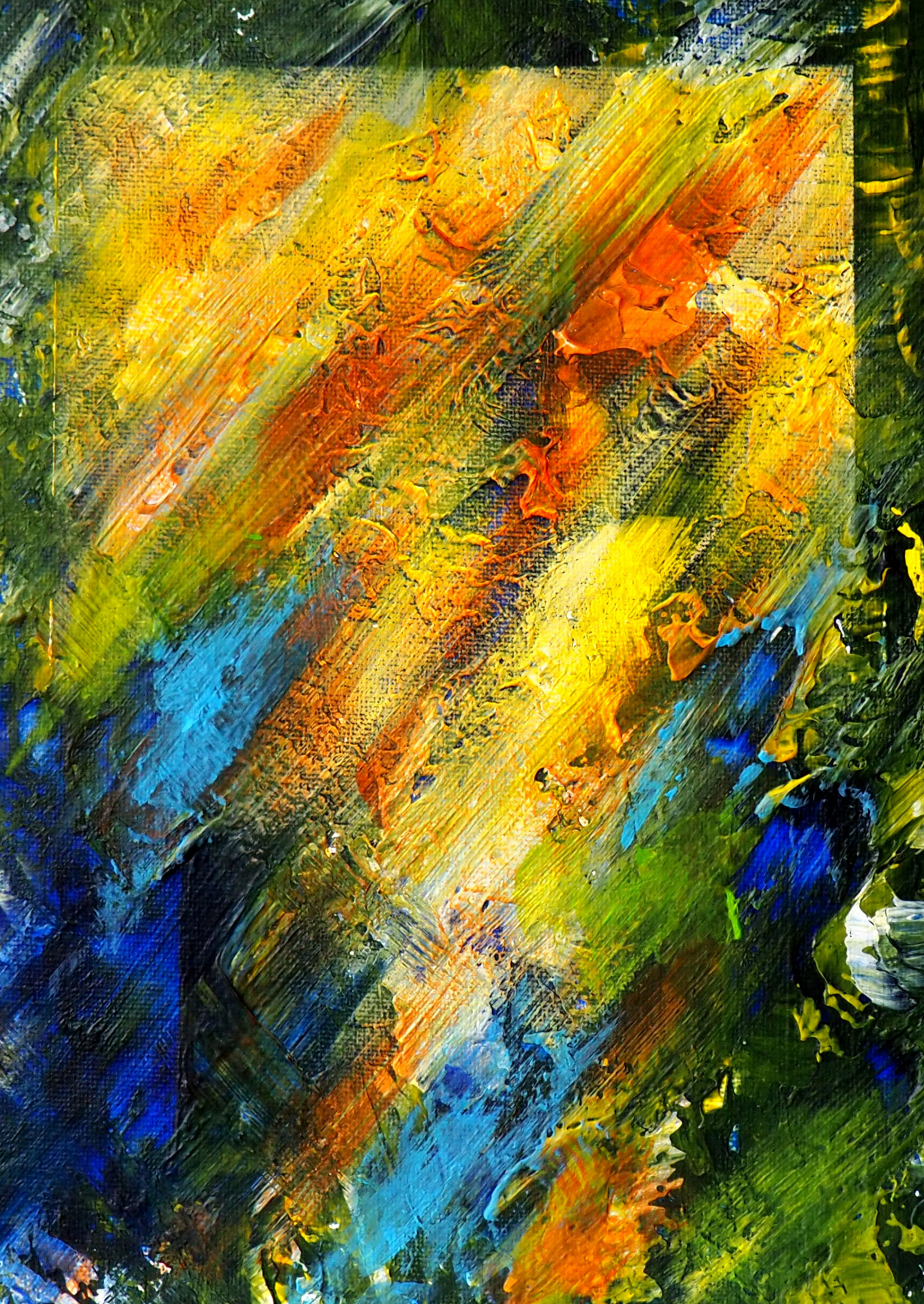
Physical Activity promotion in prostate and colorectal cancer patients and survivors

PHYSICAL ACTIVITY PROMOTION IN PROSTATE AND COLORECTAL CANCER PATIENTS AND SURVIVORS

Development and evaluation of the computer-tailored OncoActive intervention

RIANNE GOLSTEIJN



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GENERAL INTRODUCTION

Cancer is a major health problem and burden to society in developed countries. For example, although Europe contains only 9% of the world's population, it accounts for a quarter of the global cancer cases (Ferlay et al., 2018). Cancer incidence is expected to increase due to aging and growth of the population (Bray et al., 2018). In the Netherlands, over the last 2 decades yearly cancer incidence increased from 68,000 in 1998 to 116,500 new cases in 2018 (Comprehensive Cancer Center of the Netherlands (IKNL), 2018). Worldwide estimates indicate that during lifetime, one in five males and one in six females will be confronted with a cancer diagnosis (Bray et al., 2018). Prostate cancer was the most commonly diagnosed cancer in males in the Netherlands with 12,600 new diagnoses in 2018 (20.5%). Colorectal cancer ranked third both for males (7,900; 12.9%) and females (6,200; 11.2%) (Comprehensive Cancer Center of the Netherlands (IKNL), 2018).

Although cancer is the primary cause of premature death in western countries (Bray et al., 2018), fortunately, mortality decreases as a result of advances in early detection and treatment (Miller et al., 2016; Siegel, Miller, & Jemal, 2019). In the US the cancer death rate has declined with 27% from 1991 to 2016 (Siegel et al., 2019). In the Netherlands, 5-year survival rates for all cancers increased steadily from 48% in 1995 to 64% in 2015. Prostate cancer has one of the highest 5-year survival rates with 89% for all stages combined. The overall 5-year survival rate for colorectal cancer is 65%. However, survival rate vary, with lower survival rates if cancer is diagnosed at a more advanced disease stage (Comprehensive Cancer Center of the Netherlands (IKNL), 2018).

Increasing incidence and declining mortality result in a growing population of cancer survivors. In the Netherlands, the prevalence of people currently living up to 5 years after a cancer diagnosis more than doubled in the last two decades from 189,500 in 1998 to 382,600 in 2018. Prostate and colorectal cancer populations also more than doubled to 48,300 and 52,900 respectively in 2018 (Comprehensive Cancer Center of the Netherlands (IKNL), 2018). Cancer is associated with substantial healthcare expenditures, productivity losses and informal care costs. In the Netherlands, the costs of cancer on society (including informal care and productivity losses) were estimated to be 6.35 billion euro in 2009. Costs for colorectal and prostate cancer ranked second and fourth out of all cancers in the Netherlands. Healthcare expenditures accounted for a major part of total costs and were substantially higher compared to individuals without a cancer history (Luengo-Fernandez, Leal, Gray, & Sullivan, 2013; Zheng et al., 2016). As the cancer survivorship population grows, costs are expected to increase even further in the future (National Cancer Institute, 2019).

The increasing population living after cancer thus imposes a significant burden on society, as cancer and cancer treatment are associated with both acute and chronic physical, psychological and psychosocial problems (Harrington, Hansen, Moskowitz, Todd, & Feuerstein, 2010; Miller et al., 2016; Wu & Harden, 2015). Decreased muscular strength, decreased physical fitness, functional limitations, bowel dysfunction, sexual dysfunction, altered body constitution, pain, fatigue, sleep disorders, depression, anxiety, fear of recurrence, challenges with body image and cognitive limitations are often reported in a variety of cancer types including prostate and colorectal cancer (El-Shami et al., 2015; Harrington et al., 2010; Skolarus et al., 2014; Wu & Harden, 2015). Other treatment related side effects are specifically related to the type of cancer and its associated treatment. Prostate cancer patients and survivors (CPS) may experience urinary incontinence and side effects related to hormonal treatment (Miller et al., 2016; Skolarus et al., 2014). Stoma related limitations, peripheral neuropathy and nausea are more common in colorectal cancer (El-Shami et al., 2015; Miller et al., 2016). Additionally, colorectal cancer survivors have a higher risk of developing comorbidities such as type II diabetes and cardiovascular disease, second colorectal cancers and other primary cancers (Denlinger & Engstrom, 2011; Grimmett, Bridgewater, Steptoe, & Wardle, 2011; Van Blarigan & Meyerhardt, 2015). Physical activity (PA) is suggested to positively influence numerous problems associated with cancer and cancer treatment (Rock et al., 2012; Schmitz et al., 2010), and thereby to improve health and health-related quality of life (HRQoL) of prostate and colorectal CPS. The beneficial effect of PA in cancer treatment and survivorship is increasingly recognized, as described below, and accordingly indicates the need for effective interventions to improve PA. Therefore, promoting PA in prostate and colorectal CPS is the focus of this thesis.

PHYSICAL ACTIVITY AND CANCER

Although for a long time cancer patients were recommended to rest and avoid activity, in the last decades it has become clear that PA plays an important role in cancer recovery and may even improve cancer treatment and survival from cancer (Schmitz et al., 2010). PA can be defined as “any bodily movement produced by the contraction of skeletal muscles to increase energy expenditure” (Caspersen, Powell, & Christenson, 1985). It can thus include activities during leisure time, occupation, transport or household chores. A still increasing amount of studies highlights the numerous benefits of being physically active after a cancer diagnosis.

PA is consistently associated with improvements in cardiorespiratory fitness, bodily strength, body composition, physical functioning, pain, depression, anxiety, self-esteem, and quality of life both during and after primary treatment (Craft, Vaniterson, Helenowski, Rademaker, & Courneya, 2012; Fong et al., 2012; Loughney, West, Kemp, Grocott, & Jack, 2015; Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; Schmitz et al., 2010; Speck, Courneya, Masse, Duval, & Schmitz, 2010; Szymlek-Gay, Richards, & Egan, 2011). A review of systematic reviews confirmed these findings and concluded that exercise is beneficial before, during, and after cancer treatment across all cancer types. Moderate-to-vigorous exercise was found to be most optimal for improvements in physical functioning and cancer-related impairments (Stout, Baima, Swisher, Winters-Stone, & Welsh, 2017).

Studies regarding prostate and colorectal CPS specifically reported similar findings. For prostate cancer survivors positive effects of exercise on muscular strength, physical functioning, HRQoL and fatigue were reported (Menichetti et al., 2016; Thorsen, Courneya, Stevinson, & Fossa, 2008; Vashistha, Singh, Kaur, Prokop, & Kaushik, 2016). Beneficial effects of physical activity on HRQoL were also found for colorectal cancer survivors (Eyl, Xie, Koch-Gallenkamp, Brenner, & Arndt, 2018; Husson, Mols, van de Poll-Franse, & Thong, 2015; Lynch, van Roekel, & Vallance, 2016; Moug, Bryce, Mutrie, & Anderson, 2017). In addition, improvements in physical fitness, muscle strength, physical functioning and fatigue have been reported (Denlinger & Engstrom, 2011; Rock et al., 2012; van Zutphen et al., 2017). Healthcare expenditures of physically active colorectal cancer survivors were also found to be substantially lower (Yan, Wang, & Ng, 2018). Van Blarigan and Meyerhardt (2015) concluded that PA and/or structured exercise are safe and feasible for patients with colorectal cancer across the disease continuum (localized to metastatic stage, during and after treatment).

In addition to physical and psychological benefits, beneficial effects of PA regarding cancer outcomes such as cancer treatment effectiveness, cancer recurrence, cancer mortality and overall mortality are reported (Cormie, Zopf, Zhang, & Schmitz, 2017). Such outcomes are considered highly important for cancer survivors, oncologists and insurance companies, as they may be important motives for cancer survivors to engage in PA, for oncologists to prescribe PA and for insurance companies to reimburse PA programs (Courneya, 2014). Reviews examining the relation between PA and cancer outcomes found that patients who were physically active after a cancer diagnosis had a lower relative risk of cancer mortality and recurrence and experienced fewer or less severe adverse effects in comparison to those who were not physically active (Cormie et al., 2017; Li et al., 2016).

In reaction to the abundant benefits of PA in cancer treatment and survivorship, PA guidelines for cancer patients and survivors have been established in several countries. International guidelines in general state that cancer patients and survivors should aim to be physically active (moderate to vigorous) for at least 150 minutes per week (Buffart, Galvao, Brug, Chinapaw, & Newton, 2014). In the Netherlands CPS are advised to adhere (if possible) to the general Dutch PA guidelines, which at the time of starting this study, required them to be physically active with moderate to vigorous intensity for at least 30 minutes a day on at least five days per week (Stuiver, Wittink, Velthuis, Kool, & Jongert, 2011).

Despite all positive effects of PA during and after cancer treatment, only a minority of CPS adheres to PA guidelines. Between 29 and 47% of prostate cancer survivors is meeting PA guidelines (Blanchard, Courneya, & Stein, 2008; Chipperfield et al., 2013; Coups & Ostroff, 2005; Galvao et al., 2015; LeMasters, Madhavan, Sambamoorthi, & Kurian, 2014). Numbers in colorectal survivors are even lower with 20-40% (Blanchard et al., 2008; Chung et al., 2013; Coups & Ostroff, 2005; Hawkes, Lynch, Youlden, Owen, & Aitken, 2008; LeMasters et al., 2014; Stephenson, Bebb, Reimer, & Culos-Reed, 2009). PA levels are known to decline during treatment and do not reach pre-treatment levels after completing treatment (Courneya, Karvinen, & Vallance, 2007; Fassier et al., 2016; Szymlek-Gay et al., 2011). In addition, guideline adherence decreases with age and poorer health status (Chipperfield et al., 2013; Tarasenko, Chen, & Schoenberg, 2017). Low PA levels in the population thus implicate that the majority does not take full advantage of the positive effects of PA during and after treatment. Interventions to increase PA in CPS are thus warranted.

It should be noted that most studies examining guideline adherence in cancer populations are based on self-report questionnaires. Such questionnaires are prone to over-reporting, indicating that guideline adherence may be even lower when assessed with more objective measures (Roberts, Fisher, Smith, Heinrich, & Potts, 2017; Smith et al., 2019; Vassbakk-Brovold et al., 2016). A study among US cancer survivors showed for example that based on accelerometer measures, only 2% of colorectal cancer survivors and 13% of prostate cancer survivors met PA guidelines (Thraen-Borowski, Gennuso, & Cadmus-Bertram, 2017). The latter therefore indicates that it is important to measure PA in a valid and reliable manner.

Physical activity measurement

PA is a complex behavior which is commonly described in four dimensions: frequency, duration, type and intensity. Frequency can be defined as the number of times that a certain activity is performed, duration involves the length of time that an activity is performed. With regard to type of activity, a distinction can be made into aerobic, strength, flexibility or balance. Intensity refers to physical effort needed to perform a certain activity (Warren et al., 2010; World Health Organization, 2010). Intensity is commonly expressed in metabolic equivalents (METs). Arbitrary cut points are used to classify activities into categories such as sedentary (≤ 1.5 MET), light (1.6-2.9 MET), moderate (3.0-5.9 MET) and vigorous (≥ 6.0 MET) (Warren et al., 2010; World Health Organization, 2010). Besides these four dimensions, it may also be interesting to assess the domain in which activity takes place. Domains are often distinguished in household, occupation, transportation and leisure (Warren et al., 2010). Leisure time PA includes activities like yard work, home repair, walking and cycling for leisure, and sports (Caspersen et al., 1985; Wendel-Vos, Schuit, Saris, & Kromhout, 2003).

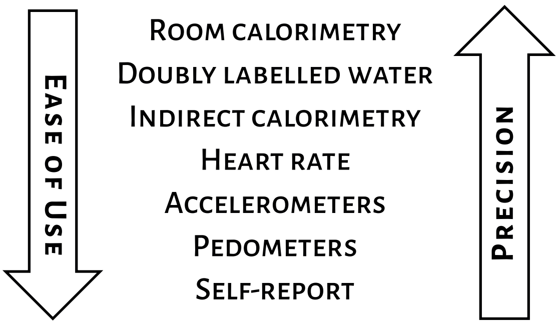

Figure 1 Precision and ease of use of PA measures (adapted from Broderick et al. (2014))

Due to this multifaceted nature of PA, assessment is complex and no single method can capture all subcomponents and domains of the activity of interest (Broderick, Ryan, O'Donnell, & Hussey, 2014; Warren et al., 2010). There are a number of possible measures to assess various PA outcomes. Broderick et al. (2014) suggested a continuum of PA measures with precision of measurement at one end and ease of use at the other (Figure 1). For the selection of an assessment tool it is important to consider research hypothesis, study design and participant burden (Broderick et al., 2014). In large-scale studies, self-report PA questionnaires and activity monitors are the most commonly used measures to assess PA behavior.

To date, both observational and large-scale intervention studies regarding PA mainly relied on self-report PA as such measures are relatively inexpensive and participants can easily administer them on their own. Due to recent developments in technology, activity monitors are increasingly used to measure PA. Activity monitors are regarded to provide a more accurate and objective estimate of PA (Corder, Brage, & Ekelund, 2007; Warren et al., 2010). Pedometers and accelerometers are examples of activity monitors. Whereas pedometers may be cheaper, their only outcome is step counts, thus making them less feasible as assessment tool in research, indicating a preference for accelerometers (Corder et al., 2007).

In theory, PA measurement techniques in the general population should be transferable to cancer populations (Broderick et al., 2014), implying that questionnaires used to assess PA in the general population can also be used in cancer populations. However, only few studies in cancer populations have compared self-report questionnaires to accelerometers in CPS and findings from these studies were mixed (Boyle, Lynch, Courneya, & Vallance, 2015; Vassbakk-Brovold et al., 2016). Therefore, we examined the validity of a frequently used questionnaire to assess PA and PA intervention effectiveness in the Netherlands (i.e., the Short Questionnaire to Assess health-enhancing PA; SQUASH) in prostate and colorectal CPS, as described in **chapter 2**.

Determinants of physical activity

As mentioned above, the low adherence to PA guidelines in a cancer population warrants interventions to improve PA. In order to develop such interventions, it is important to have insight into factors that determine PA. However, research regarding factors that motivate or form barriers to PA in CPS is limited (Husebo, Dyrstad, Soreide, & Bru, 2013). In general, PA behavior is affected by a broad range of factors which are often interrelated to each other as described in several well-known models and theories (Brug, van Assema, & Lechner, 2017; Peels, 2014). The Theory of Planned Behavior (TPB), and its successor the Reasoned Action Approach (RAA), have often been used to explain PA. According to these theories, intention to perform PA is the most proximal predictor of actual behavior, and intention in turn, is influenced by attitude, subjective norms and perceived behavior control. The latter may also influence PA directly (Ajzen, 1991; Fishbein & Ajzen, 2010).

