvantages. Except by self-report, it is difficult to monitor whether the learned skills are implemented effectively and to correct them if needed (Finfgeld, 1999). In addition, fully automated interventions are based on a limited number of circumstances and responses and, therefore, might not address all concerns experienced by participants (Tate & Zabinski, 2004). It is not always possible to anticipate the (unexpected) emotions and non-verbal behavior of the participant or to give further explanation on why certain advice is given. Second, while a greater proportion of cancer survivors are elderly (Dutch Cancer Society, 2011), this group in general has fewer computer skills (AGE Platform Europe, 2008) and is less likely to use the Internet as a source of health-related information than younger cancer survivors (Chou et al., 2011). To anticipate this problem, the KNW was developed in such way that it was relatively easy to use (**Chapter 3**). Still, the demographics of the baseline measurement showed that the participants were relatively young (see "Recruitment of participants" in this chapter). Finally, while it is argued that the module referral advice is an effective way to stimulate module use among users (**Chapter 4**), the actual use of the modules, after being referred to them, was somewhat lower than expected. It is unclear whether this had to do with the participants' engagement in the intervention or the intervention design (e.g., the content of the advice in the module referral advice).

Study design

One of the most important strengths of the study design was that the effectiveness of the intervention was evaluated in an RCT. This is considered to be the most appropriate design in the evaluation of healthcare interventions, since it minimizes systematic selection and reduces the plausibility of alternative explanations (Flay et al., 2005; Schulz, Altman, Moher, & Group, 2010). Second, there was no preselection on the baseline levels of the intervention outcomes. Thus, all cancer survivors could participate, regardless of their level of well-being. Having no preselection is a strong point from an ethical perspective, since no cancer survivors were excluded and thus had equal opportunity to receive the cancer aftercare provided by this intervention. In addition, by not preselecting participants, the results of the evaluation of the intervention provide a more realistic picture of the effectiveness of the intervention when implemented in practice. Third, measurements were taken at multiple time points (i.e., baseline, and 3, 6 and 12 months after baseline) and user data was collected, enabling us to provide a detailed description of the intervention's effectiveness. More specifically, next to the evaluation of the short-term effectiveness (i.e., the effect evaluation directly after intervention closure), the long-term effectiveness of the KNW was investigated by including a measurement 6 months after intervention closure (12 months after baseline), providing detailed information on how the effects change over time (Flay et al., 2005); working mechanisms were investigated by measuring hypothesized mediators at 3 months from baseline; and further in-depth insight into the intervention's effectiveness was provided by investigating differences in intervention effectiveness by means of subgroup analyses and by investigating the use and appreciation of the intervention. Fourth, for the evaluation of the intervention's effectiveness, the most advanced statistical techniques were used. The main effects (**Chapters 5 & 6**) were evaluated using multilevel analyses. The results were then verified with intention-to-treat analyses. Furthermore, the analyses were corrected for multiple testing using the false discovery rate approach (Benjamini & Yekutieli, 2001). For the evaluation of the mediating effects (**Chapter 7**), Hayes' PROCESS macro was used (Hayes, 2013). Finally, with respect to the moderator analyses (**Chapter 6**), determining the cut-off scores of a significant continuous by categorical interaction was done by means of margin plots. These provide much more reliable results in exploring the subgroup effects than the use of more conventional methods such as median split.

Although we aimed to make the study design as strong as possible, some limitations should be mentioned. First, the use of a waiting list control group can have an important disadvantage. That is, this group might become less proactive in changing their behavior than they would have been if they had not expected to receive treatment (Cunningham, Kypri, & McCambridge, 2013; Furukawa et al., 2014). This could lead to an overestimation of the intervention effects. Therefore, during participant recruitment, we explicitly informed potential participants that they were free to use any other form of support during the trial period, regardless of the group they would be assigned to. As demonstrated in **Chapter 7**, allowing both groups to use any other type of cancer aftercare during the trial period did not lead to between-group differences in the use of aftercare. Therefore, it is assumed that the control group was not passive in waiting for support and the influence of this bias is very limited to non-existent. Second, the data was collected through self-report questionnaires, which might have led to recall bias or socially desirable answers. However, these effects would be expected in both the interventions and control condition. Third, while the intervention developed and intervention components were selected based on theory and literature, it is difficult to draw any conclusions about which interventions components explained the intervention's effectiveness. Thus, in order to remove ineffective components and make the intervention more compact, additional research should be conducted where the influence of separate components on intervention effectiveness is investigated. Likewise, by offering multiple modules at once, it is also more difficult to determine how individual modules contribute to the intervention effects. Fourth, anxiety, depression, fatigue, and quality of life were measured at the same time points. However, models for intervention development and quality of life assume that experienced health problems precede quality of life (Bartholomew et al., 2016; Cella, 1994; Green & Kreuter, 2005) (see also Chapter 1). Thus, by addressing the health problems, quality of life will eventually improve. For the evaluation of the intervention we were primarily interested in whether the intervention would be effective in improving the health outcomes (i.e., anxiety, depression, and fatigue) as well as improving quality of life in the short and the long term, and, therefore, we measured them at the same time points. As a consequence, it could not be evaluated whether improvement in health outcomes during intervention usage led to an increase in quality of life after intervention usage. The reason for this choice was that we were more interested in proposed working mechanisms of the in the KNW incorporated behavioral change techniques on the health outcomes (see **Chapter 7**), and adding an additional measure would be too demanding for the participants. However, it could still be evaluated whether the health problems at 6 months from baseline mediate the effect on quality of life at 12 months from baseline. This is a suggestion for future research.

Study population

An important strength was that we managed to recruit a high number of cancer survivors both for the needs assessment study (*n* = 255) (**Chapter 2**) as well as the studies conducted within the RCT (*n* = 462) (**Chapters 4–7**), even with the specific inclusion criteria that were set. The successful inclusion of sufficient participants can be attributed to the structured recruitment strategy that was set up. Although the inclusion of a high number of participants strengthens the study results, the possibility of selection bias and dropout effects were important limitations for the interpretation of the results. This will now be discussed in more detail.

Recruitment of hospitals

For both the needs assessment study as well as the RCT, participants were recruited by staff members of multiple hospitals across the Netherlands (e.g., oncologists, research nurses, and nurse practitioners). For the needs assessment study, staff members of eight different hospitals participated in the recruitment procedure; for the RCT, staff members of 21 hospitals participated. In order to get this number of hospitals involved in the studies, we created a network of representatives (e.g., department heads, oncologists, research nurses, and nurse practitioners) from multiple hospitals' outpatient clinics in internal medicine, oncology, gynecology, urology, and breast clinics across 45 hospitals. These representatives were contacted ahead of time, for the RCT often more than half a year before the start of the trial. This time was definitely needed in order to discuss participation in the study with the representative and to make appropriate preparations for the staff members to efficiently recruit the participants.

During the recruitment of the hospitals, much time was invested in getting the representatives of the hospitals interested and keeping them informed on the progress of the project. Every hospital initially interested in the project was visited by the researchers at least once for a project presentation or discussion. When a hospital representative decided not to participate in the study, the representative was asked for their reasons for the rejection. Important reasons not to participate in the recruitment of participants were, amongst others, participation in other research projects, lack of time or excessive workload, insufficient staff members to set up the recruitment, or insufficient potential participants. For the hospitals that did participate in the recruitment of study participant, maintaining contact with these hospitals required good planning. Several strategies were used to keep hospitals involved, such as updates on the project and the recruitment by means of monthly newsletters and occasional "thank you" cards. Lessons learned from the recruitment was that timely planning of program adoption and continued attention during implementation is essential for successful intervention implementation (Bartholomew et al., 2016).

Recruitment of participants

In total, staff members from the participating hospitals invited 1303 cancer survivors to participate in the RCT, of which eventually 462 survivors filled in the informed consent form and the baseline questionnaire, and met the inclusion criteria. This provided us with sufficient power to analyze whether the intervention group, after intervention closure, improved more on the targeted health outcomes compared to the control group (**Chapter 3**). While we believe that setting up the recruitment strategy through the hospitals was the best way to get access to a large number of participants who fit the specific inclusion criteria, this strategy also had its disadvantages. The most important disadvantage was loss of control in recruiting a representative sample of cancer survivors, which might have led to *selection bias*. A great deal of effort was put into recruiting hospital staff working at different clinics, so survivors of different types of cancer would be recruited. The sample that was eventually included in the data analyses for a larger part consisted of women with breast cancer (70%), was relatively young (M_{age} = 55.9 years), and scored fairly well on quality of life and low on depression. The overrepresentation of breast cancer patients, females, younger participants, and participants scoring fairly well in well-being for online interventions has been reported earlier (Brouwer et al., 2010; Hong, Peña-Purcell, & Ory, 2012; Kohl et al., 2013). A first explanation for the selection bias is that women and more healthy individuals in general are more interested in health-related (internet) interventions (Brouwer et al., 2010). Second, while breast cancer is the most common form of cancer (28.1% of women) and this cancer type has a good overall prognosis (The Netherlands Cancer Registry, 2017), the number of former breast cancer patients that participated in the study was still higher than expected. Possibly, breast cancer patients were more accessible for the hospital staff to recruit, since breast cancer care, in general, is well organized in Dutch hospitals. A final explanation might be that hospital staff were selective in recruiting patients, by expecting that particular patients (e.g., the elderly) might not be interested in participating in the study. Since a specific group of cancer survivors is overrepresented in the study sample, it is more difficult to generalize the results of the intervention effectiveness to the general population of cancer survivors. This might have implications for the external validity of the results: when implemented in practice, this could mean that the intervention (a) primarily attracts relatively young women who have had breast cancer, and (b) is less or not effective for the older population.