Several studies in cancer populations have shown that attitude, subjective norms and perceived behavior control indeed predict intention to engage in PA and PA behavior

(Andrykowski, Beacham, Schmidt, & Harper, 2006; Basen-Engquist, Perkins, & Hughes, 2012; Blanchard, Courneya, Rodgers, & Murnaghan, 2002; Courneya, Friedenreich, Arthur, & Bobick, 1999; Courneya & Friedenreich, 1997; Courneya et al., 2007; Hunt-Shanks et al., 2006; Keogh et al., 2010; Pinto & Ciccolo, 2011; Speed-Andrews et al., 2012). A study in mixed cancer survivors showed that attitude and perceived ability to comply with PA guidelines were predictors of PA (Kanera, Bolman, Mesters, et al., 2016). A review that examined behavioral predictors of PA in cancer patients found intention and perceived behavior control to be significantly correlated to PA (Husebo et al., 2013). A study examining TPB constructs for physically active and insufficiently active cancer survivors separately, indicated that for the latter group attitude predicted PA intention, whereas for the physically active group PA intention was predicted by subjective norm (Ungar, Sieverding, Ulrich, & Wiskemann, 2015).

Forbes, Blanchard, Mummery, and Courneya (2014) reported that TPB constructs attitude, subjective norm and perceived behavioral control were indeed predictors of intention in prostate and colorectal survivors. Intention predicted PA in colorectal cancer survivors. For prostate cancer survivors, intention predicted planning (added to the model as a mediator), which subsequently predicted PA. In addition, perceived behavior control also directly predicted PA.

Perceived behavioral control is very similar to self-efficacy, a key construct of Social Cognitive Theory (SCT); another theory which has been studied in relation to PA in CPS (Husebo et al., 2013). According to SCT, PA is determined by the confidence to perform PA (self-efficacy) and the belief that engaging or not engaging in PA results in a specific outcome (outcome expectations; a construct closely related to attitude) (Bandura, 1986). Studies in cancer populations, including prostate and colorectal CPS showed that self-efficacy and outcome expectations were important determinants of PA behavior (Hawkes, Patrao, Baade, Lynch, & Courneya, 2015; Kanera, Bolman, Mesters, et al., 2016; Pinto & Ciccolo, 2011; Stacey, James, Chapman, Courneya, & Lubans, 2015).

Another theory that has been examined and used in PA interventions for cancer survivors is the Transtheoretical Model (TTM) (Husebo et al., 2013). TTM analyses the processes undergone by an individual when trying to improve PA, consisting of several stages of change (Prochaska & DiClemente, 1983). Stage of change is an important predictor of PA and of change in PA after a cancer diagnosis (Green, Steinnagel, Morris, & Laakso, 2014; Hawkes et al., 2015). In addition, a meta-analysis also found stage of change to be a strong predictor of exercise (Husebo et al., 2013).

Nevertheless, those theoretical models separately only partly explain the variance in PA or only show weak to moderate correlations to PA (Forbes et al., 2014; Husebo et al., 2013; Stacey et al., 2015), indicating that other determinants may also play a role. The I-Change model (De Vries, Mesters, van de Steeg, & Honing, 2005) integrates the above mentioned theoretical models and in addition incorporates more distal determinants (i.e., pre-motivational determinants like awareness of risk behavior, knowledge, and risk perception) and more proximal determinants (post-motivational determinants like goal setting, action planning, and coping planning to address the intention-behavior gap). Evidence from a systematic review suggested that cancer survivors lack knowledge and information about why PA could be important for them. They often do not know which PA is safe, effective, and how much PA they should perform (i.e., guidelines) (Clifford et al., 2018). A study in general adults showed that risk perception and cognizance (i.e., awareness about own behavior) are important to improve motivation (Kasten, van Osch, Candel, & de Vries, 2019). In addition, both action and coping planning were found to influence PA intention and PA in colorectal cancer survivors (Packel, Prehn, Anderson, & Fisher, 2015).

Although theoretical models may similarly explain PA in the general population and in CPS, PA determinants like attitude, confidence, social support, benefits, and barriers may be influenced by cancer variables such as cancer type, type of treatment, and stage of disease (Courneya, 2014). As CPS suffer from substantial physical and psychological complaints as a result of cancer and cancer treatment, it seems very likely that they experience barriers specifically related to their situation. Several studies indeed identified barriers specific for cancer survivors, such as fatigue, lack of energy, urinary incontinence, diarrhea, hand-foot syndrome, skin irritation, and other physical side effects that may depend on type of treatment (e.g., chemotherapy, radiation) (Charlier et al., 2012; Clifford et al., 2018; Eng et al., 2018; Menichetti et al., 2016; Romero-Elias, Gonzalez-Cutre, Beltran-Carrillo, & Cervello, 2017; Stone, Courneya, McGregor, Li, & Friedenreich, 2018). Higher levels of anxiety and depression were associated with lower levels of PA (Romero-Elias et al., 2017).

Motives or facilitators of PA may also be related to cancer. Craike, Livingston, and Botti (2011) mentioned perceived psychological and physical benefits as motives for improving PA. According to a study of Courneya, Jones, Mackey, and Fairey (2006) most cancer survivors believe that PA could improve energy level and well-being, helps to get their mind off of cancer, and that PA may reduce the risk of cancer recurrence. A mixed methods systematic review identified feeling control over health and managing emotions and mental well-being as important facilitator

(Clifford et al., 2018). A study of van Putten et al. (2016) indicated that those who performed more PA showed less fatigue and chemotherapy related side effects. The latter, could motivate others to improve PA. Within the context of this thesis, specific barriers and benefits of PA for prostate and colorectal CPS are discussed in **chapter 3.**

Besides behavioral determinants, demographic, health, and lifestyle variables such as age, gender, educational level, employment status, comorbidity, and past PA behavior, may also be associated with PA (Buffart et al., 2012; Charlier et al., 2013; Craike et al., 2011; Hawkes et al., 2015; Kanera, Bolman, Mesters, et al., 2016; Menichetti et al., 2016; Romero-Elias et al., 2017). Although such variables are not changeable, it may still be important to take them into account when trying to improve PA.

IMPROVING PHYSICAL ACTIVITY IN CANCER POPULATIONS

As a cancer diagnosis is regarded as a 'teachable moment' for behavior change, this period provides an important opportunity to promote a healthy lifestyle including improving PA (Blaney, Lowe-Strong, Rankin-Watt, Campbell, & Gracey, 2013; Bluethmann, Basen-Engquist, et al., 2015; LeMasters et al., 2014). In addition, several studies showed that a majority of CPS felt able and were interested in participating in a PA or exercise program (Basen-Engquist, Carmack, et al., 2012; Demark-Wahnefried, 2000; Szymlek-Gay et al., 2011; Wong, McAuley, & Trinh, 2018).

The term exercise is sometimes used interchangeably with physical activity. However, exercise actually is a subcategory of PA that can be defined as "planned, structured, and repetitive bodily movement done to improve or maintain one or more components of physical fitness" (Caspersen et al., 1985). The research field of PA and cancer originated from exercise physiology, therefore most studies regarding PA and cancer examined structured exercise programs (Courneya, 2009). Literature also distinguishes 'health outcomes trials', which mostly concern structured exercise programs assessing physical or psychological health outcomes (e.g., physical fitness, fatigue), and 'behavior change trials' aimed at improving and thus assessing PA (Courneya, 2010). As PA has positively influenced long-term health as described previously, changing PA behavior may be regarded crucial in improving cancer patients' and survivors health.

However, studies motivating patients to implement lifestyle changes in their daily life and thus reporting changes in PA outcomes are limited (Menichetti et al., 2016). Reviews regarding breast cancer patients indicated beneficial effects of interventions in terms of increasing PA (Bluethmann, Vernon, Gabriel, Murphy, & Bartholomew, 2015; Short, James, Stacey, & Plotnikoff, 2013). A review considering various cancer types also found significant improvements in PA, however it should be noted that again the majority of included studies were targeted at breast cancer populations (Stacey et al., 2015). Recently, reviews regarding PA behavior change interventions in prostate cancer and colorectal CPS also found preliminary evidence for short-term improvements in PA (Finlay, Wittert, & Short, 2018; Moug et al., 2017). However, at the time of the start of the current project, no studies were conducted in these patient groups in the Netherlands, indicating the relevance of developing PA interventions specifically for them.

Physical activity behavior change techniques and program preferences

Effective behavior change interventions are suggested to be based on theory and incorporate behavior change techniques (Bluethmann, Bartholomew, Murphy, & Vernon, 2017; Gourlan et al., 2016). A recent review regarding PA in cancer survivors reported behavior change techniques such as prompts, gradually reducing prompts, graded tasks, non-specific reward, and social reward to generate larger effects. Self-monitoring was a borderline significant predictor of larger effects (Finne et al., 2018). Turner et al. (2018) in their review found that interventions that improved PA included program goal setting, setting graded tasks, and instruction on how to perform the behavior. According to Pinto and Ciccolo (2011), social-cognitive techniques for self-management, increasing self-efficacy, developing realistic outcome expectations, increasing intention and developing plans in line with motivational readiness are key concepts in a PA program for CPS. Modeling to increase self-efficacy, emphasizing benefits and fun (strengthening attitude), and informing significant others about the importance of PA (subjective norms) are important intervention components according to the Dutch cancer rehabilitation guideline (Comprehensive Cancer Center of the Netherlands (IKNL), 2011).

In addition to using effective behavior change techniques, it is important to consider the preferences of the target population. Several studies and a recent review of 41 studies indicated that PA at moderate intensity was preferred, with walking being the preferred exercise mode (Buffart et al., 2014; McGowan et al., 2013; Murnane, Geary, & Milne, 2012; Wong et al., 2018). The majority prefers an unsupervised, home-based PA program that can be done in the morning. Notwithstanding the preference for a home-based program, it was also highlighted that there was a wide variation for other PA preferences, indicating the need for tailored solutions (Wong et al., 2018). Hardcastle and Cohen (2017) also suggested that home-based, unsupervised PA interventions that are tailored to cancer survivors' needs and preferences may be needed to achieve sustained behavior change. Behavior change techniques and program preferences are important to take into account when developing an intervenion for CPS, as described in **chapter 3**.

eHealth interventions for physical activity promotion

In light of the rapidly growing population living with or after cancer and the preference for home-based PA programs, as illustrated above, there is a clear need for affordable PA programs that are easily accessible and in which you can participate from your own home. Cancer survivors, healthcare providers, insurers and policy makers are increasingly interested in eHealth solutions to improve supportive cancer care (Aaronson et al., 2014). eHealth can be defined in various manners, but in the Netherlands most often the definition of the Council for Health and Society is used: "eHealth is the use of new information and communication technologies, especially internet technology, to support and improve health and healthcare" (van Reijen, de Lint, & Ottes, 2002).

With rapid increases in internet access in recent years, preconditions for the use of web-based interventions have improved substantially. In 2016, 94% of the Dutch population had internet access and eHealth applications were increasingly used, especially by adults aged over 65 and adults with a chronic disease (Centraal Bureau voor de Statistiek (CBS) [Statistics Netherlands], 2017; Krijgsman et al., 2016). Research also indicates that cancer surivors increasingly use the internet as a source of information (Chou, Liu, Post, & Hesse, 2011; Shea-Budgell, Kostaras, Myhill, & Hagen, 2014). A majority of Dutch cancer survivors showed a positive attitude towards eHealth for healthy lifestyle information or programs (Jansen, van Uden-Kraan, van Zwieten, Witte, & Verdonck-de Leeuw, 2015).

Promising results have been found for improving PA through eHealth interventions. Kanera, Bolman, Willems, Mesters, and Lechner (2016) reported significant improvements in PA of moderate intensity shortly after the end of a web-based, multidomain, self-management cancer aftercare intervention and at long term follow-up (Kanera et al., 2017). A meta-analysis regarding distance-based PA intervention without face-to-face contact (including print materials, telephone counseling and web-based platforms) found a small significant effect of 0.21 in favor of interventions for moderate to vigorous PA (MVPA) predominantly based on self-report (Groen, van Harten, & Vallance, 2018). However, most of the included studies used print or telephone delivery modes and only few used mobile or eHealth platforms. Another meta-analysis was conducted specifically on digital behavior change interventions using technologies like text messaging, email, mobile applications, websites or online portals (Roberts et al., 2017). Significant improvements in self-reported MVPA both for RCTs (49 minutes) and pre-post studies (30 minutes) were found. In addition, effects on health-related outcomes showed a non-significant trend for improvements in fatigue, but not in HRQoL, mental health and sleep disturbance. A third review regarding the use of eHealth to promote PA in cancer survivors did not perform a meta-analysis, but reported that 8 out of 10 included studies showed significant improvements in PA (Haberlin et al., 2018).

Using the internet for promoting PA has several benefits, including convenience for users with information and support being accessible at any time, the ability to access information anonymously, the potential to reach large groups, ease of updating information, use of interactive tools such as video, graphics, animations or hyperlinks, and the ability to provide personalized feedback (Corbett et al., 2018; Haberlin et al., 2018; Kanera, 2018; Kuijpers, 2015).

As discussed above, PA interventions should preferably be tailored to cancers survivors' needs and preferences to address the high variety of needs within the population (Buffart et al., 2014; Hardcastle & Cohen, 2017). Computer-tailoring provides opportunities to tailor content to the individual within eHealth interventions (Webb, Joseph, Yardley, & Michie, 2010). Intervention content can easily be adapted to the specific characteristics of a patient to provide personalized feedback and thus increase personal relevance. As illustrated in Figure 2, questionnaires are used to assess characteristics, beliefs, behavior, etc., of the individual participants. Subsequently, this assessment is used to create feedback by using a message library and computer-based if-then algorithms to select the right messages. The feedback is personalized and automatically tailored to the personal characteristics of the participant and can thus also be tailored to cancer-specific needs and beliefs in a PA program (Krebs, Prochaska, & Rossi, 2010; Kreuter & Skinner, 2000).

Despite all benefits, providing computer-tailored interventions over the internet may also have some limitations. Sufficient eHealth literacy, i.e., the ability to seek, find, understand and appraise health information from electronic resources and apply that knowledge to solving a health problem or making a health-related decision

(Norman & Skinner, 2006), is important for eHealth interventions to be succesfull. Studies showed that older age and lower socioeconomic status (SES) are related to lower eHealth literacy (Neter & Brainin, 2012) and that older adults may lack skills and knowledge needed for the use of eHealth interventions (Choi & Dinitto, 2013). In addition, internet access in the Netherlands decreases substantially from the age of 75 (60% compared to 90% among 65-to-75-year olds in 2016) and frequency of internet use is also substantial lower with increasing age (Centraal Bureau voor de Statistiek (CBS) [Statistics Netherlands], 2017). As cancer is often diagnosed at an older age, a substantial part of cancer survivors may not have access to web-based interventions and may thus not benefit from them. Therefore, it may be important to provide PA information both through the internet and on paper (Kamel Ghalibaf, Nazari, Gholian-Aval, & Tara, 2019). Computer-tailoring provides the opportunity to provide personalized information both online and in print. In **chapter 4** we examined the participant characteristics of using online and print intervention materials.

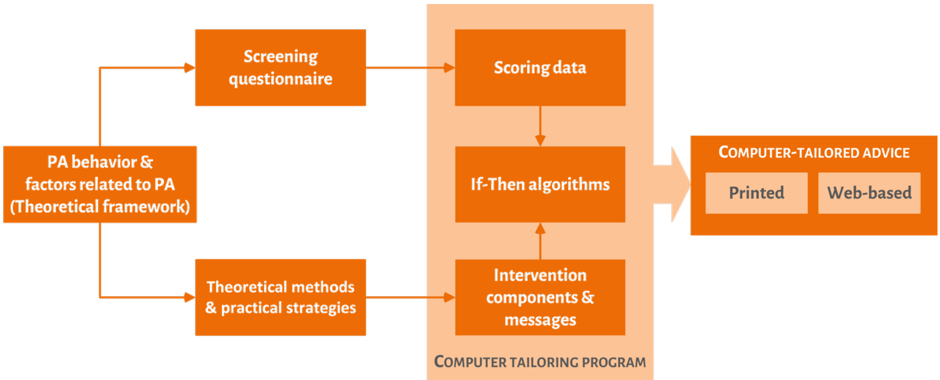

Figure 2 Computer-tailoring procedure (adapted from Peels (2014))

The Active Plus intervention

A computer-tailored PA intervention that provided participants with print- and web-based intervention materials was developed previously. This program, called ActivePlus, was developed to stimulate PA among people aged over 50 (Peels, van Stralen, et al., 2012; van Stralen et al., 2008). In a first project, a computer-tailored intervention to provide PA advice and environmental information regarding PA was systematically developed using Intervention Mapping (van Stralen et al., 2008). PA advice was delivered through print materials. This intervention proved to be succesfull in improving PA up to a year after the start of the intervention (van Stralen, de Vries, Mudde, Bolman, & Lechner, 2009, 2011). In a second stage, the original Active Plus intervention was systematically translated to a web-based version, using the results of the evaluation of the print-based version (Peels, van Stralen, et al., 2012). Both the print-based and web-based version were studied in a randomized controlled trial (RCT). Results showed that although at 6 months after the start of the intervention both interventions were effective in increasing PA, PA was only maintained on the long-term in the print-based versions (Peels, Bolman, et al., 2013a; Peels et al., 2014). Process evaluation showed that print materials were used more often and appreciated better (Peels, de Vries, et al., 2013).

The Active Plus intervention had several characteristics that provide a good starting point for a computer-tailored PA intervention for prostate and colorectal CPS. Cancer is often diagnosed at older ages: the median age for a prostate or colorectal cancer diagnosis are 66 and 68 years respectively, and more than 96% of CPS are aged fifty and over (Miller et al., 2016). By being effective in stimulating PA in older adults, the Active Plus intervention provides a promising opportunity. Moreover, Active Plus is aimed at changing PA behavior in daily life and can be followed home-based, which is highly relevant for CPS as illustrated previously. However, adaptations are necessary as cancer and cancer treatment may influence determinants of PA. The Intervention Mapping protocol was used to systematically adapt the Active Plus intervention for prostate and colorectal CPS into the OncoActive intervention as described in **chapter 3**.