While the study population scored fairly well on quality of life and low on depression, the results still showed that the intervention was effective in improving aspects of quality of life and reducing depression. It could, however, be expected that these effects would be stronger when the participants in the RCT would score less well on these health outcomes, because they would have had more room for improvement (Faller et al., 2013; Schneider et al., 2010). As explained earlier, the KNW was developed for the general population of cancer survivors by addressing multiple frequently occurring health-related problems. Therefore, there was no preselection on the baseline levels of the targeted health outcomes. By means of moderator analyses, it could be evaluated whether the intervention is more effective for those who score less well on the health outcomes. Unfortunately, since there was little variation in the baseline score of these health outcomes within the current study sample, moderation analyses would provide unreliable results. We did, however, find an indication that those who followed the Fatigue module scored significantly higher on fatigue than those who did not use this module, and only this group reported a significant decrease in fatigue 6 months after baseline (see **Chapter 5**). It should be noted that these analyses were not moderator analyses, since these groups were compared to the complete control group (in the control group, no distinction could be made between those who followed a particular module or not, since they received no intervention). Therefore, by collecting additional data, future research should adequately investigate how the effects of the KNW differ between groups with more or less experienced problems.

A final notion that should be made on the study sample is that participants were eligible for participation only if they had completed primary treatment for at least 4 weeks, but for no more than 56 weeks. In this period, cancers survivors' distress is particularly high (Hinnen et al., 2008). However, it can be expected that the intervention might have had different effects for those who started immediately after finishing primary treatment versus those who started one year after their primary treatment had finished. Thus, those who scored highest in distress during the intervention period may benefit more from the intervention than those who may already be over the peak of their distress. Future research should investigate whether this suggestion is supported by data.

Dropout

A strong point of the RCT was that, in comparison to other eHealth trials (Christensen et al., 2009; Reinwand et al., 2015a), the dropout rate at the three follow-up measures was fairly low: 7.8%, 11.5%, and 17.5% at 3, 6, and 12 months from baseline, respectively. Several reasons could explain this low attrition rate. First, participants were frequently reminded by automated e-mail reminders to fill in the questionnaire (Nakash, Hutton, Jorstad-Stein, Gates, & Lamb, 2006; Schneider, de Vries, Candel, van de Kar, & van Osch, 2013). Second, e-mails included personalized salutations, which has been shown to be effective in increasing response rates (Short, Rebar, & Vandelanotte, 2015b). Third, with telephone contact being an effective strategy in increasing response rate (Nakash et al., 2006), participants were asked during the baseline questionnaire to fill in their phone number so they could be contacted for research purposes. While participants were free (and this was explicitly stated) not to provide this information, most participants did. When participants who provided their contact details did not fill in a questionnaire, they were contacted to ask them whether they received the reminders, were willing to fill in the questionnaire, or wanted to withdraw from the study. Most participants, however, wanted to continue participating. A final reason for the low dropout rate might be that the target group for this intervention, cancer survivors, experience more problems and may be more motivated to change their behavior than in interventions in which healthy individuals are encouraged to change their behavior. That is, the cancer experience might have served as a teachable moment in which the KNW facilitated behavioral change (Bluethmann et al., 2015).

Still, the dropout rate might have had an influence on the results. First, while the appreciation of the intervention was high (**Chapter 4**), it might be a little overestimated, since participants who did not like the intervention or for whom the intervention was not helpful might be more likely to drop out. Since these results were descriptive, it was not possible to control these results for dropout influence. Next, the RCT was subject to selective dropout. The dropout analyses of all three studies conducted within the RCT (**Chapters 5–7**) showed that participants in the intervention group were more likely to drop out 3 months (control 3.5%; intervention 12.1%), 6 months (control 4.3%; intervention 18.6%), and 12 months (control 8.2%; intervention 26.8%) from baseline. Long-term discontinuation of eHealth and health behavioral change interventions is a widely recognized phenomenon, and might be explained by the intervention being experienced as too time intensive by some participants, or by the intervention not meeting the participant's expectations (Crutzen et al., 2015; Eysenbach, 2005; Kohl et al., 2013). Another explanation is that the intervention group received all the information and support they needed and then decided to discontinue their participation in the research project; that is, they reached a point of therapy saturation (Donkin et al., 2013). This idea is supported by the finding that 83.9% of the participants in the intervention group used a module for the last time within 18 weeks of their first login during the 26 weeks that the program was available (see **Chapter 5**). Finally, it also might be that the control group was more motivated to continue in the research, since they would receive access to the intervention after the last measurement.

Since the dropout rate was low and the analyses were corrected for differences between completers and non-completers, minimal influences of dropout effects may be expected. In addition, intention-to-treat analyses were conducted to verify the results of the mixed models (Armijo-Olivo, Warren, & Magee, 2013) (**Chapters 5 & 6**). Both approaches showed significant effects on depression and fatigue in the short term, but the intention-to-treat analyses failed to find effects on emotional and social functioning (**Chapter 6**). This does not mean, however, that there were no effects on emotional and social functioning, but rather that the evidence is less clear. A reason for not finding effects on emotional and social functioning in the intention-to-treat analysis may be that boundaries were set in the imputation of the data (i.e., truncated regression). This meant that, as the score range for emotional and social functioning was 0–100, imputing a value outside these boundaries was not possible. As the mean score for emotional and social functioning were relatively close to the upper boundary, there was a greater chance for the imputed values to be imputed below the original means of the outcomes. This might have led to non-significant differences in the intention-to-treat analysis. In the study in which the working mechanisms were investigated, explaining the short-term effects on depression and fatigue (**Chapter 7**), only complete case analyses were used. This was done since this method would provide the most realistic estimates of the mediator effects.

Measurements

Only validated measures were used to measure the health outcomes and working mechanisms. All measures were self-report measures which may be considered as a limitation, since the results could have been influenced by social desirability. However, if social desirability might have had an effect, then this would most likely be the case for both research conditions. With the broad approach of the KNW, the questionnaires measured a variety of constructs, and therefore the measurements were fairly long. It is, however, not expected that this had an impact on the quality of the answers (Iglesias & Torgerson, 2000). More important points of discussion are described below.

Two measures might not have sufficiently captured the constructs which we wanted to investigate. First, no intervention effect was found for a reduction in anxiety. The Hospital Anxiety and Depression Scale (HADS) was used for measuring anxiety and depression (Zigmond & Snaith, 1983). While the HADS is considered to be a valid tool for screening purposes (Mitchell, Meader, & Symonds, 2010), cancer-related anxiety has different manifestations and the HADS might not be specific enough to investigate these within our study population (Stark et al., 2002; Stark & House, 2000; Wittchen et al., 2000). Second, as mentioned earlier, a 10-item version of the SPSI-R was used to measure problem-solving skills (Dreer et al., 2009). While the 10-item version might be a more efficient way to measure problem-solving skills, it might also have been less sensitive in detecting changes in problem-solving skills over time (Dreer et al., 2009).

Finally, next to effect evaluation, the measures were also used to provide tailored information. Amongst others, the results from the questionnaires were used to refer participants to the modules that would best serve their needs (**Chapter 4**). For some modules (e.g., Fatigue module), the referral advice could easily be based on the validated cutoff scores of a scale measuring that specific concept. For other modules (e.g., Mood module) more complex cutoff scores were determined based on a combination of scales measuring different concepts addressed in the particular module (i.e., coping, anxiety, and depression). Although there was careful thought about the implementation of the cutoff scores, for future implementation it is suggested to investigate how participants received the given advice (e.g., does the advice match with how participants feel) and how the chosen cutoff scores influence intervention usage.

IMPLICATIONS AND RECOMMENDATIONS FOR RESEARCH AND PRACTICE

The studies described in this thesis are, to our knowledge, the first to describe the development and evaluation of a web-based computer-tailored intervention aimed at stimulating self-management among cancer survivors of any type of cancer in dealing with a broad area of psychosocial and lifestyle-related issues. This thesis describes the effectiveness of the intervention in improving psychosocial well-being (i.e., quality of life, anxiety, depression, and fatigue), and shows the intervention as being effective in improving emotional and social functioning and reducing depression and fatigue. The evaluation of the effectiveness of the intervention in changing lifestyle behaviors (i.e., physical activity, diet, and smoking cessation) shows that the intervention is also effective in improving moderate physical activity and vegetable consumption (Kanera et al., 2016b; Kanera et al., 2017). The results of these studies provide several suggestions for further research and have important implications for practice.

Future directions for research

The studies described in this thesis provided valuable insight into the effectiveness of the KNW, but also provide new directions for research. The most important suggestion is to study the effects in a more representative sample (e.g., in terms of different cancer types, age, and well-being) of the general population of cancer survivors. In addition, several suggestions for future research can be made to provide more in-depth knowledge of the intervention's effectiveness. These suggestions will now be discussed.

First, future research should further investigate for whom the intervention is most effective. In the evaluation of the long-term effectiveness of the KNW (**Chapter 6**), the research questions that were investigated were (a) whether the significant effects found in the short term remained in the long term and (b) whether these intervention effects differed among subgroups in the short term as well as the long term. As a consequence, no moderator analyses of the non-significant effects in the short term (i.e., global health status; physical, role, and cognitive functioning; and anxiety) were investigated. It would be interesting to investigate subgroup effects for these outcomes, since the intervention might still be effective on these outcomes for particular subgroups (Tamagawa et al., 2012). As mentioned earlier, it would also be interesting to investigate whether the baseline value of the health outcomes serves as a moderator. It could be expected that participants who score higher on fatigue or depression or lower on quality of life at baseline will benefit more from the intervention, since they have more room for improvement than those who functioned better at the start of the intervention (Faller et al., 2013; Schneider et al., 2010; Tamagawa et al., 2012). Future research should therefore investigate how the effects of the KNW differ between groups with greater or lesser experienced problems. Also, as mentioned earlier, it could be investigated whether time since primary treatment moderates intervention effectiveness, as it can be expected that the intervention might have had different effects for those who started very shortly after finishing primary treatment in comparison to those who finished primary treatment longer ago. Further, while moderator analyses provide some insight into whether the intervention is more effective for participants with a specific characteristic (i.e., gender, age, educational level, treatment type, or baseline score of the health outcome), the intervention might also be more effective for participants who share a specific set of characteristics. For example, patients that experience higher levels of fatigue, depression, sleep disturbance, and pain in general are younger and unmarried/unpartnered, and report lower quality of life (Miaskowski et al., 2006). Thus, survivors with a particular symptom cluster and demographic profile could benefit most from the KNW intervention. Cluster analyses can provide valuable insight into the intervention's effectiveness for specific patient profiles. With this information, more efficient implementation of the intervention in clinical practice can be ensured.

Second, future research should investigate how to optimize the intervention to facilitate user engagement and further improve intervention effectiveness. Further in-depth information should be retrieved on (1) how the intervention is used, (2) how well the (tailored) advice is followed, and (3) which elements of the intervention or combination of modules are most effective in improving the health outcomes. First, there is, as yet, little knowledge on what happens when a participant decides to use a module. Do participants in general complete the whole module or do they quit after seeing the first pages and receiving their first advice? Are there elements within a module that are never visited or are there assignments that are always skipped? Analyzing logs of access and module use can provide answers to these questions (Couper et al., 2010). While the KNW addresses two important aspects to facilitate user engagement in health interventions, namely targeting participants with pressing health concerns and tailoring the intervention to individual needs (Schubart, Stuckey, Ganeshamoorthy, & Sciamanna, 2011), having better insight into user engagement provides new options to optimize intervention usage (Kuijpers et al., 2013; Morrison, Yardley, Powell, & Michie, 2012; O'Brien & Toms, 2008; Short, Rebar, Plotnikoff, & Vandelanotte, 2015a). Second, the tailored advice is considered a very important strategy in the KNW. Future research should further investigate the quality of the tailored information and how well the tailored advice is followed. As mentioned earlier, it would be worthwhile to investigate the extent to which the tailored advice within the module referral advice matches with how the users actually feel (i.e., does the advice sufficiently capture the participants' most urgent needs?). Further, while the process evaluation of the KNW indicated that the module referral advice encouraged participants to follow a particular module, it could not be investigated how the modules would be visited when no such advice was given. Thus, there was no adequate control condition within the intervention group to assess these effects. In addition, while modules were better visited when receiving the advice to do so (i.e., receiving a "red" or "orange" advice), the actual percentage of participants visiting the advised module was lower than expected. Future research should therefore investigate how to optimize the module referral advice. Next, it is suggested that more long-term feedback is provided on how participants are doing. At the moment, participants receive one piece of tailored advice on how they are doing at baseline. Although within each module, a follow-up session was provided after 30 days in which the progress of the participants' goal was evaluated, no new information on their health status (e.g., anxiety, depression, and fatigue) was provided. By providing feedback on participants' health status at multiple moments (i.e., dynamic tailoring), better feedback can be provided on their progress, which may optimize their motivation and engagement and facilitate the long-term effectiveness of the intervention (Couper et al., 2010; Krebs et al., 2010; Short et al., 2015a). Third, while the study on the working mechanisms of the KNW (**Chapter 7**) provided insight into which psychological constructs explained the intervention effects on depression and fatigue, there is, as yet, no knowledge on how specific intervention components (e.g., psychoeducation, assignments, or videos) contribute to the intervention effects. By gaining more insight into both the ineffective and the most effective components, the intervention can be made more efficient, facilitating user engagement. In addition, it can also be expected that a specific combination of modules leads to optimal intervention effectiveness on a specific health outcome. For example, increasing physical activity is an effective method to reduce depression (Craft et al., 2012). Likely, a combination of the Physical Activity module and Mood module may have a bigger impact on reducing depression than the Mood module alone. While within each module, referral advice was given to other modules if necessary (e.g., visitors to the Mood module were also referred to the Physical Activity module if they scored low on physical activity), it is not known whether this combination also leads to better health outcomes. This information provides valuable information for further development of the intervention, such as providing optimal module referral advice. Future research should therefore investigate the influence of separate intervention components on the intervention's effectiveness and which combination of modules contributes best to a specific health outcome.

Third, as mentioned earlier, theory assumes that the experienced health problems precede quality of life (Bartholomew et al., 2016; Cella, 1994; Green & Kreuter, 2005). In this project, no data on the health problems (i.e., anxiety, depression, and fatigue) was collected during the intervention period (i.e., the period between baseline and 6 months from baseline), and thus it could not be evaluated whether improvement in health outcomes during intervention usage led to an increase in quality of life after intervention usage. Therefore, in future research, it is suggested that data be collected on the health problems during the intervention period. With the current data, however, it is possible to evaluate whether the health problems at 6 months from baseline mediate the effect on quality of life at 12 months from baseline, which is a useful suggestion for further evaluation.

Fourth, a strong point of our data collection was that we were able to collect information about the cancer survivors that did not participate when invited for either the needs assessment study or the RCT. The hospital staff that recruited the patients wrote down basic demographic information on a registration form (i.e., age, gender, cancer type, treatment type, and time since last treatment) before inviting the person for participation in the study. For the RCT, 1303 cancer survivors were invited for participation, of which 60% were not randomized into the trial (**Chapter 5**). There were several reasons for not participating, including explicitly declining to participate, not meeting the inclusion criteria, and low (self-perceived) computer literacy. However, for most survivors, the reason for declining to participate was unknown. The background information of the survivors who did not participate in the trial without a clear statement of reason can provide a useful insight into whether this group differs in certain aspects from the group that did participate, and based on this information, the KNW be could be adjusted to make it more interesting for these people. Due to time constraints, this data has not been analyzed yet.

A final valuable direction for research is to evaluate the cost-effectiveness of the intervention. Analyses of cost-effectiveness were not a part of the current project. It is, however, expected that the KNW, being a low-intensity and relatively low-cost intervention, is a cost-effective option in cancer aftercare (Leykin et al., 2012; Lustria et al., 2009; Meregaglia & Cairns, 2015). Therefore, gaining detailed insight into the cost-effectiveness of the KNW is highly recommended.

Implications for practice

The promising results of the KNW intervention lead to several important implications for practice. First of all, the KNW seems to be an adequate and efficient intervention to integrate in a stepped-care approach for cancer aftercare. In stepped care, aftercare is provided in a series of steps, with more intensive treatments (e.g., long-term individual therapy) being reserved for those who do not achieve significant health gain in more basic forms of support, such as (guided) self-help (Andersen et al., 2014; Bower & Gilbody, 2005; Haaga, 2000; Krebber et al., 2012). The KNW fits within this approach by offering cancer survivors initial guided support through a web-based self-management intervention targeting the psychosocial and lifestyle-related problems that are often present after cancer treatment. For a proportion of the cancer survivors, this approach will sufficiently meet their needs. This puts less pressure on the limited therapy resources available and, therefore, leaves more room for those more dependent on higher intensity professional help. With the KNW being considered as a relevant step in a stepped-care approach, it fits perfectly within the recommended guidelines for cancer aftercare (Comprehensive Cancer Centre the Netherlands, 2011b).

Providing the KNW as an eHealth intervention has some important benefits. The KNW is easily accessible, is available 24/7, can reach many patients at once, offers privacy and anonymity, and information is stored safely (Leykin et al., 2012; Lustria et al., 2009; Tate & Zabinski, 2004). With these benefits, it is suggested that the KNW stimulates cancer survivors' search for and use of cancer aftercare, as it takes away some important barriers, such as shame regarding experienced problems, lack of time, or lack of nearby services (Tate & Zabinski, 2004). Providing the KNW only through a web browser has some limitations. While user statistics showed that approximately 70% of the time participants visited the KNW through a computer and approximately 26% through a tablet, participants might not always have easy access to a computer or tablet. Less than 5% of the time, the KNW was used on a smartphone. This is not unexpected, since the intervention was not developed for use on this device. Therefore, providing the intervention through a mobile application (app) might be a valuable suggestion for further dissemination of the KNW (Mosa, Yoo, & Sheets, 2012). Most people have a smartphone or tablet within arm's reach. Offering the KNW through an app makes the information of the KNW more easily accessible and can improve user experience. It should, however, be noted that providing the information through an app has some implications for the intervention. For example, the KNW in its current form makes much use of written information. For the KNW as an app, it is recommended to shorten these texts and to provide information in smaller chunks (Bartholomew et al., 2016). In addition, more use of video material could be made to reduce the amount of written information.

While offering the intervention through an app might increase dissemination and user experience, this might not account for all survivors, especially those with lower computer literacy. In general, the elderly have lower computer literacy (AGE Platform Europe, 2008). Our study sample supports this, since relatively few elderly people participated in the RCT. For this group, the KNW might be offered in a paper printed version. Although offering the KNW as a printed intervention requires more resources (i.e., time and money), it still seems to be a feasible and cost-effective option (Golsteijn et al., 2014; Peels et al., 2014). However, offering the KNW on paper also has implications for the intervention. While it would be feasible to tailor information on problem areas and points of attention, it would be more difficult to tailor information within specific modules, making the KNW less dynamic as it is in its current state. In addition, it is not possible to provide the video-material (peer and expert information), which is considered an important component of the KNW.

Now the first version of the KNW has been developed and proven effective in stimulating self-management and improving well-being, it is important to investigate how the intervention can further be improved. As mentioned in the previous paragraphs, providing more long-term feedback or offering the intervention through different channels might be relevant suggestions. Another suggestion would be to add new modules to the intervention or further improve existing modules. For example, pain is not discussed in the KNW, while it is strongly related to anxiety, depression, and fatigue (Dauchy et al., 2013; Finan, Goodin, & Smith, 2013; Stepanski et al., 2009; Vahdaninia et al., 2010). Thus, adding a module on pain management could be a relevant addition. Further, as suggested earlier, the Mood module probably needs some revision, as it was not effective in decreasing anxiety.