ONCOACTIVE PROJECT

The need for easy accessible and affordable interventions to improve PA in CPS has already been stressed before. In the Netherlands however, at the time of the start of the OncoActive project, most PA programs were hospital/healthcare-based, supervised exercise programs, which are demanding for both patients and health care professionals. Besides being costly, CPS may also be unable (e.g., due to distance/transportation difficulties) or unwilling to attend such facility-based programs (Courneya, 2009).

Facility-based programs are often aimed at exercise with little attention for other forms of PA. Although such programs are valuable as there is extensive evidence for improvements in cancer outcomes and treatment related side effects (e.g., fatigue, depression) and HRQoL (Bourke et al., 2016; Davies, Batehup, & Thomas, 2011; Fong et al., 2012; Schmitz et al., 2010; Stout et al., 2017), few of such programs examined effects with regard to PA behavior (Courneya et al., 2012; Stout et al., 2017). Possibly, because they are not aimed at integrating PA into daily life and may lack real world application after ending the program (Lahart, Metsios, Nevill, Kitas, & Carmichael, 2016; Stacey, Lubans, Chapman, Bisquera, & James, 2017).

As a result, the OncoActive project was initiated. Within this project a computer-tailored intervention aimed at increasing awareness, initiation and maintenance of PA in prostate and colorectal CPS was developed. As mentioned above, the effective evidence-based Active Plus intervention provided a solid starting point. The intervention was aimed at only two cancer types in order to be able to better fine-tune the intervention to the specific needs and capabilities of the target group. Prostate and colorectal were chosen because they represent a substantial proportion of the total cancer survivorship population in the Netherlands as described previously. In addition, five year survival rates of 88-99% for prostate cancer and 62-65% for colorectal cancer are relatively high (Comprehensive Cancer Center of the Netherlands (IKNL), 2018; Miller et al., 2016). Although breast cancer is more prevalent and may have better survival rates, historically research was mainly focused on breast cancer resulting in limited evidence for other cancer types. Recognizing this lack of knowledge and thus also practical interventions for other cancer types, it was decided to target the OncoActive intervention at prostate and colorectal cancer.

Although the process of adapting the intervention is described in detail in **chapter 3**, some adaptations were already suggested at the time of drafting the research proposal. As monitoring and goal setting are associated with larger effects (Finne et al., 2018; Turner et al., 2018), we explored options to strengthen these behavior change techniques. Research in general populations (Bravata et al., 2007; Donnachie, Wyke, Mutrie, & Hunt, 2017; Kang, Marshall, Barreira, & Lee, 2009; Koring et al., 2013) and specifically with CPS (De Cocker et al., 2015; Knols, de Bruin, Shirato, Uebelhart, & Aaronson, 2010; Vallance, Courneya, Plotnikoff, Dinu, & Mackey, 2008) revealed that pedometers could be a valuable application for self-monitoring of PA behavior and goal setting. Therefore, pedometers were integrated in the OncoActive intervention. By providing participants with instructions for monitoring, goal setting and adjusting goals, they are encouraged to self-regulate their PA behavior.

Further detail regarding OncoActive intervention development and evaluation is described in the separate chapters in this thesis as outlined below.

Aim and outline

The main aims of this thesis are: (1) to compare self-report PA and accelerometer-measured PA in prostate and colorectal CPS, (2) to provide insight in the development of OncoActive, (3) to evaluate characteristics of intervention use, and (4) to study intervention efficacy. An overview of the different studies in this thesis is provided in Table 1.

As discussed previously, valid and reliable PA measurement is important. Therefore, PA according to the SQUASH questionnaire was compared to accelerometer outcomes in a population of prostate and colorectal CPS to examine its validity as described in **chapter 2**. As the SQUASH questionnaire is also often used to assess intervention effects over time, this study also assessed the ability to detect changes in PA over time (i.e., responsiveness) in the OncoActive intervention.

In **chapter 3** the development of the OncoActive intervention using the Intervention Mapping protocol is described. Interviews with both cancer survivors and healthcare professionals were conducted and this information was taken into account in the development process. A pretest with survivors and healthcare professionals was conducted to evaluate intervention materials in terms of usability, appropriateness and safety. In addition, a small scale pilot-test was conducted in which the intervention was followed by a small group of CPS during a shortened time period.

As the OncoActive intervention was delivered both in print materials and through a website, participant characteristics in relation to delivery mode and use of print- or web-based materials were examined in **chapter 4**. This information may be useful for further implementation of the intervention.

The efficacy of OncoActive was examined in a RCT. Effects regarding PA and health-related outcomes including fatigue, distress (anxiety and depression), and HRQoL (physical functioning and overall HRQoL) at 3 and 6 months are described in **chapter 5**. Exploratory, effects in several subgroups were examined.

As previous research has shown the positive effects of PA on cancer outcomes such as recurrence and mortality and on possible comorbidities, it is important that improvements in PA are maintained on the long-term. Therefore, the long-term effects of OncoActive are described in **chapter 6**. In this study, it was assessed whether intervention effects regarding PA and health-related outcomes at 6 months were maintained at the 12 month follow-up measurement. Again, differences in subgroups were examined exploratory.

This thesis concludes with a general discussion presented in **chapter 7**. In this chapter main findings of this thesis are summarized and integrated. Methodological considerations as well as directions for future research are described.

Table 1 *Overview of the studies in this thesis*

Chapter	Objectives	Design & Follow-up	Sample	Sample size	Method of data collection
2	To compare the Short Questionnaire to Assess Health-enhancing PA (SQUASH) to accelerometer-measured PA in prostate and colorectal CPS cross-sectionally and to detect changes in PA	Longitudinal, 6 months	Prostate & colorectal CPS	n = 360	Questionnaire & ActiGraph
3	To describe the systematic development including pre- and pilot study, and study design for evaluation of OncoActive	Cross-sectional, interviews and pretest	Prostate & colorectal CPS	n = 29	Interviews & questionnaire
			Healthcare professionals	n = 15	Interviews & questionnaire
		Longitudinal, pilot study	Prostate & colorectal CPS	n = 21	Questionnaire & ActiGraph
4	To assess OncoActive participants' characteristics related to delivery mode and use of intervention materials	Longitudinal, 3 and 6 months	Prostate & colorectal CPS	n = 249	Questionnaire
5	To evaluate the overall and subgroup efficacy of OncoActive at 3 (during) and 6 months (2 months after intervention) with regard to PA and health-related outcomes including fatigue, anxiety, depression, physical functioning, and HRQoL	Longitudinal, 3 and 6 months	Prostate & colorectal CPS	n = 478	Questionnaire & ActiGraph
6	To assess if short-term effects of OncoActive regarding PA, fatigue, depression, and physical functioning are maintained on the long-term	Longitudinal, 6 and 12 months	Prostate & colorectal CPS	n = 478	Questionnaire & ActiGraph

2

PHYSICAL ACTIVITY MEASUREMENT IN PROSTATE AND COLORECTAL CANCER PATIENTS AND SURVIVORS: A LONGITUDINAL VALIDATION STUDY

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ABSTRACT

Background

Since physical activity (PA) can improve physical and psychological health of cancer patients and survivors (CPS), valid PA measurement is of major importance. This study aimed to assess the validity of the Short Questionnaire to Assess Health-enhancing PA (SQUASH) in prostate and colorectal CPS. Since evidence of self-report questionnaires being able to detect PA changes in longitudinal or intervention studies (i.e., responsiveness) is scarce, validity for PA change was also assessed.

Methods

Prostate and colorectal CPS (n=478) wore an ActiGraph GT3X-BT and completed the SQUASH afterwards at baseline and 6 months. Validity and responsiveness were assessed using Spearman's rho, intraclass correlation coefficients (ICC) and Bland-Altman plots. Additionally, agreement, sensitivity and specificity for classifying participants as having increased their PA (κ-statistic) were assessed.

Results

At baseline, both measures correlated moderately for moderate-to-vigorous PA (MVPA; rho=.356) and the number of days with ≥ 30 min PA (rho=.387). Agreement was better for days with PA (ICC=.553) than for MVPA (ICC=.271). Bland-Altman plots showed substantial higher MVPA for the SQUASH compared to the ActiGraph. Correlation and agreement for PA change were low, but increased when both measurements concerned the exact same week at both time points. Classification of individual participants having increased their PA was poor.

Conclusions

Validity of the SQUASH is reasonable and comparable to other self-report questionnaires but absolute values are substantially higher. Individual level classification of PA change was limited, but group level classification of PA change was reasonably valid, particularly when both measurements concern the exact same week.

BACKGROUND

In 2012, over 14 million people were newly diagnosed with cancer. As a result of aging and advances in early detection and cancer treatment, the number of people confronted with a diagnosis is expected to increase even more in the near future (Ferlay et al., 2015). Cancer patients and survivors (CPS) are often confronted with several negative health effects as a result of their disease and treatment, in both the short- and long-term (Harrington et al., 2010). An increasing amount of research shows that physical activity (PA) can improve disease symptoms and treatment-related side effects. PA improves cardiorespiratory fitness and health-related quality of life (HRQoL) and reduces fatigue, pain, distress, anxiety, and depression both during and after active treatment (Cormie et al., 2017; Fong et al., 2012; Speck et al., 2010). PA is also a preventive factor for the development of other chronic diseases and comorbidities for which cancer survivors are at risk (e.g., obesity, coronary heart disease, diabetes), as well as secondary or new cancers, or cancer recurrence (Cormie et al., 2017; Speck et al., 2010).

As PA is associated with many positive health effects, increasing PA behavior is of major importance in a population of CPS. Effective interventions aimed at increasing and maintaining PA should be developed and evaluated. Valid and reliable measures to assess PA levels are highly needed and necessary to gain insight into PA behavior of CPS and to accurately measure intervention efficacy.

Commonly used PA measures include self-report PA questionnaires and accelerometers. Both measures have their strengths and limitations, and the preference for a measure also depends on the study objective (Broderick et al., 2014). Questionnaires are frequently used in large-scale PA intervention studies, as they are relatively inexpensive and participants can easily administer them on their own. Besides being a research instrument, PA self-report questionnaires can also be used as a base in the delivery of computer-tailored interventions to stimulate PA. Questionnaires are able to provide detailed information regarding type of PA (e.g., occupational PA, transportation PA, leisure time PA), frequency and duration of specific PA behaviors. Such specific information is particularly useful in targeting and tailoring PA interventions and cannot be obtained from accelerometers. However, self-report PA questionnaires are known for their overestimation of PA which might occur due to misclassification of activities, double reporting, recall bias, and social desirability (Helmerhorst, Brage, Warren, Besson, & Ekelund, 2012).

Due to recent developments in technology, accelerometers are increasingly used to measure PA. Accelerometers measure the quantity and intensity of movement, which are registered in counts. Algorithms are used to translate counts into meaningful measures such as the time spent in sedentary, light, moderate, or vigorous activity. Although accelerometers result in objective PA measurements, they also have their limitations; they do not provide information on the type of activity and they are limited in the measurement of swimming/water-based activities (due to not being waterproof), cycling, step/inclined activity, or strength exercises (Broderick et al., 2014; Helmerhorst et al., 2012). Nevertheless, accelerometers are regarded as providing more accurate and objective estimates of physical activity (Broderick et al., 2014).

Studies conducted in the general population have shown that self-report questionnaires have a low to moderate construct validity in measuring PA when compared to objective measures like accelerometers (van Poppel, Chinapaw, Mokkink, van Mechelen, & Terwee, 2010). Only a few studies have compared self-report questionnaires to accelerometers in CPS and findings from these studies were mixed. Spearman correlations between both measures ranged from .05 to .71 (Boyle et al., 2015; Lewis, Hernon, Clark, & Saxton, 2017; Liu et al., 2011; Pinto, Papandonatos, Goldstein, Marcus, & Farrell, 2013; Su, Lee, Yeh, Kao, & Lin, 2014; Ungar, Sieverding, Weidner, Ulrich, & Wiskemann, 2016). As studies were performed using different questionnaires, using different outcome measures (e.g., activity scores, time in moderate to vigorous PA (MVPA), total PA), and among different populations of CPS (e.g., colorectal, breast, mixed) it is difficult to draw conclusions and additional research is necessary.

In addition, self-report questionnaires should also be able to detect changes in PA when used in longitudinal or intervention studies. Little research has been done regarding the responsiveness (i.e., the ability of an instrument to detect change over time) of self-report PA questionnaires in general and among CPS specifically. To the best of our knowledge, the few studies that compared PA change assessed by a self-report PA questionnaire to accelerometer data showed mixed findings regarding the validity to assess change in PA. Two studies found moderate correlations of .35 (Ungar, Sieverding, et al., 2016) and .52 (Cleland et al., 2014), whereas two other studies found both measures to be largely uncorrelated (Hoos, Espinoza, Marshall, & Arredondo, 2012; Nicaise, Crespo, & Marshall, 2014).

A self-report questionnaire that is commonly used in the Netherlands is the Short Questionnaire to Assess Health-enhancing Physical Activity (SQUASH)

(Wendel-Vos et al., 2003). This questionnaire is also used in a computer-tailored PA program to stimulate and maintain PA in prostate and colorectal CPS (Golsteijn, Bolman, Volders, et al., 2017). The questionnaire contains questions regarding transportation-, occupation-, household-, and leisure time activities and was found to be reasonably valid in a general adult population (r = .45) (Wendel-Vos et al., 2003) and in patients with ankylosing spondylitis (r = .35) (Arends et al., 2013) when compared to an accelerometer. For patients after total hip arthroplasty, Spearman correlations of.40 and .35, respectively, for time in moderate and vigorous activities were found (Wagenmakers et al., 2008), whereas correlations ranging from .08 to .41 were found in a Dutch multi-ethnic population (Nicolaou et al., 2016). Furthermore, a study among patients with mixed types of cancer found a Pearson correlation of .71 for time in MVPA for a modified version of the SQUASH, indicating a high validity (Ungar, Sieverding, et al., 2016). However, the latter study had a relatively small sample size, included only inactive CPS, and only examined validity regarding MVPA. Therefore, the aim of the current study is to compare self-reported and accelerometer-based measures of moderate- and vigorous PA in a study with a large sample size. As very little research has been done regarding responsiveness, the secondary aim of the current study is to examine the responsiveness of the SQUASH questionnaire to detect changes in PA.

METHODS

This study was conducted within the OncoActive intervention study, a randomized controlled trial (RCT) to assess the effectiveness of a computer-tailored PA intervention for prostate and colorectal cancer patients and survivors. A detailed description of the intervention and the RCT can be found elsewhere (Golsteijn, Bolman, Volders, et al., 2017). The RCT was approved by the Medical Ethics Committee of the Zuyderland hospital (NL47678.096.14) and is registered in the Dutch Trial Register (NTR4296). All participants provided written informed consent.

Study sample

Prostate and colorectal cancer patients and survivors (N = 478) were recruited from urology and/or oncology departments of 17 hospitals and through other channels (e.g., calls in local newspapers, on relevant websites, discussion groups, and flyers in hospitals) in 2015 and 2016. Eligible participants were aged 18 and older and completed treatment for prostate or colorectal cancer successfully up to one year prior to inclusion, or were currently undergoing treatment with curative intent. Surgery should have taken place at least 6 weeks before the start of the study. Participants with severe medical, psychiatric or cognitive illness (e.g., Alzheimer's disease, severe mobility limitations) were excluded from participation. Proficient Dutch reading and speaking skills were required for the completion of questionnaires.

Procedure

After providing informed consent, participants were randomized to either the OncoActive intervention group or a usual-care waiting list control group and received an accelerometer by mail. The accelerometer was provided with detailed written instructions on how and when to wear the device. The written instructions also contained a hyperlink to a short instruction movie about the accelerometer. Participants were instructed to wear the accelerometer for 7 consecutive days on specific dates. Subsequently, accelerometers were returned in a padded, prepaid return envelope by mail. Immediately after wearing the accelerometer, every participant received an email with an invitation to fill out a web-based version of the questionnaire and an identical paper-based version of the questionnaire by normal mail. They could choose to complete either of them. Participants were instructed to complete the questionnaire regarding their PA during the previous week.

Intervention group participants subsequently received computer-tailored PA advice at three time points, accompanied with a pedometer for their own use (to monitor their own goals). Six months after completing the first questionnaire, both groups wore the accelerometer again and completed a questionnaire, according to the same procedure as the baseline measurement.

Self-reported Physical Activity

Self-reported PA was measured using the SQUASH, which is validated in the general population (Wendel-Vos et al., 2003). PA regarding commuting, household, occupation, and leisure time was assessed. These categories were illustrated with specific activities. Each activity was assessed in terms of frequency (number of days in the previous week), duration (hours and minutes), and perceived intensity (low, moderate or high). Total minutes of PA were classified into light (metabolic equivalent (MET) < 3.0), moderate (MET 3.0 – 5.9) and vigorous (MET > 6) in accordance with international guidelines (Cleland et al., 2014). Minutes of moderate-to-vigorous PA (MVPA) were calculated by adding up total time in moderate and vigorous

PA. Participants with extreme values (i.e., >6720 min PA/week), were excluded in accordance with the SQUASH scoring manual. The SQUASH questionnaire also contains a single-item measure assessing the number of days in the past week, of which one is at least moderately physically active for 30 minutes or more.

Accelerometer data

PA was objectively assessed using an ActiGraph accelerometer (ActiGraph GT3X-BT). The ActiGraph is generally considered a good method for measuring time in MVPA (Boyle et al., 2015). Participants were instructed to wear the small and lightweight device (4.6 x 3.3 x 1.5 cm; 19 g) on an elastic belt around the waist over their right hip, during all waking hours for 7 consecutive days. The devices had to be removed during water-based activities (i.e., swimming, showering) and during medical exams. If participants indicated to the researchers that they were not able to start on the required date, they were instructed to start as soon as possible and wear the device for 1 or 2 additional days in order to obtain a 7 day measurement. If the delay was larger than 2 days, they were rescheduled for a new date.

The ActiGraph was initialized using ActiLife software to record data for 9 days at a sampling rate of 30 Hz in 1 second epochs. After returning, data was downloaded with the ActiLife software using the low frequency extension (Migueles et al., 2017), and integrated into 60 second epoch data. Non-wear periods were excluded from the analyses and were identified according to Choi, Ward, Schnelle, and Buchowski (2012): intervals of at least 90 consecutive minute of zero counts with allowance of a maximum of 2 minutes of nonzero counts during a non-wear interval. If necessary, mail days were manually deleted. Monitoring days were assumed as valid if wear time exceeded 10 hours (Migueles et al., 2017).