One suggestion would be to include more specific information on cancer-related anxiety, such as (dysfunctional) fear of cancer recurrence (Simard et al., 2013). A final suggestion would be to provide an option within the KNW to receive online therapist support. As discussed earlier, although the KNW provided tailored feedback, it is based on a limited number of circumstances and responses, and is therefore not likely to address all of the specific concerns of every participant (Tate & Zabinski, 2004). Offering online therapist support within the KNW would be a next step when the non-therapist version of the KNW does not sufficiently meet the participants' needs. In addition, an online therapist might be helpful in encouraging user engagement in the program.

GENERAL CONCLUSION

Survivors within the first year after primary treatment experience a great variety of unmet information and support needs. Offering a web-based computer-tailored self-management intervention aimed at providing information and support on dealing with the most prominent issues experienced by cancer survivors might be a valuable strategy in improving cancer aftercare. This thesis finds support for this notion by demonstrating that the web-based computer-tailored KNW intervention is proven to be effective in improving psychosocial well-being in the short term. More specifically, the KNW improved emotional and social functioning and reduced depression and fatigue among participants. While the improved outcomes of the intervention group maintained, the control group caught up in the long term, showing equal levels of emotional and social functioning, depression, and fatigue as the intervention group. These results suggest that the KNW provides a head start in cancer recovery by showing that survivors receiving the intervention recovered faster than those who did not receive the intervention. Next, the thesis supports the idea of the KNW serving as a self-management intervention, as it shows that the effects of depression and fatigue are partly mediated by cancer survivors' perceived personal control over their cancer recovery. Further, it is shown that the KNW and its specific modules were highly appreciated by the users, and it is suggested that providing module referral advice is a useful means to stimulate module use among users.

The studies in this thesis provide new evidence for the benefits of integrating eHealth interventions in cancer aftercare. The KNW is an easy to implement, easily accessible, and relatively low-intensity intervention that is expected to be cost-effective and can be considered to be clinically relevant. Therefore, it is suggested that the KNW is a very relevant tool for implementation in a stepped-care approach in cancer aftercare.

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Appendices

A

APPENDIX A

Items added to the Cancer Survivors' Unmet Needs questionnaire (CaSUN)

CaSUN need description **I need…**	**% (Reporting unmet need/ completing item)**	**Mean (*SD*) strength rating**
Changing lifestyle		
help to quit smoking	26.7 (12/45)[a]	2.17 (0.83)
help to exercise more	18.0 (46/255)	1.76 (0.85)
help to learn to eat healthier	6.3 (16/255)	1.31 (0.48)
help to reduce my alcohol consumption	3.0 (6/197)[b]	1.17 (0.41)
Returning to work		
help with carrying out my work	19.6 (21/107)	2.14 (0.91)
information about the rules and legislation on returning to work, such as regulations on working hours and recovering from disease	17.8 (19/107)	2.16 (0.96)
help to make adjustments to my job or to find a new job	15.0 (16/107)	2.38 (0.81)
help to discuss the topic of cancer in work situations	10.3 (11/107)	1.73 (0.90)
help to talk to and/or deal with colleagues	7.5 (8/106)	1.50 (0.76)

[a] Percentage based on smokers only (*n* = 45)
[b] Percentage based on people who drink alcoholic drinks (*n* = 197)

APPENDIX B

Determination of the "module referral advice"-categories (red, orange, green)

The module referral advice (MRA) for the Return to Work module was based on four items from the extended Cancer Survivors' Unmet Needs questionnaire (CaSUN) (Hodgkinson et al., 2007b; Mesters et al., 2015; Willems et al., 2016) (see also Chapter 2), that were formulated as follows: (1) "I need help to make adjustments to my job or to find a new job", (2) "I need help to find out about financial support and/or government benefits to which I am entitled", (3) "I need help with carrying out my work", (4) "I need information about rules and legislation on returning to work, such as regulations on working hours and recovering from disease". Respondents indicated whether they had no need (score 0), a met need (score 0), or an unmet need (score 3–5). Strength of unmet needs was rated as weak (3), moderate (4), or strong (5). When participants indicated to have no needs or only met needs (total score 0), a green MRA was given. A total score ranging from 3 to 12 (some unmet needs) were classified into an orange MRA, and a total score higher than 12 (strong unmet needs) into a red MRA.

The MRA for the Fatigue module was based on the eight items of the subjective fatigue subscale of the Checklist Individual Strength (CIS) (e.g., "I am feeling tired") with an item range of 1 to 7 (total score range: 8–56) (Vercoulen et al., 1994). The classification into a green, orange, and red MRA corresponded to the cutoff scores of the CIS subjective fatigue subscale, with a score lower than 27 indicating no fatigue (green), 27–35 indicating elevated fatigue (orange), and higher than 35 indicating severe fatigue (red).

The MRA for the Relationships module was based on the discrepancy subscale of the six-item version of the Social Support List (SSL-D) (van Sonderen, 2012) and two items of the CaSUN concerning unmet needs with respect to fertility and sexuality issues (Hodgkinson et al., 2007b). The items of the SSL-D ranged from 1 to 4, with a total score range of 6 to 24, and measures the extent to which the respondent is experiencing a lack of social support. A score lower than 8 on the SSL-D (satisfied with the received social support) resulted in a green MRA, a score of 8 or 9 on the SSL-D (experiencing two or three problems with social support) with or without unmet needs concerning fertility or sexuality resulted in an orange MRA, and a score of 10 or higher on the SSL-D (experiencing at least four problems with social support) with or without a strong need concerning sexuality issues resulted with in a red MRA.

The MRA for the Mood module was based on the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) and the negative adjustment dimension of the Mental Adjustment to Cancer scale (MAC) (Watson & Homewood, 2008). Concerning the HADS, seven items for anxiety and seven items for depression were measured on a four-point scale (item range 0–3). Subscale scores ranged from 0 to 21, with a score of 8 or higher being an indication for anxiety or depression. Negative mental adjustment of the MAC comprises 16 items measured on a four-point scale (item range 1–4) with the total score ranging from 16 to 64 and a cutoff score of 36 indicating problematic functioning. Scores lower than 8 on both the anxiety and depression scale of the HADS, and a MAC score of 36 or lower resulted in a green MRA, indicating no/low psychological distress and no/low problematic functioning. A MAC score higher than 36 or a score of 8–15 on one of the HADS subscales was categorized into an orange MRA. When the scores on one of the HADS subscales were higher than 15, or when both subscale scores were higher than 15, a red MRA was provided.

The MRAs for the modules Physical Activity and Diet were constructed according to the lifestyle recommendations of the World Cancer Research Fund/American Institute for Cancer Research (WCRF/AICR) and the American Cancer Society (Rock et al., 2012; WCRF/AICR, 2007). The classification criteria are displayed in Table 4.1. Physical activity was assessed by applying the validated 11-item self-report Short Questionnaire to Assess Health Enhancing Physical Activity (SQUASH) (de Hollander et al., 2012; Wendel-Vos et al., 2003). The number of days a week of physical activity (≥30 minutes of moderate intensity), the average number of minutes per day, and the intensity (light, moderate, vigorous) were rated for activities during commuting, work, household, leisure time, and sports (Kanera et al., 2016b). Dietary behavior was measured by using 14 items from the Dutch Standard Questionnaire on Food Consumption to assess vegetable, fruit, fish, whole-grain bread, oatmeal, cereal, potato, whole-grain rice, and whole-grain pasta consumption (Kanera et al., 2016b; van den Brink et al., 2005). A green MRA was provided when respondents met four out of five dietary recommendations as displayed in Table 4.1. When reporting that two or three out of five conditions were met an orange MRA was provided, and respondents who met one or none of the five conditions received a red MRA.

The MRA for the Smoking module was based on current and former smoking behavior, which was measured by using three standardized questions from Dutch Measuring Instruments for Research on Smoking and Smoking Cessation (Kanera et al., 2016b; Mudde et al., 2006). Respondents who had never smoked before and former smokers who quit smoking prior to the cancer diagnosis received a green MRA, former smokers who quit when the cancer was diagnosed received an orange MRA, and current smokers received a red MRA.

APPENDIX C

Overview of cancer diagnoses among the KNW sample (*n* = 231)

Type of cancer	*n*	%
Breast	162	70.13
Colon	29	12.55
Non-Hodgkin's lymphoma	10	4.33
Lung	5	2.16
Uterus	4	1.73
Prostate	3	1.30
Esophagus	3	1.30
Kidney	3	1.30
Ovary	2	0.87
Vulva	2	0.87
Testicle	2	0.87
Cervix	1	0.43
Thyroid	1	0.43
Stomach	1	0.43
Bladder	1	0.43
Hodgkin's lymphoma	1	0.43
Multiple myeloma	1	0.43

APPENDIX D

Violin plots for the outcomes emotional and social functioning, depression, and fatigue with individual data points of these outcomes at baseline and 6 and 12 months after baseline. Vertical bars represent the 95% CI of the mean. The colored areas represent the estimated kernel density. Violin plots were made in R 3.2.3 with the function dlvPlot of the package userfriendlyscience.

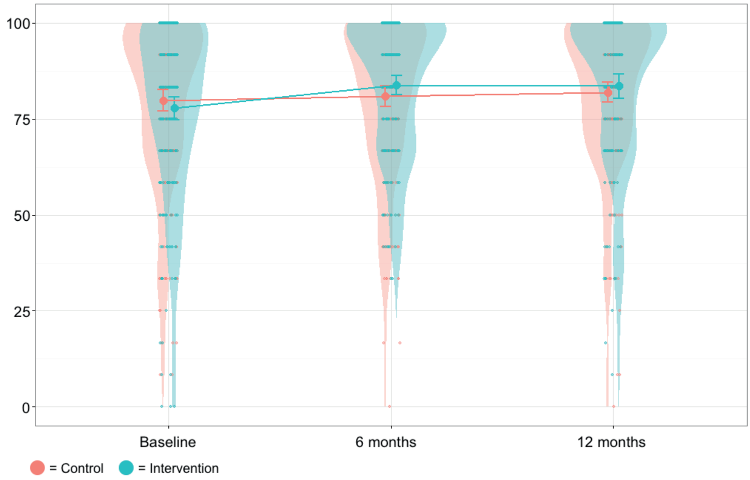

Figure D.1: Emotional functioning

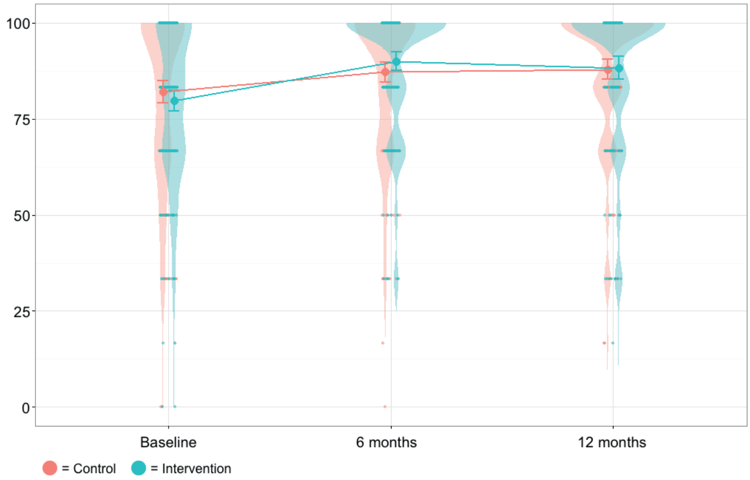

Figure D.2: Social functioning

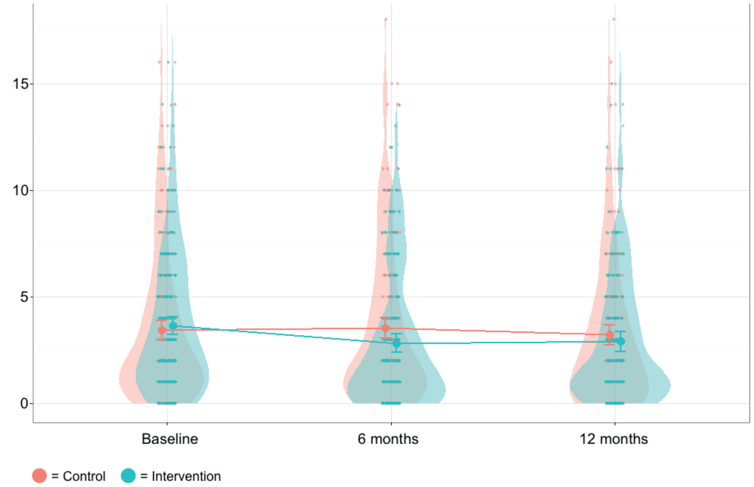

Figure D.3: Depression

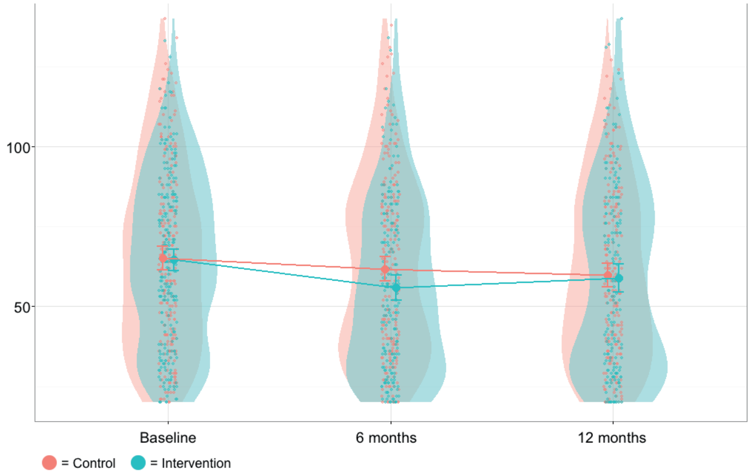

Figure D.4: Fatigue

APPENDIX E

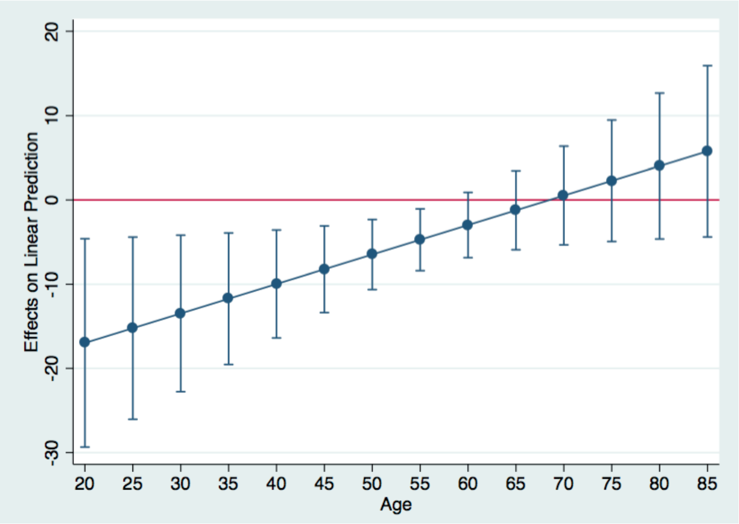

Figure E.1: Average marginal effects of condition on fatigue at 6 months from baseline for different ages. Vertical bars represent the 95% CI.

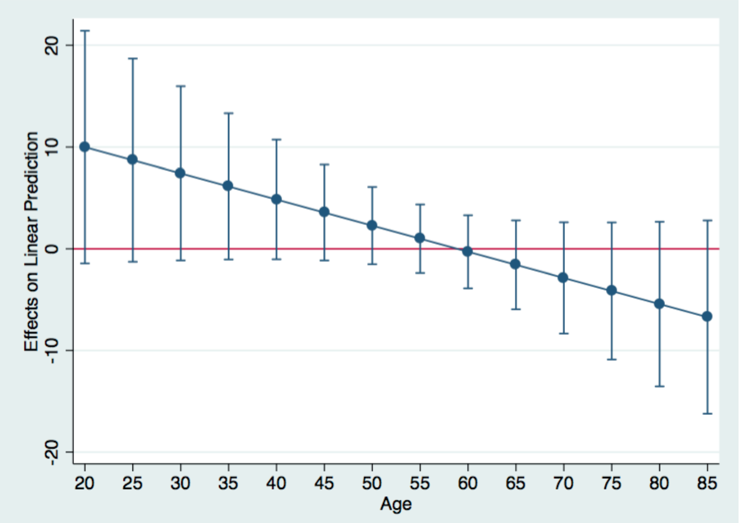

Figure E.2: Average marginal effects of condition on social functioning at 12 months from baseline for different ages. Vertical bars represent the 95% CI.

Abbreviations

A

BMI	Body Mass Index
CaSUN	Cancer Survivors' Unmet Needs questionnaire
CBT	Cognitive Behavioral Therapy
CIS	Checklist Individual Strength
CO	Change Objective
eHealth	Electronic health
EORTC	European Organization for Research and Treatment of Cancer
HADS	Hospital Anxiety and Depression Scale
fdr	False discovery rate
I-Change Model	Integrated Model for explaining motivational and behavioral change
IM	Intervention Mapping
IPQ-R	Illness Perception Questionnaire–Revised
KNW	Kanker Nazorg Wijzer (Cancer Aftercare Guide)
MAC	Mental Adjustment to Cancer scale
MRA	Module Referral Advice
PA	Physical Activity
PO	Performance Objective
PST	Problem-Solving Therapy
QLQ-C30	Quality of Life Questionnaire–C30
RCT	Randomized Controlled Trial
SPSI-R	Social Problem-Solving Inventory–Revised
SPSI-R:S	Short Social Problem-Solving Inventory–Revised
SQUASH	Short QUestionnaire to ASsess Health-enhancing physical activity
SSL-D	Social Support List–Discrepancies
T0	Baseline measurement
T1	Measurement 3 months from baseline
T2	Measurement 6 months from baseline
T3	Measurement 12 months from baseline
WCRF/AICR	World Cancer Research Fund/American Institute for Cancer Research

Summary

With advances in cancer detection and treatment and an aging population, the number of cancer survivors has increased significantly over the past decade and will continue to do so. Many cancer survivors face a variety of difficulties and challenges following cancer treatment, such as anxiety, depression, fear of cancer recurrence, fatigue, pain, social relationship and intimacy issues, difficulties in returning to work, or lifestyle-related problems (e.g., unhealthy diet, lack of physical activity, smoking). These issues may negatively affect survivors' quality of life. Current guidelines propose that cancer survivors are mainly responsible for managing their health and well-being, and that healthcare professionals should encourage and support them in self-management. However, cancer survivors do not always feel confident in managing their health: they do not always know what to expect after finishing cancer treatment, where to get help, or do not have sufficient skills to manage their problems. Providing an easily accessible tool stimulating self-management in managing life after cancer treatment might therefore fill an important gap in cancer aftercare.

The aim of this thesis was to develop and evaluate an easily accessible web-based computer-tailored self-management intervention, the *Kanker Nazorg Wijzer* (Cancer Aftercare Guide; KNW), aimed at supporting cancer survivors during life after cancer treatment. The KNW was systematically developed using the Intervention Mapping protocol, which is a theory- and empirically-based approach for intervention development. The intervention is fully automated (i.e., there is no therapist support) and provides tailored information and support on multiple domains: cancer-related fatigue, return to work, anxiety and depression, social relationships and intimacy, physical activity, diet, and smoking cessation. It is assumed that by providing tailored support on dealing with issues experienced within these domains, quality of life will increase. The current thesis describes the systematic development of the KNW and evaluates the effectiveness of the intervention on quality of life, anxiety, depression, and fatigue.