Four valid wear days are assumed to provide a reliable estimate of weekly PA (Migueles et al., 2017). However, for the current study, the ActiGraph had to be worn for at least 7 days in order to have a comparable reference period to the SQUASH questionnaire. This ensures data free from noise due to extrapolation. A sensitivity analysis has been performed with at least 4 valid measurement days.

Monitor data (counts per minute (CPM) were classified into sedentary (<200 CPM), light (200-2690 CMP), moderate (2691-6166 CPM), and vigorous (>6167 CPM), based on the vector magnitude of the three axes to calculate the time in each intensity (Aguilar-Farias, Brown, & Peeters, 2014; Sasaki, John, & Freedson, 2011). These cut points are also based on the MET values of international guidelines. Time in moderate and vigorous PA wa added up to calculate MVPA. Days on which participants were at least moderately physically active for 30 minutes or more were summed up to a total score ranging from 0 to 7.

Statistical analyses

Participant characteristics

Participants with valid data on both the SQUASH and the ActiGraph were included in the analyses. As mentioned above for the current study only participants with 7 days of ActiGraph data on each relevant time point were included in the analyses. Descriptive statistics were calculated for the complete sample, the valid sample at baseline, and for the valid sample for which we had data on change in PA. Chi-square tests and ANOVAs were used to assess whether there were differences between the included an excluded participants.

Primary outcomes

As this study was conducted to validate the SQUASH questionnaire as an instrument for the evaluation of an intervention aimed at increasing MVPA, we were primarily interested in the validity regarding MVPA measures. Primary outcomes, therefore, were minutes of MVPA per week and the number of days on which participants were at least moderately physically active for 30 minutes or more. For the primary outcomes, correlation between the two measures was assessed using Spearman's rho. Agreement between the measures was assessed using two-way random effect intraclass correlation coefficients (ICC) and Bland-Altman plots. Change scores between the first and second measurement were calculated by subtracting the value of the first measurement from the value of the second measurement. Correlations and agreement (Spearman's rho, ICC, and Bland Altman plots) were also assessed for the change scores.

For the primary outcomes we assessed the ability to detect change over time, which was examined by classifying participants as having increasing their PA (1) or not (0). For MPVA, classification of participants into these categories was done based on Cohen's effect size. A small effect size (.20) was considered as a minimal improvement in PA. Based on the following formula $0.2*SD_{\text{mean difference}}$, boundaries for improvement in MVPA were calculated (Copay, Subach, Glassman, Polly, & Schuler, 2007). For the outcome days ≥ 30 min MVPA, an increase of at least 1 day was assumed to be improvement. Classifications for both measures were compared. Percentage agreement, sensitivity, specificity, and -statistic were used to assess agreement between the methods when classifying participants as having increased PA or not.

Secondary outcomes

Secondary outcomes included light, moderate, and vigorous PA separately and total PA. Correlation (Spearman's rho) and agreement (ICC) between the two measures were assessed for the cross-sectional values as well as the change scores.

Sensitivity analyses

Since the second measurement in this study was conducted within an intervention study, we were not able to control the timing of the ActiGraph and SQUASH measurements as well as at baseline. As a result, both measures may not always report PA regarding the exact same week at the second measurement. We expected that this might influence the validity of the change scores. Therefore, we performed a sensitivity analysis in which we compared correlation, agreement, and classification of change for only those participants with exactly the same measurement week and those without exact agreement. As mentioned above, sensitivity analyses were also conducted with all participants with 4 days of valid ActiGraph measurement days (compared to 7 days in the main analyses). In addition, sensitivity analyses with PA accumulated in bouts of at least 10 minutes was conducted.

As the total sample included both participants from the intervention group and the control group, data were analyzed in a split file to examine if there were differences between the groups. The same approach was used to examine if there were differences between prostate and colorectal CPS.

All analyses were performed using SPSS version 22. Bootstrapping with 1000 replications was applied to assess 95% confidence intervals (95% CI). STATA version 13.1 was used to construct Bland-Altman plots.

RESULTS

Participant characteristics

In total, 478 participants were included in the study. Baseline characteristics for the complete sample are presented in Table 1. Participants with 7 valid ActiGraph days were included in the cross-sectional analyses (n=360) and those with 7 valid

ActiGraph days on both time points were included in the analyses regarding change scores (n=272). Baseline characteristics for the valid baseline and valid change samples are also presented in Table 1. The participants included in these samples (i.e., valid baseline (VB) and valid change (VC) did not differ significantly from those excluded with regard to age (VB p = .17 and VC p = .61), body mass index (BMI; VB p = .23 and VC p = .85), sex (VB p = .30 and VC p = .31), education (VB p = .86 and VC p = .89), and type of cancer (VB p = .81 and VC p = .87).

Table 1 *Characteristics of the study population*

	Complete sample (n=478)	**Valid sample Baseline (n=360; 75%)**	**Valid sample PA change (n=272; 57%)**
Age (mean, sd)	66.46 (7.68)	66.74 (7.43)	66.62 (7.21)
BMI (mean, sd)	26.56 (3.91)	26.68 (4.08)	26.53 (3.90)
Sex (n, %)			
Female	62 (13)	50 (13.9)	39 (14.3)
Male	416 (87)	310 (86.1)	233 (85.7)
Education (n, %)			
Low	223 (46.8)	170 (47.5)	127 (47.0)
Middle	117 (24.6)	86 (24.0)	68 (25.2)
High	136 (28.6)	102 (28.5)	75 (27.6)
Type of Cancer (n, %)			
Prostate	292 (61.1)	221 (61.4)	167 (61.4)
Colorectal	186 (38.9)	139 (38.6)	105 (38.6)

Abbreviations: PA, physical activity; BMI, body mass index.

Primary outcomes

Correlation and agreement

The difference between MVPA reported by the SQUASH questionnaire and the ActiGraph at baseline was considerable with total MVPA being almost three times as high for self-report compared to the ActiGraph. Nevertheless, both measures were significantly correlated (rho=.356, p < .001) and agreement was fair (ICC=.271, p = .001) (Table 2). The difference between the mean number of days on which participants were at least 30 minutes physically active was small. There was a significant correlation (rho=.387, p < .001) and agreement was moderate (ICC=.553, p < .001).

With regard to change in MVPA, the minutes reported with the SQUASH questionnaire were almost 5 times higher than the change in MVPA according to the

ActiGraph. Both correlation (rho=.202, p = .001) and agreement (ICC=.144, p = .101) were lower for the change scores than for the baseline scores. The same holds for days with sufficient PA (rho=.289, p < .001 and ICC=.452, p < .001).

Table 2 *Mean, correlation, and agreement between SQUASH and ActiGraph for primary outcomes*

	Mean (SD) SQUASH	Mean (SD) ActiGraph	Spearman's rho [95% CI]	ICC [95% CI]
Baseline				
MVPA	848 (737)	287 (219)	.356** [.259 - .447]	.271* [.103 - .407]
Days ≥ 30 min PA	3.81 (1.98)	3.47 (2.40)	.387** [.292 - .484]	.553** [.449 - .637]
PA difference				
MVPA	128 (754)	27 (180)	.202** [.079 - .313]	.144 [-.087 - .326]
Days ≥ 30 min PA	0.98 (1.98)	0.43 (2.16)	.289** [.179 - .397]	.452** [.301 - .570]

Abbreviations: SD, standard deviation; SQUASH, short questionnaire to assess health-enhancing physical activity; 95% CI, 95% confidence interval; ICC, intraclass correlation coefficient; MVPA, moderate to vigorous physical activity; PA, physical activity.

Bland-Altman analyses

Figure 1a shows the Bland-Altman plot for the agreement between MVPA assessed with the SQUASH and the ActiGraph at baseline. For the majority of participants, the difference between the two measures was positive, indicating an overestimation of MVPA assessed by the SQUASH questionnaire. Additionally, the plot shows a positive association between the mean and difference; differences between the measures increase when higher levels of MVPA are reported. The mean difference between both measures was 561 min MVPA per week and limits of agreement were wide (e.g., -823 to 1,945 minutes MVPA per week).

For some participants change in MVPA was overestimated by the SQUASH questionnaire, whereas for others this change was underestimated (Figure 1b). The positive association indicated a larger difference between both measures at more extreme changes in PA. The mean difference between both measures was 101 min MVPA per week and again, limits of agreement were wide (-1,358 to 1,560).

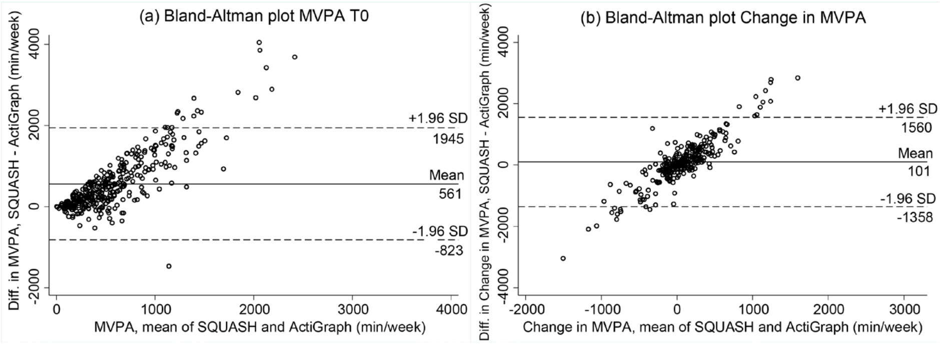

Figure 1 Bland-Altman plots for MVPA at baseline (a) and change in MVPA (b)

The Bland-Altman plots for days with at least 30 minutes MVPA are shown in Figure 2. As points are concentrated on specific combinations, bar charts were added to provide information about the distribution, and the size of the dots depend on the frequency. At baseline, 19% of all participants reported the same number of days on both the SQUASH and the ActiGraph. Both over-reporting (44%) and underreporting (36%) were observed. As can be noted, over-reporting was more present in participants who were less physically active and underreporting was more present in those who were at the upper range of days ≥ 30 min PA. The mean difference was close to zero: 0.33, but limits of agreement were wide (-4 to 5 days).

From Figure 2c and 2d, it can be noted that over-reporting was present with regard to change in the number of days. Fourteen percent reported the same change in days with the SQUASH and the ActiGraph, 56% over-reported change in days according to the SQUASH, and 30% underreported the number of days. Nevertheless, the mean difference was close to zero: 0.57 days, but again limits of agreement were wide (-4 to 5).

Classification of change

The agreement between both measures in classifying participants as having increased their MVPA was poor (κ .13; p = .038). Overall agreement was 57%. The SQUASH correctly classified 50% (60/121 participants) as having increased in MVPA (sensitivity) and 63% (95/151 participants) as not having increased PA (specificity).
For days with sufficient PA, agreement in classification of participants who increased the number of days with sufficient PA was also poor (κ .16; p = .006). Overall agreement was 56%. The SQUASH correctly classified 72% (82/114 participants) as having increased their days (sensitivity) and 45% (66/148 participants) as not having increased their days (specificity).

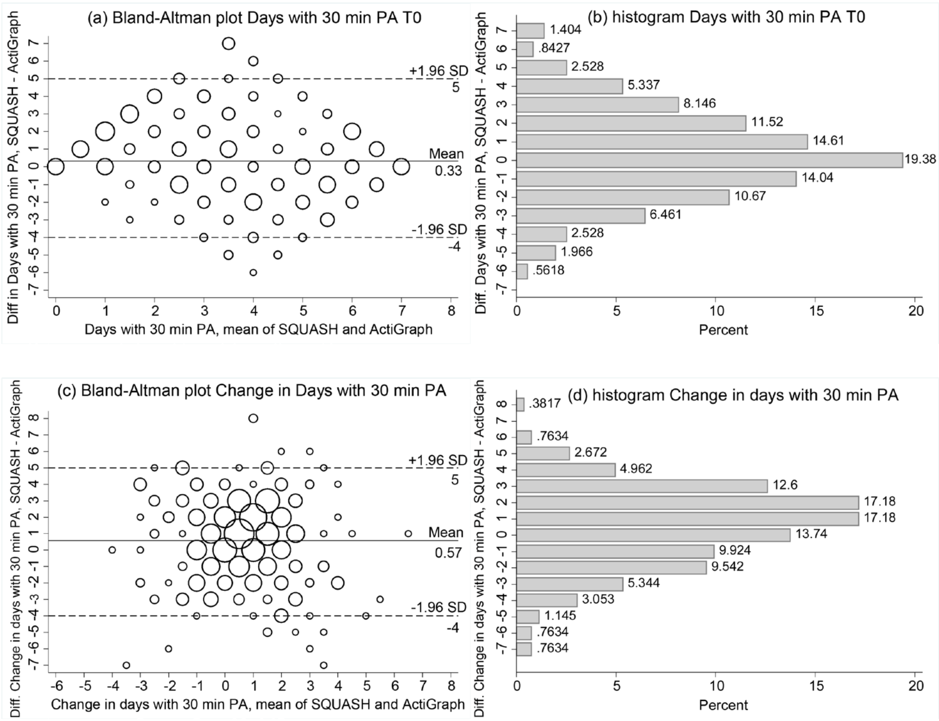

Figure 2 Bland-Altman plots and histograms for days with PA at baseline (a&b) and for change (c&d)

Secondary outcomes

In addition to MVPA we also examined correlation and agreement for light, moderate, vigorous, and total PA (Table 3). Self-reported light PA and total PA were lower than their equivalents measured by the ActiGraph. There was over-reporting of moderate PA and vigorous PA, which is not surprising since it was observed that there was also over-reporting for MVPA. All measures were significantly correlated and agreement was poor to moderate.

Similar patterns of over and underreporting were found for change in PA. Significant correlations were found for moderate and total PA. Agreement ranged from poor to fair (Table 3).

Table 3 *Mean, correlation, and agreement between SQUASH and ActiGraph for secondary outcomes*

	Mean (SD) SQUASH	**Mean (SD) ActiGraph**	**Spearman's rho [95% CI]**	**ICC [95% CI]**
Baseline				
Light PA	756 (820)	2319 (590)	.152** [.049 - .263]	.203* [.020 - .352]
Moderate PA	786 (706)	277 (208)	.328** [.219 - .425]	.274* [.106 - .409]
Vigorous PA	62 (174)	10 (44)	.215** [.102 - .323]	.075 [-.138 - .248]
Total PA	1604 (1100)	2607 (677)	.354** [.254 - .446]	.455** [.330 - .557]
PA difference				
Light PA	73 (769)	101 (473)	.084 [-.034 - .219]	.178 [-.043 - .353]
Moderate PA	92 (726)	25 (171)	.180* [.060 - .311]	.154 [-.074 - .334]
Vigorous PA	35 (288)	2 (32)	.086 [-.036 - .216]	-.002 [-.272 - .211]
Total PA	201 (1100)	128 (528)	.256** [.135 - .378]	.339** [.161 - .480]

Abbreviations: SD, standard deviation; SQUASH, short questionnaire to assess health-enhancing physical activity; 95% CI, 95% confidence interval; ICC, intraclass correlation coefficient; PA, physical activity.

Table 4 *Correlation and agreement for change scores compared for measurement period*

	Exact week (n=29)		**Not exact week (n=243)**	
	Spearman's rho [95% CI]	**ICC [95% CI]**	**Spearman's rho [95% CI]**	**ICC [95% CI]**
Δ Light PA	.061 [-.319 - .421]	.163 [-.784 - .607]	.087 [-.060 - .206]	.185 [-.050 - .367]
Δ Moderate PA	.401* [.028 - .711]	.309 [-.471 - .676]	.162* [-.027 - .292]	.140 [-.107 - .332]
Δ Vigorous PA	-.202 [-.577 - .202]	-.138 [-1.423 - .466]	.134* [-.002 - .282]	.043 [-.231 - .257]
Δ MVPA	.426* [.020 - .742]	.178 [-.751 - .614]	.182* [.039 - .314	.141 [-.105 - .333]
Δ Total PA	.306 [-.126 - .646]	.436 [-.202 - .735]	.243** [.103 - .353]	.327** [.134 - .477]
Δ Days ≥ 30 min PA	.389* [.015 - .717]	.397 [-.285 - .717]	.283** [.168 - .391]	.458** [.298 - .581]

Abbreviations: 95% CI, 95% confidence interval; ICC, intraclass correlation coefficient; PA, physical activity; MVPA, moderate to vigorous physical activity.

Sensitivity analyses

For the analyses regarding change scores with measurement in the same week on both time points, it can be noted that the correlations for moderate PA, MVPA, and days ≥ 30 min PA are higher and comparable to baseline for the participants with exactly the same measurement week. Results of this analysis can be found in Table 4. Agreement for classification of PA increases was also slightly higher for the participants with the exact same measurement week both for MVPA ($\kappa = .23$; $p = .184$ compared to $\kappa = .12$; $p = .068$) and days ≥30 min PA ($\kappa = .22$; $p = .16$ compared to $\kappa = .15$; $p = .015$).

Correlation and agreement between the SQUASH and the ActiGraph seemed to be of the same order when using 4 valid days (n=427) instead of 7 or using ActiGraph MVPA accumulated in bouts of at least 10 minutes. The analyses comparing the intervention and control group revealed that although correlations and agreement were slightly higher in the intervention group compared to the control group, but still only fair to moderate in both groups. Comparison between prostate and colorectal CPS revealed that baseline correlation and agreement were comparable for both groups, but with regard to change scores, it was noted that correlation for MVPA was higher in colorectal CPS (rho = .343) compared to prostate CPS (rho = .116). In addition, classification of change in MVPA was also better for colorectal CPS ($\kappa_{MVPA} = .326$; $\kappa_{days} = .241$) than for prostate CPS ($\kappa_{MVPA} = .001$; $\kappa_{days} = .105$).

DISCUSSION

The aim of the current study was to assess the validity of the self-report SQUASH questionnaire to assess PA and change in PA in cancer patients and survivors. Results of the current study showed fair correlations and agreement for most PA variables at baseline.