Chapter 1 describes the importance and rationale of developing a web-based computer-tailored self-management program for cancer survivors within the first year after cancer treatment. The chapter provides an overview of the problems cancer survivors may encounter during life after cancer treatment. A detailed description of cancer-related fatigue, anxiety, and depression and their impact on quality of life is provided. The chapter further describes cancer survivors' role in managing these problems, and highlights the importance of eHealth in supporting cancer survivors in self-management.

Chapter 2 aims to identify cancer survivors' most prominent information and support needs within the first year after primary treatment, and investigates whether the type of experienced needs varies among survivors' demographic, disease-related, and psychosocial characteristics. The results show that cancer survivors experience a great variety of unmet information and support needs. Almost two in three survivors experience one or more unmet needs. The most frequently reported unmet needs concerned receiving adequate emotional and social support, managing side effects or complications, dealing with fear of recurrence, receiving adequate cancer care and up-to-date information, and carrying out work. Unmet needs varied greatly among survivors' characteristics. Higher age, high educational level, participation in support programs, and higher levels of anxiety, depression, and negative adjustment style were associated with a higher number of unmet needs; being female, a longer time since last treatment, and a higher level of quality of life were associated with a lower number of unmet needs. The number of unmet needs also differed among cancer type. These relationships differed per need domain. The results indicate that a general approach for information and support provision might not be efficient and that a tailored approach focusing on a broad array of subjects is more suitable.

Chapter 3 describes the systematic development of the KNW. The web-based computer-tailored self-management intervention was developed using the Intervention Mapping protocol, which describes a systematic, theory- and empirically-based approach for intervention development. The KNW consists of eight modules, of which seven are self-management training modules. The training modules cover the topics return to work, fatigue, anxiety and depression, social relationships and intimacy issues, physical activity, diet, and smoking cessation. The eighth module provides general information and some basic advice on the most common residual symptoms. To improve *self-management skills*, several evidence-based approaches were integrated into the intervention to change the behavioral determinants: all training modules were structured according to the principles of problem-solving therapy, elements of cognitive behavioral therapy were implemented in the modules covering problems which have strong psychosocial components (i.e., fatigue, anxiety and depression, return to work, and social relationships and intimacy issues), and social cognitive and self-regulation theories were integrated into the modules covering lifestyle behaviors (i.e., physical activity, diet, and smoking cessation). Since cancer survivors experience a great variety of unmet needs and experienced needs differ among patient characteristics (see also Chapter 2), a *tailored approach* was considered as a more efficient way of providing information within the intervention. By tailoring information to the survivors' characteristics, the information is made more personally relevant, which facilitates behavioral change. The chapter further provides a detailed description of the scope and sequence of the intervention modules and other website elements. Finally, the evaluation plan for determining intervention effectiveness, a randomized controlled trial comparing an intervention group with a waiting list control group, is described.

Chapter 4 provides a detailed description of how the participants in the intervention group used and appreciated the KNW intervention. One of the main components of the intervention was the tailored advice referring participants to the intervention modules that best suited the participants' needs. The results showed that participants on average were referred to three modules, indicating that the topics discussed in the KNW were highly relevant. In total, 86% of the participants visited at least one module. The most-visited modules were the modules discussing diet (58%) and fatigue (36%). Participants were more likely to visit a module when they were advised to visit that module, indicating that the tailored advice worked well. The KNW in general, as well as the individual modules, were highly appreciated. Higher perceived personal relevance of the KNW and its contents was associated with a higher appreciation of the KNW.

Chapter 5 presents the short-term effectiveness of the KNW (i.e., 6 months from baseline; directly after intervention closure) on quality of life, anxiety, depression, and fatigue. The results showed that the KNW was effective in reducing depression and fatigue. That is, participants in the intervention group reported significantly lower levels of depression and fatigue than participants in the control group after intervention closure. In addition, significant effects were found for emotional and social functioning (both are components of quality of life), with the intervention group reporting higher levels of emotional and social functioning than the control group after intervention closure. Intention-to-treat analyses verified the results for depression and fatigue, but showed non-significant differences for emotional and social functioning. In-depth analysis aimed to provide insight into whether module use influenced these results. The results suggest that the effect for fatigue in particular could be explained by participants who used the module covering fatigue.

Chapter 6 provides insight into the long-term effectiveness of the KNW. It was investigated whether the effects found in the short term (i.e., 6 months from baseline) remained in the long term (i.e., 12 months from baseline). In addition, the chapter aims to provide insight into whether the short- and long-term effects differ among subgroups of survivors. The results show that at 12 months from baseline, the intervention group no longer differed from the control group in levels of emotional and social functioning, depression, and fatigue. The lack of maintenance of effect could be explained by the levels of emotional and social functioning, depression, and fatigue within the intervention group remaining fairly stable between 6 and 12 months after baseline, and the control group slowly improving in these outcomes over the trial period. The subgroup analyses showed that, in the short term, the intervention was only effective in improving social functioning for men, reducing fatigue for participants aged 56 and younger, and reducing depression for participants who received chemotherapy with or without surgery. In the long term, educational level moderated the effect of social functioning.

Chapter 7 provides insight into the working mechanisms of the KNW. It was hypothesized that the KNW would increase problem-solving skills and perceived personal control in managing cancer recovery at 3 months from baseline, which would result in a reduction in depression and fatigue at 6 months from baseline. The outcomes depression and fatigue were chosen, since the complete case analyses, as well as the intention-to-treat analyses, in the short-term evaluation (Chapter 5) showed significant intervention effects in reducing these outcomes. The results of the mediation analyses showed that personal control, but not problem-solving skills, partially mediated the intervention effect of depression (24%) and fatigue (40%). This mediation effect was not explained by a significant increase of personal control in the intervention group, but by a significant decrease of personal control in the control group, suggesting that the intervention helped to prevent a decline in perceived personal control in managing cancer recovery. The results provide evidence for the relevance of addressing personal control in web-based interventions in order to improve psychosocial well-being in early cancer survivors.

Chapter 8 provides a summary and discussion of the main findings, reflects on the strengths and limitations, and discusses the implications for practice and future research. Important strengths are the innovative nature of the intervention (e.g., providing tailored information; addressing multiple problems; being developed for survivors of any type of cancer), strong study design, long-term follow-up, high number of participants, low drop-out rate, and the use of advanced statistical techniques to evaluate the intervention's effectiveness. Further, by means of process evaluation, effect evaluation of module use, subgroup analyses, and analyses of the working mechanisms, in-depth information was retrieved concerning *why* and *for whom* the intervention is effective and whether the intervention worked as intended. Limitations include selective dropout and possibility of selection bias. A disadvantage of the broad design of the intervention (e.g., addressing multiple problems) was that we were not able to preselect on the baseline values of the health outcomes. The strengths and limitations should be taken into account when interpreting the results of the research project. Implications for future research include further specifying for whom the intervention is most effective, investigating how to optimize the intervention to facilitate user engagement, and evaluating the cost-effectiveness of the intervention. The most important implication for practice is that the KNW might serve as an important step in a stepped-care approach, since this easily accessible and low-intensity intervention is considered to be effective in maintaining personal control in cancer recovery and to be effective in increasing cancer survivors' well-being. While effect sizes were small, they can be considered as clinically relevant, since a large population of cancer survivors can be reached with this intervention.

To conclude, the thesis shows that the fully automated KNW intervention is an effective tool in improving cancer survivors' well-being. The KNW gave cancer survivors a head start in recovery after the end of cancer treatment. With the KNW being a relatively low-intensity, easily accessible, and low-cost tool, which has the potential to reach a large group of cancer survivors, it is believed to be a relevant step in stepped care for needs assessment and initial support for the psychosocial problems that are often present after cancer treatment.

Samenvatting

Door de betere opsporing en behandeling van kanker en doordat mensen steeds ouder worden, is het aantal mensen dat kanker heeft overleefd in het afgelopen decennium significant toegenomen. Dit aantal zal ook in de komende jaren blijven toenemen. Veel voormalig kankerpatiënten worden tijdens hun herstel geconfronteerd met een grote variëteit aan problemen en uitdagingen, zoals angst (voor terugkeer van kanker), depressie, vermoeidheid, pijn, problemen betreffende sociale relaties en intimiteit, problemen bij terugkeer naar werk, of problemen gerelateerd aan levensstijl (zoals ongezonde voeding, gebrek aan beweging, en roken). Deze problemen kunnen de kwaliteit van leven van voormalig kankerpatiënten verminderen. Huidige richtlijnen voor herstel na kanker stellen dat voormalig kankerpatiënten hoofdzakelijk zelf verantwoordelijk zijn voor het managen van hun gezondheid en welzijn. Professionals in de gezondheidszorg dienen wel ondersteuning te bieden bij de zelfmanagement van voormalig kankerpatiënten. Echter, voormalig patiënten vinden het niet altijd eenvoudig om hun eigen gezondheid te beheren: ze weten niet altijd wat ze kunnen verwachten na de behandeling van kanker, waar ze hulp kunnen vinden, of hebben niet voldoende vaardigheden om goed om te gaan met hun problemen. Het aanbieden van een toegankelijk hulpmiddel gericht op het verbeteren van zelfmanagementvaardigheden tijdens herstel na kanker kan daarom een belangrijke kloof in nazorg voor voormalig kankerpatiënten vullen.

Het doel van het huidige project, zoals beschreven in dit proefschrift, betreft de ontwikkeling en evaluatie van een gemakkelijk toegankelijk, online computer-tailored zelfmanagementprogramma – de *Kanker Nazorg Wijzer* (KNW). De KNW richt zich op het bieden van ondersteuning tijdens herstel na kanker. De KNW is systematisch ontwikkeld met behulp van het Intervention Mapping protocol. Dit protocol beschrijft een theoretisch en empirisch gefundeerde aanpak voor het ontwikkelen van een interventie. De KNW is volledig geautomatiseerd (wat wil zeggen dat er geen ondersteuning van een therapeut is) en biedt advies op maat over verschillende onderwerpen: kanker-gerelateerde vermoeidheid, terugkeer naar werk, angst en depressie, sociale relaties en intimiteit, beweging, voeding, en roken. Er wordt verondersteld dat door het aanbieden van advies op maat over hoe om te gaan met de ervaren problemen binnen deze domeinen, de kwaliteit van leven zal toenemen. In dit proefschrift wordt de systematische ontwikkeling van de KNW beschreven en de effectiviteit van de interventie op kwaliteit van leven, angst, depressie, en vermoeidheid geëvalueerd.

Hoofdstuk 1 beschrijft het belang en de rationale van het ontwikkelen van een web-based computer-tailored zelfmanagementprogramma voor voormalig kankerpatiënten die de behandeling van kanker minder dan een jaar geleden hebben afgerond. Het hoofdstuk biedt een overzicht van de veelvoorkomende problemen die voormalig kankerpatiënten tegenkomen na de behandeling van kanker. Een gedetailleerde beschrijving van kanker gerelateerde vermoeidheid, angst, en depressie en de relatie hiervan met kwaliteit van leven wordt gegeven. Verder beschrijft het hoofdstuk de rol van voormalig kankerpatiënten in het aanpakken van deze problemen en benadrukt het belang van eHealth programma's in het ondersteunen van voormalig kankerpatiënten in hun zelfmanagement.

Hoofdstuk 2 richt zich op het identificeren van de meest vooraanstaande informatie en ondersteuningsbehoeften van voormalig kankerpatiënten die de behandeling van kanker minder dan een jaar geleden hebben afgerond. Daarnaast wordt onderzocht of deze ervaren behoeften verschillen als wordt gekeken wordt naar specifieke demografische, ziekte-gerelateerde, en psychosociale kenmerken van deze populatie. De resultaten tonen aan dat voormalig kankerpatiënten een grote variëteit aan onvoldane informatie en ondersteuningsbehoeften ervaren. Bijna twee op de drie voormalig kankerpatiënten ervaren een of meer onvoldane behoeften. Meest genoemde onvoldane behoeften omvatten het verkrijgen van adequate emotionele en sociale steun, omgaan met bijwerkingen en complicaties van de behandeling, omgaan met angst voor terugkeer van kanker, het verkrijgen van goede nazorg en actuele informatie, en het uitvoeren van werk. De ervaren onvoldane behoeften varieerden sterk als er gekeken werd naar de specifieke kenmerken van de groep. Een hogere leeftijd, hoger opleidingsniveau, deelname in nazorgprogramma, en hogere mate van angst, depressie, en negatieve aanpassingsstijl werden geassocieerd met een hoger aantal onvoldane behoeften; vrouw zijn, langere tijd sinds laatste behandeling, en hogere mate van kwaliteit van leven werden geassocieerd met minder onvoldane behoeften. Het aantal onvoldane behoeften verschilde ook nog tussen verschillende kankervormen. De beschreven relaties verschilden echter per categorie van ondersteuningsbehoeften. De resultaten tonen aan dat een algemene aanpak voor het aanbieden van informatie en ondersteuning niet efficiënt is en dat advies op maat gericht op individuele kenmerken en verschillende ondersteuningsdomeinen een betere aanpak zou zijn.

Hoofdstuk 3 beschrijft de systematische ontwikkeling van de KNW. Deze web-based computer-tailored zelfmanagement interventie is ontwikkeld met behulp van het Intervention Mapping protocol. Dit protocol beschrijft een systematische en op theorie en empirie gebaseerde benadering voor interventieontwikkeling. De KNW bestaat uit acht modules, waarvan zeven zelfmanagement training modules zijn. De training modules omvatten de thema's terugkeer naar werk, vermoeidheid, angst en depressie, sociale relaties en intimiteitsproblemen, beweging, voeding, en stoppen met roken. De achtste module bevat algemene informatie en enkele basisadviezen over de meest voorkomende restverschijnselen. Om *zelfmanagementvaardigheden* te vergroten, zijn verschillende evidence-based benaderingen geïntegreerd in de interventie om de determinanten van het gedrag te veranderen. Zo zijn alle training modules gestructureerd volgens de principes van problem-solving therapy, zijn elementen van cognitieve gedragstherapie toegepast in de modules die problemen behandelen met sterke psychosociale componenten (i.e., terugkeer naar werk, vermoeidheid, angst en depressie, en sociale relaties en intimiteitsproblemen), en zijn sociaal cognitieve en zelfregulatie theorieën geïntegreerd in de modules die leefstijlgedragingen behandelen (i.e., beweging, voeding, en stoppen met roken). Gezien voormalig kankerpatiënten een grote verscheidenheid aan onvoldane behoeften ervaren en deze behoeften sterk verschillen tussen patiënten (zie ook Hoofdstuk 2), werd een *getailorde* (i.e., advies op maat) aanpak gezien als een efficiënte manier om informatie aan te bieden binnen de interventie. Door informatie aan te passen aan de karakteristieken van de voormalige kankerpatiënten, wordt de informatie meer persoonlijk relevant gemaakt, waardoor gedragsverandering gefaciliteerd wordt. Verder bevat het hoofdstuk een gedetailleerde beschrijving van de inhoud van de modules en andere website-elementen. Tot slot wordt een beschrijving gegeven van het evaluatieplan – een randomized controlled trial waarbij de interventiegroep wordt vergeleken met een wachtlijst controlegroep – om de effectiviteit van de interventie te bepalen.

Hoofdstuk 4 geeft een gedetailleerde beschrijving over hoe de deelnemers in de interventiegroep de KNW gebruikt en gewaardeerd hebben. Een van de belangrijkste elementen van de interventie was het advies op maat dat deelnemers doorverwees naar de interventiemodules die het beste bij hun behoeften pasten. De resultaten van de procesevaluatie laten zien dat de deelnemers gemiddeld naar drie modules werden doorverwezen, wat impliceert dat de thema's die werden besproken in de KNW erg relevant waren. Van alle deelnemers bezocht 86% op zijn minst één module. De meest bezochte modules waren de modules die advies gaven over voeding (58%) en vermoeidheid (36%). Deelnemers bezochten vaker een module als ze geadviseerd werden om deze module te volgen, wat aangeeft dat het advies op maat goed heeft gewerkt. De KNW in het algeheel evenals de individuele modules werden hoog gewaardeerd. Hoe persoonlijk relevanter iemand de KNW vond, hoe hoger de KNW werd beoordeeld.

Hoofdstuk 5 presenteert de korte termijn effecten van de KNW (i.e., 6 maanden na de baseline meting; direct na afloop van de interventie) op kwaliteit van leven, angst, depressie, en vermoeidheid. De resultaten lieten zien dat de interventie effectief is in het verminderen van depressie en vermoeidheid. Dit betekent dat deelnemers in de interventiegroep, direct na afloop van de interventie, significant lager scoorden op depressie en vermoeidheid dan deelnemers in de controlegroep. Daarnaast werden ook significante verschillen gevonden in emotioneel en sociaal functioneren (beiden componenten van kwaliteit van leven), waarbij de interventiegroep hoger scoorde op emotioneel en sociaal functioneren dan de controlegroep. Intention-to-treat analyses verifieerden de resultaten voor depressie en vermoeidheid, maar liet niet-significante verschillen zien voor emotioneel en sociaal functioneren. Verder werden er verdiepende analyses uitgevoerd, die inzicht gaven in of modulegebruik de resultaten beïnvloedde. De resultaten suggereerden dat het effect voor vermoeidheid in het bijzonder verklaard kon worden door deelnemers die gebruik hadden gemaakt van de module die vermoeidheid behandelde.

Hoofdstuk 6 biedt inzicht in de lange termijn effecten van de KNW. Er werd onderzocht of de effecten die gevonden werden op de korte termijn (i.e., 6 maanden na baseline) behouden bleven op de lange termijn (i.e., 12 maanden na baseline). Verder beoogt het hoofdstuk inzicht te verschaffen in of de effecten op de korte en de lange termijn verschillen tussen subgroepen van voormalig kankerpatiënten. De resultaten laten zien dat de interventiegroep op 12 maanden na baseline niet meer verschilt in de mate van emotioneel en sociaal functioneren, depressie, en vermoeidheid ten opzichte van de controlegroep. Dit gebrek van behoud van effect kan verklaard worden doordat de mate van emotioneel en sociaal functioneren, depressie, en vermoeidheid binnen de interventiegroep redelijk stabiel bleef tussen 6 en 12 maanden na baseline, terwijl de controlegroep langzaam verbeterde in deze uitkomsten gedurende de onderzoeksperiode. Dit leidde tot non-significante verschillen op de lange termijn. De subgroep analyses laten zien dat, op de korte termijn, de interventie alleen effectief was in het verhogen van sociaal functioneren van mannen, het verminderen van vermoeidheid voor deelnemers van 56 jaar en jonger, en het verminderen van depressie voor deelnemers die chemotherapie – met of zonder chirurgie – als behandelvorm hadden. Op de lange termijn bleek opleidingsniveau een mogelijke moderator te zijn voor het effect op sociaal functioneren.