Findings for the time in different categories (i.e., light, moderate, vigorous, MVPA and total PA) are comparable to previous validation studies of the SQUASH questionnaire (Arends et al., 2013; Nicolaou et al., 2016; Wagenmakers et al., 2008; Wendel-Vos et al., 2003), and to validation studies of other frequently used self-report questionnaires (Cleland et al., 2014; Hoos et al., 2012; Lewis et al., 2017; Liu et al., 2011). A review of self-report questionnaires by Skender et al. (2016) found correlations ranging from .08 to .58 and a review of Helmerhorst et al. (2012) found a median validity correlations from .25-.41. The results are also similar to other studies performed in cancer populations (Boyle et al., 2015; Lewis et al., 2017; Liu et al., 2011; Pinto et al., 2013; Su et al., 2014; Ungar, Sieverding, et al., 2016). The results suggest that the SQUASH questionnaire can be assumed to be an acceptable instrument for cross-sectional PA assessment.

The single item assessing the number of days on which one is physically active for at least 30 minutes, might be a short alternative to assess PA with a questionnaire. Although several studies showed that a single item may reliably estimate PA (Milton, Clemes, & Bull, 2013; Portegijs, Sipila, Viljanen, Rantakokko, & Rantanen, 2017), to the best of our knowledge there are only three studies that have assessed 'days of ≥ 30 min MVPA'. These studies found correlations of 0.44 in adolescents (Scott, Morgan, Plotnikoff, & Lubans, 2015), 0.46-0.57 in adults (Milton et al., 2013), and 0.50 in the complete study population (e.g., adults and older adults), and 0.44 specifically for older adults (Wanner et al., 2014). Although the correlation in our study (e.g., 0.39) was slightly lower than in these studies, we found that agreement was better than for MVPA.

Correlation and agreement for assessing change in PA behavior indicated a limited responsiveness of the SQUASH questionnaire to correctly assess change in PA behavior. However, additional analyses with exact agreement between measurement periods of both time points indicated that correlation and agreement were comparable to cross-sectional PA assessment. Very few studies have been done regarding the validity of assessing change in PA. One study in cancer patients found a correlation of .35 for change in PA according to exercise variables of the SQUASH as part of an intervention (Ungar, Sieverding, et al., 2016). This correlation was much lower than the correlation found for the cross-sectional validation ($r = .71$). Another study assessed change in MVPA between two time points without further intervention. This study found a correlation of .52 for change in MVPA between self-report and ActiGraph (Cleland et al., 2014). We are not aware of any studies regarding the validity of any questionnaires regarding change in days ≥ 30 min PA. As the correlations in the assessment of change in PA were substantially higher for both MVPA ($r=.426$) and days ≥ 30 min PA ($r=.389$) after correcting for measurement period, our results acknowledge the recommendation that additional research with strict measurement protocols is necessary to gain more insight into the correlation and agreement between self-report and accelerometer to assess change in PA.

With regard to the absolute amount of PA it was noted that MVPA and (accordingly) moderate and vigorous PA at baseline were much higher for self-report. This is also reported in other studies both for the SQUASH questionnaire (Wagenmakers et al., 2008), as for other self-report questionnaires (Bonn, Bergman, Trolle Lagerros, Sjolander, & Balter, 2015; Hekler et al., 2012). Higher levels of self-report moderate and vigorous PA compared to accelerometer were also found in studies regarding cancer patients (Ruiz-Casado et al., 2016; Vassbakk-Brovold et al., 2016). Nevertheless, the overestimation of the absolute amount of PA behavior was substantially lower for days ≥ 30 min PA as also reported by others (Milton et al., 2013; Wanner et al., 2014). This finding may suggest that self-report may not be suitable to assess absolute individual levels of MVPA, but that it is possible to get an absolute value of the number of days with at least 30 minutes of MVPA with a single question.

In contrast, the time in light and total PA was lower when estimated by the SQUASH questionnaire, compared to the ActiGraph, as also reported in other studies examining self-report questionnaires (Bonn et al., 2015; Hekler et al., 2012; Nicolaou et al., 2016). Light activities are often more variable and more difficult to recall and the SQUASH was not specifically designed to assess this type of activities (Nicolaou et al., 2016; Wendel-Vos et al., 2003). Furthermore, the ActiGraph measures continuously throughout a day and picks up every minute of light PA, which might explain the discrepancy between both measures. Furthermore, as intensity can be subjective, it may be possible that in our population of CPS, participants experience light activities as moderate intensity, as discussed in more detail below.

Assessment of PA is challenging as PA is a complex behavior that reflects type of activity, duration, frequency, and intensity (Broderick et al., 2014). Both questionnaires and accelerometers measure different dimensions of this behavior and may, therefore, not perfectly agree due to the different underlying constructs being measured (Kelly, Fitzsimons, & Baker, 2016). Whereas questionnaires are able to distinguish between types of activity, accelerometers are not yet able to do this. As a result, it can be argued that the preferred measurement instrument also depends on the research question and the aim of the study (Broderick et al., 2014; Sternfeld & Goldman-Rosas, 2012). For intervention studies, we could be interested in both the objective increase in PA, but also in the different PA behaviors. In such cases it may be important to combine both assessments (Broderick et al., 2014; Helmerhorst et al., 2012).

The systematic difference between both measures may be due to either an underestimation of PA by the ActiGraph or over-reporting of PA through self-report. The latter is a well-known phenomenon in PA questionnaires and, therefore, very likely (Sternfeld & Goldman-Rosas, 2012). Providing socially desirable answers on the questionnaire is a reason that has been suggested to cause over-reporting. In addition, the nature of the questionnaire, by asking average times and frequencies, difficulties with assessing intensity level (as mentioned above), or recall of PA activities or double reporting of the same activities may induce over-reporting (Hekler et al., 2012; Nicolaou et al., 2016). ActiGraphs, in turn, are known to have a limited ability to measure cycling, upper body movement, and swimming (due to not being water proof) (Broderick et al., 2014; Helmerhorst et al., 2012). In addition, the algorithm for calculation time in different PA intensities (Sasaki et al., 2011) used in the current study has not been validated specifically for our target group.

As addressed several times, the intensity of activities may have an influence on the validity of PA measurements. Differences in perception of activity intensity may contribute to discrepancies between both measures (Shook et al., 2016). This is especially important in our target group. Cancer patients and survivors may experience decreased cardiorespiratory fitness due to their treatment and disease. As a result, they might experience difficulties in correctly classifying the intensity of their PA; they may perceive an activity as moderately intensive, whereas it is actually classified as light activity in the questionnaire (Vassbakk-Brovold et al., 2016). For the ActiGraph, the same argument can be made. Cut points to classify accelerometer counts into light, moderate, or vigorous are developed and validated for healthy adult populations (Lewis et al., 2017; Sasaki et al., 2011) and may not reflect the right intensity levels for cancer patients and survivors with a decreased physical fitness. In order to increase validity of PA measurement, it may be recommended to develop cut points for specific populations or to combine ActiGraph measurements with heart rate measurement (Helmerhorst et al., 2012; Watson et al., 2017).

With regard to the higher amount of PA reported by self-report questionnaires, it should also be noted that the majority of reported health effects and recommendations regarding PA for CPS are based on self-reports (Vassbakk-Brovold et al., 2016). As the current study showed that these values are much higher, it may be argued that health effect can be obtained with even smaller increases in PA as currently assumed. However, future longitudinal and intervention studies have to confirm this (Watson et al., 2017).

Agreement between the two methods in classifying participants who increased their PA was poor in the current study. Although agreement increased slightly when looking at the exact same measurement week, was still only fair both for MVPA and days ≥ 30 min PA. A possible explanation might be that although the questionnaire asked about PA in the previous week, participants may tend to report an optimal week instead of the previous week (social desirability) creating noise at two time points, influencing the comparability between the two measurement instruments. For classification according to MVPA the specificity (i.e., correct classification of those who did not improve) was higher than the sensitivity (i.e., correct classification of those who improved). In contrast, days ≥ 30 min PA was better in correctly classifying those who improved (higher sensitivity) than in correctly classifying those who did not improve (lower specificity).

To the best of our knowledge, there are no other studies that compared the classification of participants in having increased their PA behavior between self-report and accelerometers. From the current outcomes, it can be concluded that the agreement between the two methods in assessing change in PA in single participants is poor, which can possibly be explained by the fact that single, individual measurements may have a wide error margin. As a result, we have less confidence in interpreting change scores for single participants (Beaton, Bombardier, Katz, & Wright, 2001). For intervention efficacy, however, we are mainly interested in group level changes over time instead of change at the individual level. By assessing change in groups of participants, an increased sample size reduces the error margin and increases the confidence in interpreting change in PA (Beaton et al., 2001). The results (Spearman's correlation and ICC) of the current study implicate that the validity of the SQUASH questionnaire to assess group level change is reasonable.

Strengths and limitations

By measuring PA both with a self-report questionnaire and an ActiGraph, the current study provides a solid base for the validation of the SQUASH questionnaire in a target group of CPS. A major strength of the current study is the large number of participants. A checklist regarding validation studies proposed a minimum of 50 participants (Terwee et al., 2010). The current study included 360 participants for validity at time point 1 and 272 for validity of change in PA behavior, which is much higher. Besides cross-sectional validity, we also examined the validity of change in PA. Although self-report questionnaires are frequently used in intervention studies for reporting intervention effects over time, there is only minimal evidence that questionnaires are actually able to measure change in PA correctly. Therefore, the current study adds important new insights for the use of questionnaires in longitudinal PA assessment.

The validity of the SQUASH questionnaire was assessed using an ActiGraph. Although regarded as the best alternative, accelerometry also relies on assumptions (cut points) in the actual classification of PA into light, moderate, or vigorous, thereby introducing uncertainty. Doubly labeled water is often regarded as the gold standard, but is not able to provide information regarding duration, frequency and intensity and therefore not feasible in the current validation study aimed at assessing time in PA (Kelly et al., 2016). In addition, as a result of our study design (i.e., validation as part of an intervention study) the number of participants with exact agreement between the measurement weeks at both time points was limited. It is known that very few people will conduct the exact same behavior each week (Kelly et al., 2016). Therefore, not using the exact same week might have biased our initial findings (Hagstromer, Ainsworth, Kwak, & Bowles, 2012). As our results showed that correlation and agreement were better for those with exact agreement in their measurement period, additional research with more participants with exact agreement is necessary.

Perspectives

The current study addressed the validity of the SQUASH questionnaire in prostate and colorectal CPS. Analyses have shown that the validity of the SQUASH questionnaire in this population is comparable to self-report questionnaires in other populations (Helmerhorst et al., 2012; Skender et al., 2016). Yet, as self-report questionnaires are associated with over-reporting PA, this may possibly indicate that health benefits of PA can be obtained from smaller amounts of PA than currently prescribed in PA guidelines (Vassbakk-Brovold et al., 2016).

At the individual level, classification of change in PA is limited, but at the group level, the SQUASH questionnaire showed reasonable validity in assessing cross-sectional PA and change in PA. Nevertheless, in general, additional research is necessary to provide more insight into the ability of questionnaires to assess change in PA over time (Watson et al., 2017).

In addition, assessing PA with a single item has reasonable validity. As differences between this item and objectively assessed PA are not as big as with MVPA, single items may provide a more reliable estimate of self-report PA (Portegijs et al., 2017).

However, such measures still not provide any information regarding different PA behaviors (e.g., transportation, leisure, occupational), which could be of interest in intervention studies. Therefore, it may be important to combine accelerometry and self-report measures.

3

DEVELOPMENT OF A COMPUTER-TAILORED PHYSICAL ACTIVITY INTERVENTION FOR PROSTATE AND COLORECTAL CANCER PATIENTS AND SURVIVORS: ONCOACTIVE

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ABSTRACT

Background

Cancer and cancer treatment coincide with substantial negative physical, psychological and psychosocial problems. Physical activity (PA) can positively affect the negative effects of cancer and cancer treatment and thereby increase quality of life in CPS. Nevertheless, only a minority of CPS meet PA guidelines. We developed the OncoActive (OncoActief in Dutch) intervention: a computer-tailored PA program to stimulate PA in prostate and colorectal CPS, because to our knowledge there are only a few PA interventions for these specific cancer types in the Netherlands

Methods

The OncoActive intervention was developed through systematic adaptation of a proven effective, evidence-based, computer-tailored PA intervention for adults over fifty, called Active Plus. The Intervention Mapping (IM) protocol was used to guide the systematic adaptation. A literature study and interviews with prostate and colorectal CPS and health care professionals revealed that both general and cancer-specific PA determinants are important and should be addressed. Change objectives, theoretical methods and applications and the actual program content were adapted to address the specific needs, beliefs and cancer-related issues of prostate and colorectal CPS. Intervention participants received tailored PA advice three times, on internet and with printed materials, and a pedometer to set goals to improve PA. Pre- and pilot tests showed that the intervention was highly appreciated (target group) and regarded safe and feasible (healthcare professionals). The effectiveness of the intervention is being evaluated in a randomized controlled trial (RCT) (n = 428), consisting of an intervention group and a usual care waiting-list control group, with follow-up measurements at three, six and twelve months. Participants are recruited from seventeen hospitals and with posters, flyers and calls in several media.

Discussion

Using the Intervention Mapping protocol resulted in a systematically adapted, theory and evidence-based intervention providing tailored PA advice to prostate and colorectal CPS. If the intervention turns out to be effective in increasing PA, as evaluated in a RCT, possibilities for nationwide implementation and extension to other cancer types will be explored.

BACKGROUND

The number of newly diagnosed cancer patients and survivors (CPS) will increase significantly given the aging population and improved survival resulting from advances in early detection and cancer treatment (Meulepas & Kiemeney, 2011; Siesling, Sonke, de Raaf, & Jansen-Landheer, 2014). The growing population of CPS will pose increasing demands on healthcare, as cancer and cancer treatment coincide with substantial negative physical, psychological and psychosocial problems (Bourke et al., 2015; Carlsson et al., 2016; Denlinger & Barsevick, 2009; Denlinger & Engstrom, 2011; El-Shami et al., 2015; Harrington et al., 2010; Resnick et al., 2013; Skolarus et al., 2014; Wu & Harden, 2015). These problems can persist for years or even develop years after treatment. Interventions to reduce these negative effects of cancer and cancer treatment are therefore warranted.

Physical activity (PA) can positively affect the negative effects of cancer and cancer treatment and thereby increase quality of life in CPS (Bourke et al., 2016; Davies et al., 2011; Denlinger & Engstrom, 2011; Fong et al., 2012; Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; Santa Mina et al., 2014; Schmitz et al., 2010; Speck et al., 2010; Szymlek-Gay et al., 2011; Thorsen et al., 2008). PA improves cardiorespiratory fitness and health-related quality of life (HRQoL), and reduces treatment-related side effects, fatigue, pain, distress, anxiety and depression both during and after active treatment (Davies et al., 2011; Denlinger & Engstrom, 2011; Kampshoff et al., 2015; Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; van Waart et al., 2015). Some studies have even indicated that PA decreases cancer-specific and total mortality risk (Kenfield, Stampfer, Giovannucci, & Chan, 2011; Meyerhardt, Giovannucci, et al., 2006; Meyerhardt, Heseltine, et al., 2006). Besides these positive effects during and after active cancer treatment and on cancer recurrence and survival, being physically active is also important for CPS as they have a higher risk of developing second primary cancers and of developing comorbidities such as cardiovascular disease, diabetes and osteoporosis on which PA has a preventive effect (Rock et al., 2012).

Despite these benefits, and although PA is regarded as safe and feasible both during and after cancer treatment (Rock et al., 2012; Schmitz et al., 2010; Van Blarigan & Meyerhardt, 2015), only 30-47% of CPS meet PA guidelines (Blanchard et al., 2008; LeMasters et al., 2014). Moreover, PA behavior declines during treatment, and does not reach pre-treatment levels after completing treatment (Chung et al., 2013; Szymlek-Gay et al., 2011). Thus, interventions to stimulate PA are needed for this population.

Diagnosis of cancer can be a 'teachable moment' for behavior change and a majority of CPS are interested in information about PA or participating in an exercise program (Basen-Engquist, Carmack, et al., 2012; Blaney et al., 2013; Buffart et al., 2014; Demark-Wahnefried, 2000; Jones & Courneya, 2002; Murnane et al., 2012; Szymlek-Gay et al., 2011). The majority prefers an unsupervised, home-based PA program, with walking as the preferred exercise mode (Buffart et al., 2014; McGowan et al., 2013; Murnane et al., 2012; Szymlek-Gay et al., 2011). However, currently most PA programs in the Netherlands are hospital/healthcare-based, supervised exercise programs, aimed at sports. Although valuable, these programs are also demanding for both patients and health care professionals. An easily accessible, home-based PA program, aimed at stimulating PA in daily life and leisure time, offered at low costs and requiring minimal staff may offer a valuable alternative. Accordingly, we developed the OncoActive (OncoActief in Dutch) intervention: a computer-tailored PA program provided online and with printed materials. This paper describes the development process of the intervention, using the Intervention Mapping (IM) protocol and the design of a randomized controlled trial (RCT) to evaluate the effectiveness of the program. The intervention was targeted at prostate and colorectal CPS, because to our knowledge there are only a few PA interventions for these specific cancer types in the Netherlands (Kampshoff et al., 2010; Persoon et al., 2010; van Waart, Stuiver, van Harten, Sonke, & Aaronson, 2010; Velthuis et al., 2010). More detailed rationale for the specific target population can be found in the methods section (needs assessment).

METHODS

The OncoActive intervention was developed through systematic adaptation of a proven effective, evidence-based, computer-tailored PA intervention for adults over fifty, called Active Plus (Peels, Bolman, et al., 2013b; van Stralen et al., 2011). The Active Plus intervention has been delivered in either a print-based or a web-based version (Peels, Bolman, et al., 2012; Peels, van Stralen, et al., 2012). Since the median age for a prostate or colorectal cancer diagnosis are 66 and 68 years respectively, and more than 96% of CPS are aged fifty and over (Miller et al., 2016), this intervention was assumed to be an ideal starting point. Computer-tailoring provides the opportunity to tailor the content to the specific needs of individual CPS. The IM protocol was used to adapt the intervention in a systematic way (Bartholomew et al., 2016).
IM provides a systematic approach for the development of theory and evidence-based health promotion programs comprising six steps (Table 1). Although the IM protocol is primarily used to develop new interventions, the protocol is also

useful for adapting evidence-based interventions for new target populations as is the case in our study. The protocol helps in finding a balance between containing the core elements of the original intervention while making it relevant for the new target population (Bartholomew et al., 2016). The application of these six steps for the development of the OncoActive intervention is briefly described below.

Table 1 *Intervention mapping steps (Bartholomew et al., 2016)*

Step 1. Needs Assessment	*Assessing the health problem, its impact on quality of life and its related behavior*
Step 2. Program outcomes and objectives	*Adapting performance objectives, determinants and change objectives for the new target population*
Step 3. Program design	*Adapting theoretical methods and practical applications based on new change objectives or inadequate methods from the original intervention*
Step 4. Program production	*Adapting scope, sequence, materials and delivery channels and pretesting materials*
Step 5. Program implementation plan	*Developing an implementation plan for the new program*
Step 6. Evaluation	*Planning and implementing an effectiveness and process evaluation for the new program*

Step 1: Needs assessment

The OncoActive intervention is aimed at prostate and colorectal CPS. Prostate and colorectal CPS represent a large proportion of the total CPS population in the Netherlands. Prostate cancer is the most common cancer site among Dutch men with 10 497 new cases in 2015, representing 19% of all newly diagnosed male cancer patients. Colorectal cancer is the second most common cancer site in both men and women in the Netherlands with 15 549 new cases in 2015, representing 15% of all newly diagnosed male and female cancer patients. Both cancer types have relatively high survival rates: a 5-year survival rate of 88-99% for prostate cancer and 62-65% for colorectal cancer (Comprehensive Cancer Center of the Netherlands (IKNL), 2015; Miller et al., 2016). By selecting only two cancer types, we could better fine-tune the intervention to the specific needs and capabilities of prostate and colorectal CPS.

Cancer and cancer-treatment related side effects have a profound influence on quality of life. Although treatment improves survival rates, the inherent side effects have a negative influence on both physical and social functioning and thereby on quality of life (Denlinger & Engstrom, 2011; Thorsen et al., 2008). Prostate and colorectal CPS both experience some similar and some unique treatment related side effects. Decreased muscular strength, decreased physical fitness, functional limitations, bowel dysfunction, sexual dysfunction, altered body constitution, pain, fatigue, sleep disorders, emotional distress, depression, anxiety, fear of recurrence, challenges with body image and cognitive limitations are experienced in both cancer types. Urinary incontinence and hormonal treatment related side effects are more common in prostate cancer, while stoma related limitations, peripheral neuropathy and nausea are more common in colorectal cancer (Baumann, Zopf, & Bloch, 2012; Bourke et al., 2015; Denlinger & Barsevick, 2009; El-Shami et al., 2015; Harrington et al., 2010; Jorgensen, Young, & Solomon, 2015; Keogh & MacLeod, 2012; Lynch, Boyle, et al., 2016; Lynch, Cerin, Owen, Hawkes, & Aitken, 2008; Ottenbacher et al., 2013; Pinto et al., 2013; Schneider et al., 2007; Skolarus et al., 2014; Thorsen et al., 2008). In particular, colorectal CPS have a higher risk of developing comorbidities such as type II diabetes and cardiovascular disease, second colorectal cancers and other primary cancers (Denlinger & Engstrom, 2011; Grimmett et al., 2011; Van Blarigan & Meyerhardt, 2015).

PA has consistently been shown to improve prostate and colorectal cancer treatment related side effects and thereby quality of life both during and after treatment (Baumann et al., 2012; Bourke et al., 2016; Davies et al., 2011; Galvao et al., 2015; Keogh & MacLeod, 2012; Knols, Aaronson, Uebelhart, Fransen, & Aufdemkampe, 2005; Lynch, Boyle, et al., 2016; Lynch et al., 2008; Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; Schmitz et al., 2010; Speck et al., 2010; Thorsen et al., 2008; Thraen-Borowski, Trentham-Dietz, Edwards, Koltyn, & Colbert, 2013; Van Blarigan & Meyerhardt, 2015). PA is also a preventive factor for the associated comorbidities and secondary/new cancers. As a result, PA guidelines for CPS have been established in several countries. International guidelines in general state that CPS should aim to be physically active (moderate to vigorous) for at least 150 minutes per week (Buffart et al., 2014). In the Netherlands CPS are advised to adhere (if possible) to the general Dutch PA guidelines, which require them to be physically active with moderate to vigorous intensity for at least 30 minutes a day on at least five days per week (Stuiver et al., 2011).

Only a minority of CPS adhere to PA guidelines. Adherence to PA guidelines for prostate CPS has been reported to vary between 29 and 47 % (Blanchard et al., 2008; Chipperfield et al., 2013; Coups & Ostroff, 2005; Galvao et al., 2015; LeMasters et al., 2014) and is even lower in colorectal CPS: 20-40 % (Blanchard et al., 2008; Chung et al., 2013; Coups & Ostroff, 2005; Hawkes et al., 2008; LeMasters et al., 2014; Lynch, Boyle, et al., 2016; Stephenson et al., 2009). PA levels are known to decline during treatment and do not reach pre-treatment levels after completing treatment (Courneya et al., 2007; Szymlek-Gay et al., 2011). Thus, the majority do not take full advantage of the positive effects of PA during and after treatment, highlighting the need for an intervention to increase PA in the target group.

The negative effects of cancer and cancer treatment, the positive influence of PA on them and the low and decreasing adherence to PA guidelines already highlight the need for PA programs. Additionally, studies regarding supportive care needs have shown that CPS have a substantial perceived need for healthy lifestyle information and programs including PA (Jansen et al., 2015; Playdon et al., 2016; Willems et al., 2016). According to the literature a majority of CPS are interested in information about PA or participating in a PA program (Blaney et al., 2013; Buffart et al., 2014; Demark-Wahnefried, 2000; Jones & Courneya, 2002; McGowan et al., 2013; Murnane et al., 2012; Szymlek-Gay et al., 2011). As a result, the following program goals were formulated: Insufficiently active prostate and colorectal CPS become motivated to be physically active, initiate PA and maintain the newly attained PA level. Physically active prostate and colorectal CPS maintain or slightly increase their PA level.

In order to promote the desired behavior (i.e., being physically active) within the target population it is important to gain more insight into their specific motivating and hindering factors regarding the behavior and preferences in a PA program. Therefore, we systematically searched the literature regarding these topics. To confirm and expand this information we conducted interviews with our target group and healthcare professionals about PA advantages, cancer specific barriers to PA and information and intervention preferences regarding a computer-tailored intervention among our target group. We conducted twenty-nine semi-structured interviews with prostate (n=18) and colorectal (n=11) CPS and fifteen interviews with healthcare professionals (i.e., oncologist/urologist, physiologist, oncology nurse, oncology physiotherapist, oncology trainer) to explore the determinants of PA within the target group and their intervention preferences. Interviews were systematically analyzed with Qualicoder (www.qualicoder.com), according to the framework method (Pope, Ziebland, & Mays, 2000). By establishing such a planning group and thus involving the target group and healthcare professionals in the actual intervention development, we were able to take their wishes and preferences for the intervention into account. Findings from the interviews regarding the content of the intervention in relation to the findings from the literature are discussed in steps two and three (which concern determinants and intervention content).

Step 2: Program outcomes and objectives

Performance objectives

The main goal of the OncoActive intervention is to increase and maintain PA behavior of prostate and colorectal cancer CPS, as mentioned in Step1. Further specifying this health promoting behavior, in comparison with the original program, is the first task of Step 2 (Bartholomew et al., 2016). The original Active Plus intervention was aimed at increasing PA in two ways: by increasing and maintaining leisure time PA and by increasing and maintaining PA in people's daily routines (van Stralen et al., 2008). According to the literature influencing these PA behaviors is also relevant for, and preferred by prostate and colorectal CPS (Irwin, 2009; Jones & Courneya, 2002; McGowan et al., 2013; Szymlek-Gay et al., 2011; Wright, 2015). Subsequently specific health promoting behaviors are translated into performance objectives (POs). POs clarify what is expected from someone participating in the intervention and thus performing the desired health promoting behavior (Bartholomew et al., 2016). As the specific health promoting behaviors from the original Active Plus intervention are also relevant for prostate and colorectal CPS, the according POs can remain the same for the new target group. POs for the OncoActive intervention are mentioned in Table 2.

Table 2 *Performance objectives for awareness raising, initiation and maintenance of PA among prostate and colorectal CPS*

PO.1	*Prostate and colorectal CPS monitor their PA level*
PO.2	*Prostate and colorectal CPS indicate reasons to be physically active*
PO.3	*Prostate and colorectal CPS identify solutions to take away the barriers to be physically active*
PO.4	*Prostate and colorectal CPS decide to become more physically active*
PO.5	*Prostate and colorectal CPS make specific plans and set goals to become more physically active*
PO.6	*Prostate and colorectal CPS increase their PA*
PO.7	*Prostate and colorectal CPS make specific plans to cope with difficult situations occurring while being physically active*
PO.8	*Prostate and colorectal CPS maintain their PA level by enhancing their routine and preventing relapses*

Note: PA includes recreational PA and PA in daily life

Determinants

Several studies regarding psychosocial determinants of PA in CPS have shown that attitude, subjective norms and perceived behavioral control (constructs of the Theory of Planned Behavior (TBP)) predict intention to engage in PA and PA behavior (Andrykowski et al., 2006; Basen-Engquist, Perkins, et al., 2012; Blanchard et al., 2002; Courneya et al., 1999; Courneya & Friedenreich, 1997; Courneya et al., 2007; Hunt-Shanks et al., 2006; Keogh et al., 2010; Pinto & Ciccolo, 2011; Speed-Andrews et al., 2012; Ungar et al., 2015). Pinto and Ciccolo (2011) reported that self-efficacy and outcome expectations (constructs of Social Cognitive Theory (SCT)) were important determinants of PA behavior. Higher self-efficacy is associated with more PA (Mosher et al., 2013; Pinto, Rabin, & Dunsiger, 2009; Szymlek-Gay et al., 2011). Furthermore, PA interventions based on the Transtheoretical Model (TTM), and thus tailored to the behavioral stage of change, proved to be a predictor of exercise adherence and to be effective in improving fitness, general health and reducing pain and fatigue in CPS (Courneya et al., 2007; Pinto & Floyd, 2008). The I-Change model integrates these theories and models (De Vries et al., 2005).

Based on the original Active Plus intervention (van Stralen et al., 2008), important psychological determinants are addressed in the OncoActive intervention ranging from pre-motivational determinants (e.g., awareness, knowledge and risk perception), motivational determinants (attitude, social influence beliefs, self-efficacy) and post-motivational determinants (goal setting, action planning) using input from the following social cognitive models: the I-Change Model (De Vries, Mesters, Riet, Willems, & Reubsaet, 2006; De Vries et al., 2005; De Vries et al., 2003) (a model integrating ideas of TPB (Ajzen, 1985), SCT (Bandura, 1986), TTM (Prochaska & DiClemente, 1983), the Health Belief model (Janz & Becker, 1984) and goal setting theories (Gollwitzer & Schaal, 1998; Locke & Latham, 1990)), the Health Action Process Approach (Schwarzer, 2008, 2009), theories of self-regulation (Baumeister & Vohs, 2004; Boekaerts, Pintrich, & Zeidner, 2001; Zimmerman, 2000) and the Precaution Adoption Process Model (Weinstein, 1988). An examination of the literature and interviews with the target group and health care providers regarding the benefits of PA and barriers to PA specifically for prostate and colorectal CPS were conducted to identify differences in the operationalization of the determinants.

Benefits of PA for prostate and colorectal CPS

In order to increase understanding and motivation of prostate and colorectal CPS towards PA, it is important to inform them about the benefits of PA as attitude is an important predictor of intention for PA (Courneya et al., 2007; Denlinger & Engstrom, 2011; Lee, Park, Yun, & Chang, 2013; Murnane et al., 2012; Pinto & Ciccolo, 2011). Proven positive effects of PA during and after cancer treatment were identified by a systematic search of the literature and are listed in Table 3. Positive effects include improvements in both physical and mental aspects of health, as well as tertiary prevention of other chronic diseases (Davies et al., 2011; Denlinger & Engstrom, 2011; Galvao, Taaffe, Spry, & Newton, 2011; Holtzman et al., 2004; Keogh & MacLeod, 2012; Knols et al., 2005; Schmitz et al., 2005; Sellar & Courneya, 2011; Stevinson, Campbell, Sellar, & Courneya, 2007).

The outcomes from the interviews with CPS and healthcare professionals (see Table 3) largely confirmed the findings from the literature. Although prostate and colorectal CPS did not mention benefits as specific as stated in the literature (for example, better mental health instead of less anxiety or depression), they perceived that PA had beneficial effects on their physical and mental health and enabled them to achieve goals in their daily life. Healthcare professionals additionally mentioned an increased survival and a reduction in the risk for comorbidities (Golsteijn et al., 2014).

Table 3 *Benefits of and barriers to PA in prostate and colorectal CPS*

Benefits of PA	
Findings from literature[1]	***Findings from interviews[2]***
Increased: - physical functioning - muscle strength - quality of life - cardiorespiratory fitness - self-esteem - mood - incontinence - sense of achievement Decreased: - treatment related side effects - fatigue - anxiety - depression - distress - pain - insomnia Prevention of: - comorbidities - cancer recurrence - secondary cancers - cancer mortality	Perceived benefits CPS: - better physical fitness - better mental health - feeling better and healthier - being able to achieve goals - take mind off of cancer - better body weight Addition from healthcare professionals: - increased survival - reduced risk on comorbidities

table continues

Barriers to PA	
Findings from literature[3]	***Findings from interviews***[2]
General barriers: - bad weather - lack of time - lack of facilities - lack of support - motivational problems - financial costs - no enjoyment from PA - PA not a priority Cancer-specific barriers: - fatigue - decreased physical fitness - decreased muscle strength - pain - saving energy for treatments - infection risk - embarrassment about bodily changes - depression - fear of doing too much/injuries - symptoms from comorbidities - stoma - peripheral neuropathy - (urinary) incontinence or diarrhea - nausea and vomiting - cancer treatment	Prostate and colorectal CPS: - fatigue - pain - incontinence - peripheral neuropathy - lack of motivation - poor physical fitness - joint or muscle problems - lack of time - bad weather - stoma Healthcare professionals: - lymphedema - fear of movement - hand-foot syndrome (side effect from chemotherapy drugs for colorectal cancer) - problems with sitting on a bicycle saddle

[1] (Blaney et al., 2013; Blaney et al., 2010; Craike et al., 2011; Davies et al., 2011; Denlinger & Engstrom, 2011; Falzon et al., 2012; Fisher et al., 2016; Galvao et al., 2011; Holtzman et al., 2004; Keogh & MacLeod, 2012; Knols et al., 2005; Mustian et al., 2006; Peeters et al., 2009; Rogers, Courneya, Shah, Dunnington, & Hopkins-Price, 2007; Schmitz et al., 2005; Sellar & Courneya, 2011; Speed-Andrews et al., 2014; Stevinson et al., 2007; Thorsen et al., 2008)

[2] (Golsteijn et al., 2014)

[3] (Anderson, Caswell, Wells, Steele, & Macaskill, 2010; Blaney et al., 2013; Blaney et al., 2010; Courneya et al., 2005; Craike et al., 2011; Denlinger & Engstrom, 2011; Falzon et al., 2012; Fisher et al., 2016; Keogh et al., 2010; Lee et al., 2013; Loh, Chew, & Lee, 2011; Lynch, Owen, Hawkes, & Aitken, 2010; Murnane et al., 2012; Ottenbacher et al., 2013; Ottenbacher et al., 2011; Peeters et al., 2009; Rogers et al., 2007; Speed-Andrews et al., 2014)

Barriers to PA for prostate and colorectal CPS

As illustrated in Table 3, according to the literature, both general and cancer-specific barriers can result in CPS not being physically active and should thus get special attention in a PA program (Buffart et al., 2014; Charlier et al., 2012; Charlier et al., 2013; Denlinger & Barsevick, 2009; Lee et al., 2013; Lynch, Boyle, et al., 2016). Physical complaints are often dependent on cancer type and the associated treatment. Physical complaints for colorectal CPS may include a stoma, peripheral neuropathy, (urinary) incontinence or diarrhea, nausea and vomiting (Lynch, Boyle, et al., 2016), whereas urinary incontinence is the most important physical complaint in prostate CPS.

The findings from the literature were confirmed in the interviews, with fatigue, pain, incontinence and peripheral neuropathy being the most frequently mentioned barriers for being physically active. Besides cancer-specific barriers, the interviewed CPS also mentioned general barriers including lack of motivation, lack of time and bad weather (Golsteijn et al., 2014). Findings are listed in Table 3.

As barriers may prevent CPS from being physically active, it is important that a PA intervention for prostate and colorectal CPS pays special attention to the general barriers, but especially to the cancer-specific barriers. Providing suggestions to overcome the barriers could increase self-efficacy and perceived behavioral control, which are important predictors of intention for PA and actual PA behavior (Courneya et al., 2007).

Change Objectives

Both performance objectives and the determinants that should be addressed are comparable to the original Active Plus intervention. Consequently, major changes in the general structure of the intervention were not regarded as necessary. Yet, findings from both interviews and the literature suggested that the content should also address cancer-specific topics. Determinants like attitude, knowledge and self-efficacy should be directed at the specific needs, beliefs and cancer related issues of CPS. Therefore, we decided to add and/or adapt some change objectives to address these specific themes. For example, for the PO 'prostate and colorectal CPS identify solutions to take away the barriers to being physically active' combined with the determinant self-efficacy, we added the change objective 'prostate and colorectal CPS feel confident about being able to take away and cope with cancer-specific barriers to being physically active'. Some other examples can be found in Table 4. Findings from the literature and interviews were also used in the production of the intervention content (see Step 4).