Hoofdstuk 7 biedt inzicht in de werkingsmechanismen van de KNW. Er werd verondersteld dat dat de KNW effectief zou zijn in het verbeteren van probleemoplossende vaardigheden en waargenomen controle in het managen van herstel na kanker op 3 maanden na baseline, wat vervolgens zou resulteren in een afname van depressie en vermoeidheid op 6 maanden na baseline. De uitkomsten depressie en vermoeidheid werden voor deze studie gekozen, omdat de complete case analyses evenals de intention-to-treat analyses in de korte termijn evaluatie (Hoofdstuk 5) significante effecten aantoonden in het verminderen van deze uitkomstmaten. De resultaten van de mediatieanalyse tonen aan dat alleen persoonlijke controle gedeeltelijk de interventie effecten van depressie (24%) en vermoeidheid (40%) medieerde. Deze mediërende effecten werd echter niet verklaard door een significante toename van persoonlijke controle in de interventiegroep, maar door een significante afname van persoonlijke controle in de controlegroep. Dit suggereert dat de interventie heeft geholpen in het voorkomen van een afname in waargenomen persoonlijke controle in het managen van herstel na kanker. De resultaten bieden bewijs voor het belang van het aanpakken van persoonlijke controle in web-based interventies om zo het psychsociale welzijn van voormalig kankerpatiënten te bevorderen.

Hoofdstuk 8 geeft een overzicht en discussie van de belangrijkste resultaten van het onderzoeksproject, reflecteert over de sterke punten en de beperkingen, en geeft aanbevelingen voor de praktijk en vervolgonderzoek. Enkele belangrijke sterke punten van de interventie betreffen de innovatieve aard van de interventie (e.g., het bieden van advies op maat, aanpakken van meerdere problemen, ontwikkeld voor voormalig kankerpatiënten van elke vorm van kanker), het sterke onderzoeksdesign, het meten van de lange termijn effecten, het hoge aantal deelnemers, de lage drop-out, en het gebruik geavanceerde statistische technieken om de effectiviteit van de interventie te evalueren. Verder werd er door middel van een procesevaluatie, effectevaluatie van modulegebruik, subgroep analyses, en analyse van de werkingsmechanismen, verdiepende informatie verschaft betreffende *waarom* en *voor wie* de interventie effectief is en of de interventie werkte zoals bedoeld was. Beperkingen betreffen de selectieve uitval en de mogelijkheid van selectiebias. Een belangrijk nadeel van de brede aanpak van de interventie (e.g., het aanpakken van meerdere problemen) was dat het niet mogelijk was om deelnemers te selecteren op de baseline waarde van de problemen die aangepakt werden. Deze sterke en zwakke punten moeten in acht genomen worden bij het interpreteren van de resultaten van het onderzoeksproject. Suggesties voor vervolgonderzoek omvatten het verder specificeren voor wie de interventie het meest effectief is, uitzoeken op welke manier de interventie geoptimaliseerd kan worden om zo de betrokkenheid van de gebruiker te vergroten, en het uitvoeren van een kosteneffectiviteitsanalyse. De belangrijkste implicatie voor de praktijk is dat de KNW kan dienen als een belangrijke stap in een stepped-care aanpak, gezien deze makkelijk toegankelijke en relatief laag-intensieve interventie als effectief beschouwd wordt in het behouden van waargenomen controle betreffende herstel na kanker en effectief in het verbeteren van het welzijn van voormalig kankerpatiënten. Hoewel de effectgrootte relatief klein was, kan het toch als klinisch relevant beschouwd worden, gezien een grote groep voormalig kankerpatiënten met deze interventie bereikt kan worden.

Concluderend laat dit proefschrift zien dat de volledig geautomatiseerde KNW-interventie een effectief hulpmiddel is in met verbeteren van het welzijn van voormalig kankerpatiënten. De KNW gaf voormalig kankerpatiënten een voorsprong in herstel na kanker. Gezien de KNW een relatief laag intensieve, makkelijk toegankelijke, en relatief goedkope interventie is die de potentie heeft om een groot aantal voormalig kankerpatiënten te bereiken, wordt verwacht dat de KNW kan dienen als een belangrijke stap in een stepped-care aanpak voor het inventariseren van behoeften en het bieden van eerste hulp bij psychosociale problemen die aanwezig zijn na de behandeling van kanker.

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About the author

Roy Willems was born on 12 February 1987 in Sittard, the Netherlands. After graduating from secondary school (VWO) in 2005 at the Trevianum Scholengroep in Sittard, he studied psychology at Maastricht University and the Radboud University, graduating in 2009 with a Master's specialization in Behavioral Change at the Radboud University in Nijmegen. After his Master's degree, he studied a second Master's in Health and Social Psychology at Maastricht University, from which he graduated in 2010. During his internship at Maastricht University, Roy was a visiting scholar at Illinois State University (Bloomington, IL), where he developed his passion for research. Encouraged by his supervisors to pursue a career in academia, he started working as a junior researcher at the department of Health Promotion at Maastricht University, where he published several articles on smoking cessation and an evaluation report for STIVORO to determine the effectiveness of a campaign of smoking cessation aids.

In 2012, Roy began studying for a PhD at the department of Psychology and Educational Sciences at the Open University of the Netherlands, under the supervision of Prof. Dr. Lilian Lechner, Dr. Catherine Bolman, and Dr. Ilse Mesters. During his PhD program, he systematically developed and evaluated, together with his supervisors and colleagues Iris Kanera and Audrey Beaulen, an online computer-tailored intervention for cancer survivors to aid them in managing life after cancer treatment. The results of the studies derived from this project were published in a variety of international journals and were presented at several national and international conferences. With the intervention proven as an effective tool in cancer recovery, the intervention was selected by the Comprehensive Cancer Centre of the Netherlands to be nationally implemented.

In October 2015, Roy was elected as commission member of the Early Career Psycho-oncology Professionals special interest group of the International Psycho-Oncology Society. From February 2016 until January 2018, Roy worked as a teacher in Social Psychology and Behavioral Change at the Radboud University in Nijmegen, teaching students how to apply research in practice; since January 2018, he works as a postdoc researcher at the Open University on two European projects concerning the development and evaluation of two interventions that address (cyber)bullying.

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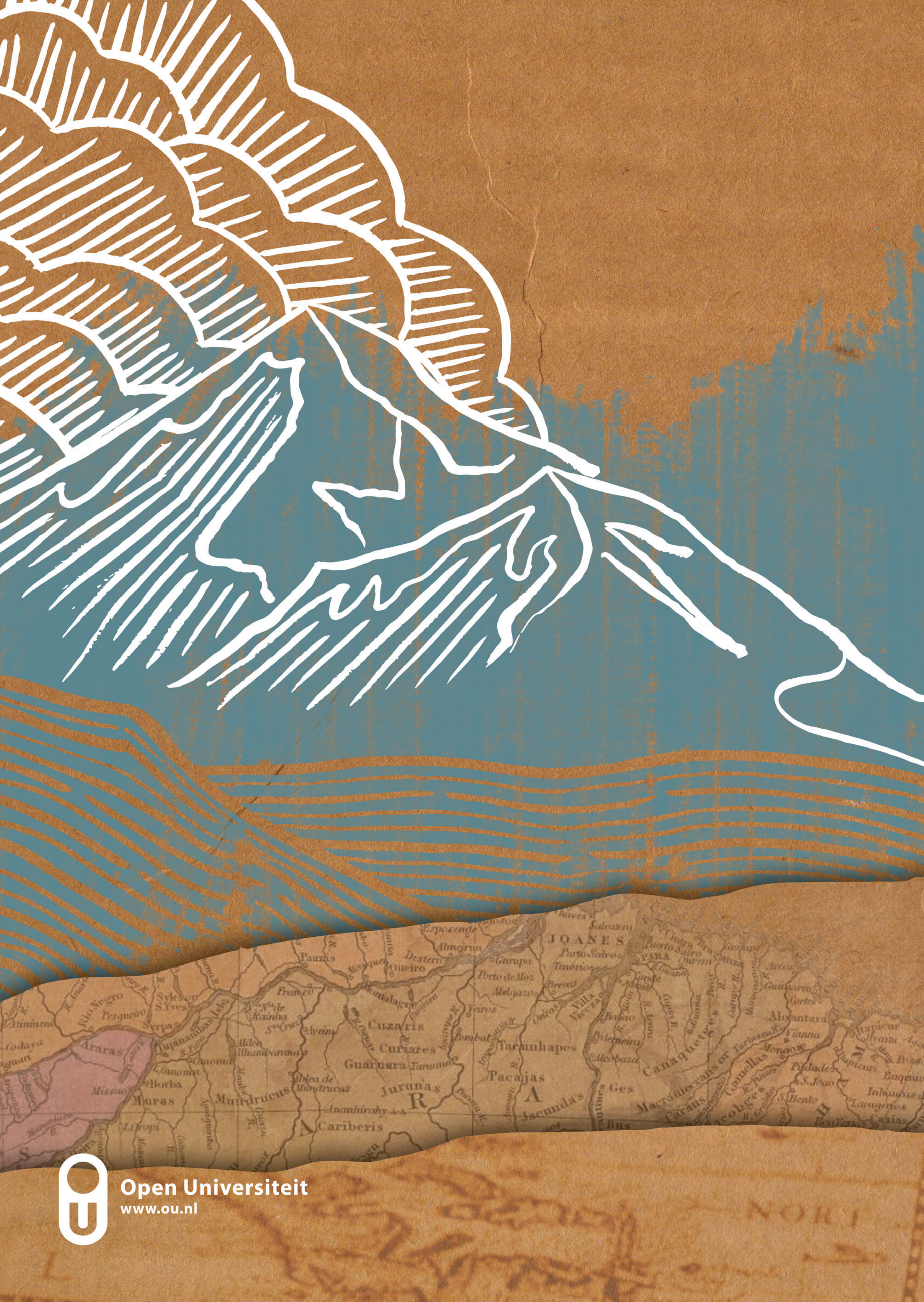

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