Table 4 *Examples of change objectives added or altered for the OncoActive intervention.*

Performance Objectives	**Determinants**				
	Awareness	***Knowledge***	***Attitude***	***Self-efficacy***	***Action Planning***
PO.1 PCa & CRC CPS monitor their physical activity level	Existing: PCa & CRC CPS become aware of their own PA level	*Old: OA know the PA recommendations and learn how to compare their own PA level with the recommendations*			
	Existing: PCa & CRC CPS monitor and report their own PA level	New: PCa & CRC CPS know the PA recommendations during and after cancer treatment and learn how to compare their own PA level with the recommendations			
PO.2 PCa & CRC CPS indicate reasons to be physically active	Existing: PCA & CRC CPS become aware of their personally relevant benefits of being sufficiently physically active	Existing: PCa & CRC CPS learn about the general health benefits of sufficient PA and can name personal relevant reasons for being sufficiently physically active Added: PCa & CRC CPS learn about health benefits of PA related to cancer and can name personal relevant reasons for being sufficiently physically active	Existing: PCa & CRC CPS feel positive about being sufficiently physically active		

table continues

3

Performance Objectives	Determinants				
	Awareness	***Knowledge***	***Attitude***	***Self-efficacy***	***Action Planning***
PO.3 PCa & CRC CPS identify solutions to take away the barriers to being physically active	Existing: PCa & CRC CPS become aware of situations and barriers that prevent them from being sufficiently physically active	Existing: PCa & CRC CPS learn how to identify general difficult situations and learn about solutions that can take away the barriers Added: PCa & CRC CPS learn how to identify cancer-specific difficult situations and learn about solutions that can take away the barriers		Existing: PCa & CRC CPS feel confident about being able to take away and to cope with general barriers Added: PCa & CRC CPS feel confident about being able to take away and cope with cancer-specific barriers Added: PCA & CRC CPS feel confident about being able to cope with physical complaints due to cancer or cancer-treatment.	
PO.5 PCa and CRC CPS make specific plans to become more physically active	Existing: PCa & CRC CPS become aware of the importance to make plans to increase their PA	Existing: PCa & CRC CPS learn how to make specific plans to increase their PA	Existing: PCa & CRC CPS feel positive about making plans to increase their PA	Existing: PCA & CRC CPS feel confident about making plans to increase their PA Existing: PCA & CRC CPS feel confident in being able to achieve their plans to increase their PA	Existing: PCA & CRC CPS make specific plans to increase their PA Existing PCA & CRC CPS set goals to increase their PA

PO = performance objective, PCa = prostate cancer, CRC = colorectal cancer, CPS = cancer patients and survivors, OA = older adults, PA = physical activity.

Step 3: Program design

Theoretical methods, practical applications and intervention preferences for CPS

Theoretical methods and practical applications are necessary to address the existing, adapted and added change objectives. In order to establish the adoption of an active lifestyle and maintenance of PA, it is important that behavior change techniques are incorporated in the intervention to improve PA behavior in CPS (Buffart et al., 2014; Denlinger & Engstrom, 2011). We searched the literature and interviewed prostate and colorectal CPS regarding relevant theoretical methods and intervention content.

According to Pinto and Ciccolo (2011), social-cognitive techniques for self-management, increasing self-efficacy, developing realistic outcome expectations, increasing intention and developing plans in line with motivational readiness are key concepts in a PA program for CPS. Modeling to increase self-efficacy, emphasizing benefits and fun (strengthening attitude) and informing significant others about the importance of PA (subjective norms) are important intervention components according to the Dutch cancer rehabilitation guideline (Comprehensive Cancer Center of the Netherlands (IKNL), 2011).

According to the literature regarding the content that should be addressed with the theoretical methods and practical applications, CPS would like to receive information, advice and support regarding ways in which they can be physically active, both during and after treatment, the necessity to take special precautions due to illness and treatment, guidance in planning PA and giving notice to and emphasizing PA guidelines to increase awareness and acknowledge maintenance of PA (Denlinger & Engstrom, 2011; Lee et al., 2013; Murnane et al., 2012). Findings from our interviews indicated that it was important that a computer-tailored PA program (like the original Active Plus intervention, but adapted to CPS) provided guidance, ways to perform PA and emphasized PA benefits (Golsteijn et al., 2014). Healthcare providers suggested more practical things, like the use of graphic materials or videos, providing the possibility to consult an expert or providing referral to an expert and using social media or apps.

Theoretical methods and applications in the OncoActive intervention

To optimize participation of CPS in a PA program, it is important that an intervention is tailored to the patients' interests, abilities, opportunities, and preferences (Blaney et al., 2013; Buffart et al., 2014; Szymlek-Gay et al., 2011). Computer-tailoring provides the opportunity to easily adapt the intervention content to the specific characteristics of a patient to increase personal relevance. It is the core method of the OncoActive intervention (just as in the original Active Plus intervention). Computer tailoring is a method that uses questionnaires to assess characteristics, beliefs, behavior, etc., of the individual participants and automatically produces feedback. The feedback, based on the assessment, is created by using a message library and computer-based if-then algorithms to select the right messages. The feedback is personalized and automatically tailored to the personal characteristics of the participant and can thus also be tailored to cancer-specific needs and beliefs (Krebs et al., 2010; Kreuter & Skinner, 2000). Computer-tailoring was an effective method in changing PA behavior in the original Active Plus intervention (Peels, Bolman, et al., 2013b; van Stralen et al., 2011). Several other studies and reviews also confirmed the effectiveness of computer tailoring in achieving behavioral change after providing tailored health promotion advice (Broekhuizen, Kroeze, Van Poppel, Oenema, & Brug, 2012; Kanera, Bolman, Willems, et al., 2016; Krebs et al., 2010; Kroeze, Werkman, & Brug, 2006; Kuijpers, Groen, Aaronson, & van Harten, 2013; Neville, O'Hara, & Milat, 2009; Noar, Benac, & Harris, 2007; Short, James, Plotnikoff, & Girgis, 2011).

Other theoretical methods used in the original Active Plus intervention included consciousness raising, self-monitoring, active learning, reinforcement, social modelling, persuasive communication and argumentation (Peels, van Stralen, et al., 2012; van Stralen et al., 2008). These methods and the related practical applications can be retained for the OncoActive intervention. Additionally, theoretical methods and practical applications are also applied to the cancer specific content, as a result of the added and altered change objectives. Adding the change objective 'Prostate and colorectal CPS learn about health benefits of PA related to cancer and can name personally relevant reasons for being sufficiently physically active' requires that the practical strategies and content for attitude and knowledge should contain information about cancer-specific (perceived) benefits. A few other examples of the way we adapted the content to the prostate and colorectal CPS group can be found in Table 5. When applying a theoretical method it is important that the underlying theoretical conditions or parameters are respected (Bartholomew et al., 2016). For example, SCT (Bandura, 1986) states that social modeling is only effective when the presentation of the methods meets certain conditions, such as participant identification with the model. For that reason, the existing role-model videos and pictures (for the paper-based version of the intervention) were replaced by videos and pictures with quotes of real cancer survivors instead of age and sex matched healthy adults.

Besides adjustments to methods and practical strategies regarding the cancer specific content, we also added some new applications based on the findings from the literature and our interviews. As self-efficacy is especially important (Courneya et al., 2007; Ungar, Wiskemann, & Sieverding, 2016) in CPS, and the interviewed CPS and healthcare professionals mentioned the importance of the possibility to consult a professional, the option to consult a physical therapist with questions regarding PA and cancer was added to the intervention.

Table 5 *Examples of adaptations in theoretical methods, practical strategies and tools used in Active Plus and OncoActive*

Personal Determinant	**Theoretical Method**	**Practical strategy**	**Tools**	
			Active Plus	**OncoActive**
Awareness	Self-monitoring	Encourage monitoring of own behavior	Self-complete logbooks to monitor own PA behavior in last week.	Using a pedometer to monitor own PA behavior. (added)
Knowledge	Tailored feedback and information delivery	Provide tailored feedback about PA recommendations, PA benefits and PA possibilities	Computer-tailored feedback in text about PA recommendations, health benefits of sufficient PA and PA possibilities (recreational, daily PA)	Computer-tailored feedback about cancer-specific PA recommendations, health benefits and possibilities. (added)
Attitude	Feedback and argumentation	Provide personal feedback and arguments about pros and cons	Computer-tailored feedback in text on perceived positive and negative consequences of PA. New arguments to change opinions are provided in text.	Computer-tailored feedback in text on perceived cancer-specific positive and negative consequences of PA. (added)
	Reinforcement	Provide ipsative feedback on changes in attitude: evaluation of changes	Computer-tailored feedback in text on positive changes in attitude towards PA at follow-up.	Computer-tailored feedback in text on cancer-specific changes in attitude towards PA at follow-up. (added)

table continues

Personal Determinant	**Theoretical Method**	**Practical strategy**	**Tools**	
			Active Plus	**OncoActive**
Self-efficacy	Feedback and argumentation	Provide personal feedback and new arguments on self-efficacy	Computer-tailored feedback in text on difficult situations. New arguments to cope with these situations are provided.	Computer-tailored feedback in text on cancer-specific difficult situations and physical complaints. New arguments to cope with these situations. (added)
	Reinforcement	Provide ipsative feedback on changes in self-efficacy: evaluation of changes	Computer-tailored feedback in text on positive changes in perceptions of difficult situations at follow-up.	Computer-tailored feedback in text on cancer-specific positive changes in perceptions of difficult situations at follow-up. (added)
	Social modelling	Provide role model stories about difficult situations and how to cope	Picture/Video of similar others (same age and sex) with quotes about a similar perceived difficult situation and how the role model coped.	Picture/video of similar others (prostate or colorectal cancer survivor) with quotes about cancer-specific difficult situations and how the role model coped. (altered)
Action Planning	Goal setting	Encourage to set PA behavior goals	Computer-tailored feedback in text about setting goals to be physically active for an extra number of minutes per week.	Computer-tailored feedback in text about setting goals to increase or maintain PA using a (provided) pedometer. (added)

Although the original Active Plus intervention influenced PA behavior directly and path analyses showed that the intervention also influenced several determinants of PA, we looked for additional methods to enhance monitoring and goal setting to address the intention-behavior gap. Research in general (Bravata et al., 2007; Kang et al., 2009; Koring et al., 2013) and specifically with CPS (De Cocker et al., 2015; Knols et al., 2010) revealed that pedometers can be a valuable application for self-monitoring of

PA behavior and goal setting. Therefore, we added the use of pedometers to the OncoActive intervention. By providing participants with instructions for monitoring, goal setting and adjusting goals, they are encouraged to self-regulate their PA behavior.

The described adaptations in methods and practical strategies were used to adapt existing and to develop new program components as described in the next section.

Step 4: Program production

Adaptation of program components

The adaptation and broadening of change objectives, theoretical methods and practical strategies also requires adaptation of program components. In general, all text messages were checked and if necessary adapted to relate them to the new target group of CPS. Additionally, intervention texts were edited and shortened by a professional editor. Some intervention elements were adapted more extensively and will be discussed below.

As mentioned in steps two and three, operationalization of the determinants for the OncoActive intervention was different from the original Active Plus intervention, as we added cancer-specific information regarding benefits of PA, attitude towards PA and difficult situations/barriers regarding PA. The change in determinants also requires adaptation in our screening instrument, in order to be able to tailor the new information to each individual CPS. As mentioned in step two, we searched the literature and used the information from the interviews to identify relevant pros, cons and barriers. This resulted in the addition of pros regarding PA being positively related to: better health, more energy/less fatigue, cancer recurrence, returning to 'normal' life, treatment related side effects, better bladder control and increased physical fitness (Blaney et al., 2013; Blaney et al., 2010; Charlier et al., 2013; Craike et al., 2011; Denlinger & Engstrom, 2011; Keogh & MacLeod, 2012; Stevinson et al., 2007). Cons were added regarding PA being related to: increased fatigue, increased pain, increased lymphedema, higher risk of infection and hindering recovery from cancer (Blaney et al., 2010; Charlier et al., 2013; Courneya et al., 2006; Loh et al., 2011; Rogers et al., 2006; Speed-Andrews et al., 2014). Difficult situations/barriers additionally included in the screening instrument and feedback library were urinary incontinence, feeling bad about bodily appearance, sleeping problems, being under treatment, suffering from treatment related side effects, lack of social support, peripheral neuropathy, afraid of falling, not knowing how much PA is allowed, fecal incontinence/diarrhea and having a stoma (Blaney et al., 2013; Blaney et al., 2010; Courneya et al., 2006; Craike et al., 2011; Denlinger & Engstrom, 2011; Lynch et al., 2010; Rogers et al., 2007; Rogers et al., 2006). Some difficult situations, like feeling fatigued or feeling sad which are highly relevant for CPS were already included in the original Active Plus intervention.

Providing information on both the already included (general) and the cancer-specific pros/cons and difficult situation/barriers would result in an overload of information in the OncoActive intervention. Therefore, we decided to provide feedback on a maximum of seven pros, six cons and ten barriers. These were the same number of feedback messages that were given in the original intervention (Peels, van Stralen, et al., 2012; van Stralen et al., 2008). As a result of this we had to apply a ranking to the delivered information. As cancer-specific determinants were expected to be of special relevance, we decided to provide feedback on these first. Complimentary feedback regarding the general determinants was provided until the maximum was reached or if there were no additional relevant determinants.

Another adaptation regarding the intervention materials involved the development of texts and information for using the pedometer for monitoring and goal setting. Tailored feedback messages regarding step goals were formulated and linked to the individual PA level of CPS. These messages also included instructions on how participants can continue on their own in setting new step goals once they have reached a goal. In addition to the tailored feedback, a brochure was provided with schemes CPS could use to keep track of their progress regarding their daily step count. The content was also translated into an interactive module on the website, to guide CPS in setting new step goals and monitoring their average daily step count.

As already mentioned in step three, role model videos and pictures of age and sex matched healthy older adults were replaced by pictures with quotes and video content from real cancer survivors. For this new content we conducted video-taped interviews with several cancer survivors. After filming the interviews, the content of the interviews was reviewed and short fragments with suitable quotes were added to the intervention. Colorectal CPS were shown videos/pictures of both (younger and older) males and females, whereas prostate CPS were only shown videos of (younger and older) males. These fragments showed for example which barriers the cancer survivors experienced and how they managed to overcome these barriers.

Based on the results of the interviews with CPS and health care providers, we also developed a module on the website in which CPS within the OncoActive intervention could consult a physical therapist with questions regarding PA, thus allowing them to receive a personal response to problems or difficulties. This module also contained a list with example questions and responses as a frequently asked questions database (FAQ). Participants were encouraged to look at these FAQ. Newly asked questions from participants were added (anonymized) to the 'database'. The aim of this module was to enhance the self-efficacy of CPS to become physically active.

Adaptation of delivery channels

The original Active Plus intervention was developed in a print-based version (exclusively in print materials, no additional website) (van Stralen et al., 2008) and a web-based version (exclusively online, no additional print materials) (Peels, van Stralen, et al., 2012). However, based on in-depth analyses it was suggested that for optimal effects the best solution would probably be to provide both delivery modes and giving the participant the choice of their preferred delivery mode (Ekman, Dickman, Klint, Weiderpass, & Litton, 2006; Kongsved, Basnov, Holm-Christensen, & Hjollund, 2007; Peels, Bolman, et al., 2012). Additionally, process evaluation data showed that in the original Active Plus intervention the print materials were used more often and better appreciated (Peels, de Vries, et al., 2013). Taking into account these findings we decided to deliver the OncoActive intervention both printed and online alongside each other. In this way people could choose their own preferred delivery channel and web-based materials were supplemented with print-based material for every participant in order to optimize use and appreciation.

Process evaluation data of the original Active Plus intervention additionally indicated that access to the web-based intervention itself and to the web-based intervention materials should be simplified (Peels, de Vries, et al., 2013). To simplify web access, we used URL's automatically logging people into the right place on the website in e-mails inviting participants to visit the website. Intervention materials were more integrated in the website, as shown in Figure 1. By integrating forms in this way, participants could start to fill out the form immediately, in contrast to the original Active Plus intervention. Additionally the website was constructed differently to increase the accessibility of the intervention content.

In order to keep participants more involved by visiting the website, we periodically provided them with additional news items, encouraging them to revisit the website. In total three news items were provided. The content and timing is described below.

The intervention

The adaptation process described above resulted in the adapted OncoActive intervention. As explained in the previous sections the intervention is based on behavior change techniques and aimed at increasing awareness of PA behavior and stimulating PA during leisure time and in daily activities. Intervention participants receive tailored advice at three time points.

First advice

Participants receive their first advice within two weeks after completing the first questionnaire. The content is based on their answers to this questionnaire. Together with the advice they receive a pedometer (for own use) to monitor their PA behavior and to continually set goals to increase their PA.

Second advice

The second 'follow-up' advice, which participants receive two months after their first advice, is also based on answers to the first questionnaire. The content of both the first and the second advice is tailored to the behavioral stage of change according to the TTM: topics shown in Table 6, were addressed either in advice one or advice two depending on the stage of change at baseline. The content of the messages was tailored to cancer type and phase (i.e., during or after active treatment).

Third advice

Three months after the first questionnaire participants receive a new questionnaire and subsequently, within two weeks after completion, a third tailored advice. This final advice addresses changes in PA and PA related determinants since the start of the program. Improvements are rewarded, whereas suggestions for improvement are given in case of stagnation or decline.

News updates

Additionally, participants receive two or three news updates with extra information by e-mail. The first news update addresses the topic of incontinence and pelvic floor therapy and contains videos in which a pelvic floor therapist provided information. Participants suffering from urinary or fecal incontinence receive an e-mail that there is new content on the website, one month after their first advice.

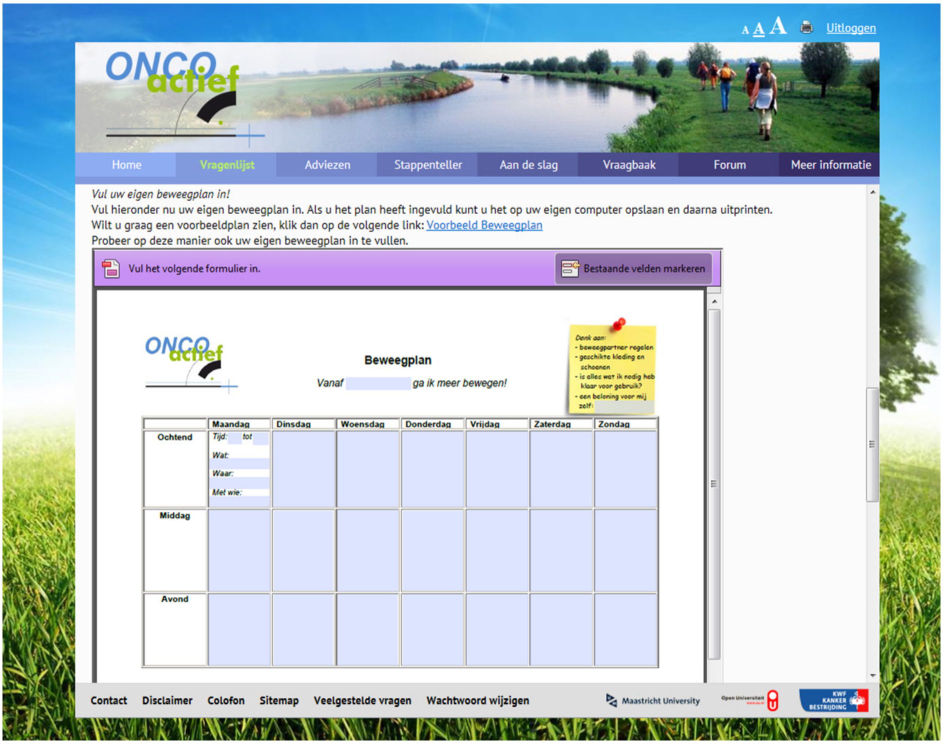

Figure 1 OncoActive website with integrated intervention materials

The second news update contains video content in which a physical therapist explains the importance of PA during and after cancer treatment. All participants receive an e-mail to draw their attention to the new content on the website, six weeks after their first advice.

The third news update reminds participants about using their pedometer and provides them with tips and tricks to collect additional steps during their daily routines. All participants receive a notifying e-mail six weeks after their third (and last) tailored advice. A schematic overview of the intervention is shown in Figure 2.

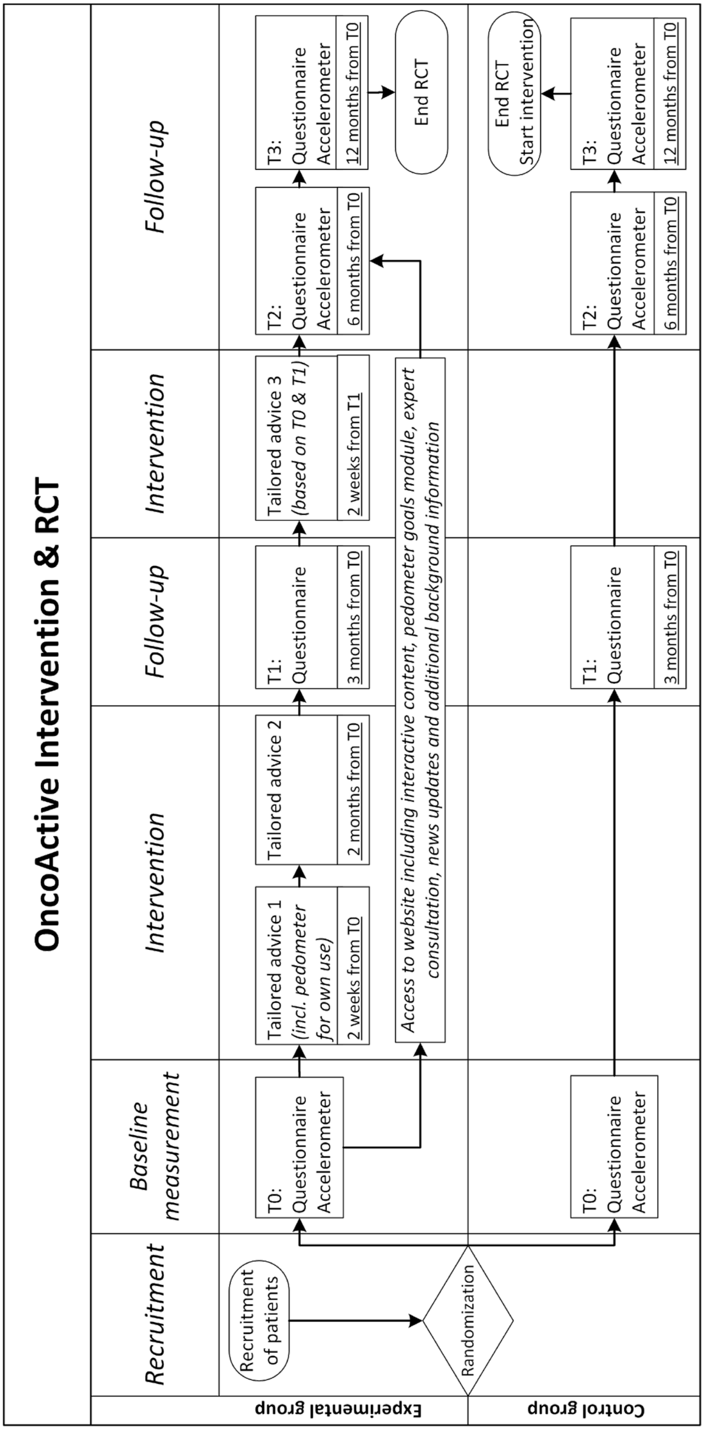

Figure 2 Schematic overview of the intervention and the associated randomized controlled trial

Delivery channel

As previously mentioned, CPS can participate in the intervention both online and via paper-based questionnaires and advice. Every participant receives both log-in details for the OncoActive website to fill out the questionnaire and a paper-and-pencil version of the questionnaire. After completion of the questionnaire of their own choice, they receive their tailored advice both on the website and by normal mail. On the website they can also find additional interactive content (e.g., role model videos, home exercise instruction videos), a module for goal setting using the pedometer, the option to consult a physical therapist and additional information. A summary of intervention content and the addressed topics can be found in Table 6.

Table 6 *Content summary of the OncoActive intervention*

Topics computer-tailored advice[1]	**Summary of content**[1]
Advice 1 & 2	
Awareness	- Graph with own behavior and guideline behavior
Knowledge	- Information regarding guideline - Information regarding positive effects of PA for prostate and colorectal CPS
Attitude	- Computer-tailored reflection and explanation on perceived pros and cons of PA
Motivation	- Role model video/picture about most important motivation for being physically active - Space to write down own (intrinsic) motivation for PA
Self-efficacy	- Computer-tailored reflection and explanation on perceived barriers and physical complaints - Suggestions to overcome barriers and deal with physical complaints - Role model video/picture demonstrating how to deal with barriers
PA suggestions	- Practical suggestions to be physically active according to the CPS' preferences - Information about walking and cycling routes - Cancer-specific PA suggestions (e.g., PA groups for CPS) - Home exercises (video/pictures)
Goal setting	- Instructions about goal setting and monitoring using a pedometer
Action planning	- Scheme to plan PA on a weekly basis
Coping planning	- Scheme to construct if-then solutions for barriers or situations in which PA is difficult
Social support	- Encourage CPS to ask for support from their social environment - Suggestions to find someone to be physically active with

table continues

Topics computer-tailored advice[1]	Summary of content[1]
Advice 3	
Ipsative feedback	Feedback on: - Changes in PA behavior, activities and goals - Changes in health related factors (fatigue, quality of life) - Changes in PA determinants (intention, attitude, self-efficacy) - Changes in social support
Monitoring behavior	- Scheme to keep track of own PA behavior - Encouragement to continue pedometer use
Website components	**Explanation**
Pedometer module	Module for registering pedometer step counts to monitor PA behavior and set new step goals
Video content	Role model videos in which real cancer survivors talk about their own experiences and coping. Instruction videos with home exercises.
Expert consultation and FAQ	Module in which CPS can consult a physical therapist with questions regarding PA. Frequently asked questions are also shown.
Discussion group	Online discussion group in which CPS can exchange information, experiences and questions
Background information	Complementary information regarding nutrition, return to work, other website and interesting mobile applications
News update message	News messages regarding pelvic floor therapy, expert opinion about PA and cancer and tips and tricks to increase PA using a pedometer

[1] *Sequence and content of topics are adjusted to the stage of change of the CPS*

Pretest and pilot-test

As several intervention components were already evaluated within the Active Plus intervention, firstly we pretested newly developed intervention materials among twenty-nine CPS (who also participated in the interviews). We evaluated two possible designs for the websites (see Figure 3). Design one was significantly more appealing and more appreciated (appeal: 3.7 vs. 3.2 on a 1-5 scale, p = .005; appreciation 7.5 vs. 6.6 on a 1-10 scale, p = .003). Furthermore, the pedometer, a role model video with a cancer survivor and the discussion group were appreciated as well (7.2, 7.7 and 7.0 respectively on a 1-10 scale) and valued as useful (3.7, 3.8 and 3.5 respectively on a 1-5 scale). Text messages for cancer specific barriers were rated 7.0 to 7.5 (on a 1-10) scale, except the text message about being physically active with a stoma, which scored a 5.6. To address this low score, we decided to add a brochure about PA with a stoma, developed by the Dutch stoma association, to the advice. Minor adaptations on the other text messages were made based on the suggestions of CPS.

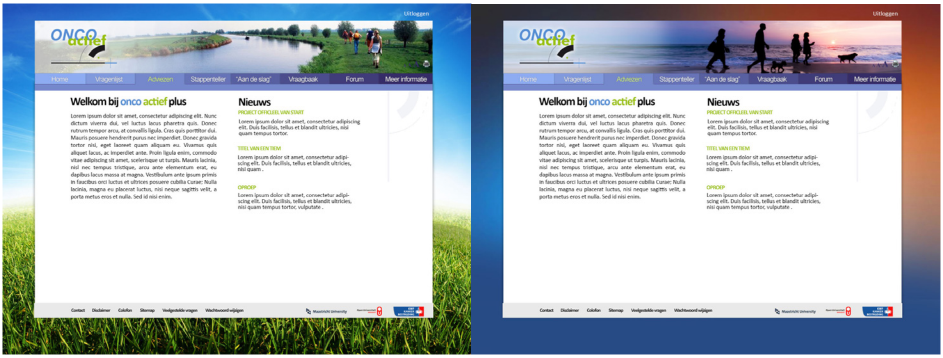

Figure 3 Potential website designs (design one on left) for the OncoActive intervention

After finishing intervention development, the complete intervention was evaluated in a small scale pilot study, in which the intervention was delivered to twenty-one CPS in a shortened time frame (i.e., two months instead of four months). CPS were recruited from one hospital and one radiotherapy institute. Findings from this pilot-test showed that the tailored advice was appreciated (7.5, 7.5 and 7.8 respectively on a 1-10 scale), as was the intervention overall (8.3 on a 1-10 scale) (Golsteijn et al., 2015).The pedometer and cancer specific role model stories (i.e., new intervention components) were highly appreciated (8.5 and 7.7 on a 1-10 scale) and regarded as useful (4.2 and 3.9 on a 1-5 scale), especially the pedometer (Golsteijn et al., 2015). The newly developed website's usability was evaluated using the System Usability Scale (Brooke, 1996) and scored a 68.86 on this scale. According to this scale a score of 68 can be seen as average. Website components, i.e., the consultation of a physical therapist and additional background information were also appreciated (7.3 and 8.8 on a 1-10 scale) and regarded as useful (3.7 and 4.6 on a 1-5 scale). Lastly we also evaluated self-reported PA. Although we did not find a significant pre- to post-test increase in the minutes of moderate to vigorous PA, we found (even in the short time period) a significant increase in the number of days CPS reported being physically active for at least 30 minutes (3.8 vs. 5.3, p=.005).

As the intervention and the newly developed components received good scores on the pilot test, we decided not to adapt these components. In the pilot we tried to use a Facebook group as a discussion group. However, as this was not broadly used in the pilot study and because it was difficult to guarantee the privacy of the participants, as well as being difficult to integrate a Facebook group on the website, we decided to use a normal discussion forum for the final intervention. Additionally we noticed that participants had difficulties with filling out some parts of the questionnaires, such as the treatments they received and the social support and modeling they received from fellow CPS. Therefore, we decided to ask questions about received treatments together with a question about the type of cancer (i.e., prostate or colorectal) in a small questionnaire added to the informed consent form. In this way we had the opportunity to clarify ambiguities, in order to be assured that the participants received advice that matched their personal situation. With regard to the questions about social support and modeling from fellow CPS, we decided to drop this from the interventions, as it turned out that participants often did not know fellow CPS very well.

Finally, we also pretested the safety and feasibility of the content with cancer care professionals (n=11) who also participated in the interviews. The scores in Table 7 show that the intervention content was regarded as highly feasible and safe. Minor adaptations (i.e., framing of a sentence) were made to the intervention texts based on suggestions of the cancer care professionals.

Table 7 *Expert rating of the intervention content regarding safety and feasibility*

Topics	**Mean (SD) (scale 1-5)**
Medical information is accurate	4.1 ± 0.8
PA recommendations are safe and suitable	4.4 ± 0.7
Sufficient safety precautions are taken	4.3 ± 0.9
Suitable for patients currently undergoing treatment	4.3 ± 0.6
Suitable for patients who finished treatment	4.4 ± 0.5
Information fits logic, language & experience of patients	4.7 ± 0.5

Step 5: Program implementation plan

For implementation of the OncoActive intervention in a RCT, we created a network of hospitals and radiotherapy institutes in the Netherlands, including the two who participated in the small scale pilot. Contact persons within these institutions were surgeons, oncologists, urologists, research nurses and nurse practitioners. Seventeen hospitals agreed to participate in the active recruitment of CPS. Another five hospitals were not able to provide enough resources to actively recruit CPS, but agreed to distribute posters and flyers. Other reasons for not participating in the recruitment were the presence of (too many) other research projects and that the hospital treated only a few patients who met inclusion criteria.

Additionally daily and weekly regional newspapers, relevant websites and discussion groups were contacted to publish a call for CPS.

Step 6: Evaluation plan

The final step entailed the development of a plan for the effect and process evaluation of the intervention. For this evaluation we compared an intervention group receiving the OncoActive intervention (who had also access to all usual care) to a usual care only control group in a RCT. The latter group had access to all usual care and received the OncoActive intervention after completion of all research measurements. Participants who provided informed consent to participate were randomly assigned to one of two study arms. The RCT was approved by the Medical Ethics Committee of the Zuyderland hospital (NL47678.096.14) and is registered in the Dutch Trial Register (NTR4296).

Participants

CPS (≥18 years) diagnosed with colorectal or prostate cancer could participate in the trial if they were undergoing treatment with a curative intent, or if they successfully completed primary treatment (surgery, chemotherapy or radiation) up to one year ago. Surgery should have taken place at least 6 weeks before the start of the study. CPS with severe medical, psychiatric or cognitive illness which could interfere with participation in a PA program were excluded from participation. Proficient Dutch reading and speaking skills were required for the completion of questionnaires and reading the tailored advice.

Power Calculation

Sample size calculations were based on the outcomes of the previous studies on the effects of the Active Plus intervention. These studies found an effect size of 0.3 and effects were assumed to be comparable in CPS. Calculations showed that approximately 300 participants were needed for the effect study, based on this effect size, a power of .80 with an alpha of .05 and a correction for multilevel analyses (intracluster correlation coefficient =.005, design effect = 1.15). Drop-out was expected to be around 30% during the study, thus 428 participants were needed for enrollment at baseline.

Design and procedure

Prostate and colorectal CPS were recruited from urology and/or oncology departments of seventeen hospitals in 2015 and 2016. Eligible CPS were identified by hospital staff and verbally informed (either in person or by telephone) about the research. Written information was handed over or sent by mail if the patient agreed to receive this information package. Additionally CPS were recruited with posters and flyers in non-participating hospitals, as well as with calls in local newspapers and on relevant websites and discussion groups. Participants responding to these messages were informed by the researchers and were also sent an information package by mail.

The information package included a letter with information about the study, a time schedule of the study, an informed-consent form and a pre-paid return envelope. Reminders were sent to participants if there was no response on the initial information package. CPS who agreed to participate, were randomized into one of the two research conditions as depicted in Figure 2. Subsequently they were mailed an accelerometer with instructions to wear it for seven days. After wearing the accelerometer they received a questionnaire both online and on paper, with the choice to fill out one of them. After completing this baseline questionnaire (T0), the intervention group received the OncoActive intervention. Both groups had to fill out follow-up questionnaires at three time points: three (T1), six (T2) and twelve (T3) months after baseline. Participants were also requested to wear the accelerometer the week before they filled out T2 and T3 questionnaires. The control group received the OncoActive intervention after completing the last measurement (T3).

Measurements

The primary outcome for this study was PA behavior, assessed both objectively with an accelerometer (Activity Monitor GT3X-BT ActiGraph, Pensacola, Florida, US) and a validated self-report questionnaire (Short questionnaire to assess health-enhancing physical activity (SQUASH)) (Wendel-Vos et al., 2003). Secondary outcome measures included fatigue (Vercoulen et al., 1994), anxiety and depression (Bjelland, Dahl, Haug, & Neckelmann, 2002; Zigmond & Snaith, 1983), mental adjustment to cancer (Watson & Homewood, 2008), quality of life (Aaronson et al., 1993) and health care consumption. Besides primary and secondary outcomes, CPS were also asked questions about demographics, cancer related characteristics (type of cancer, type of treatment currently undergoing/finished/planned for the near future), PA related determinants (awareness of personal PA level, attitude, self-efficacy, intention toward PA, habit strength). For the purpose of a process evaluation, participants of the intervention group were asked additional questions about use, appreciation, usefulness, readability, attractiveness, personal relevance and understanding of OncoActive. Besides the questionnaires, the use of the website and all accompanying elements were logged during the intervention period.

DISCUSSION

The purpose of this paper was to describe the systematic development process of the OncoActive intervention, a computer-tailored PA program for prostate and colorectal CPS both during and after treatment. The OncoActive intervention was aimed at increasing PA of prostate and colorectal CPS. By increasing PA behavior, the intervention may have a positive influence on cancer recovery and prevent other health problems. OncoActive was based on a proven-effective and evidence-based intervention for adults over fifty, the Active Plus intervention (Peels, Bolman, et al., 2013b; van Stralen et al., 2011). Systematic adaptation of this intervention to the new target group was guided by the IM protocol (Bartholomew et al., 2016).

In the first step we identified that only a minority of prostate and colorectal CPS adhered to PA guidelines, even though PA has the potential to positively influence health problems and address the decreased quality of life resulting from their disease and their treatment. In step two we identified the importance to address the cancer-specific determinants of PA as they differ from the determinants in a general population of adults over fifty. In step three we added theoretical methods and practical applications to address the cancer-specific determinants. Methods like a pedometer for goal setting and monitoring were added based on the findings from the literature and our interviews. In step four the actual program was developed and pre- and pilot tests revealed a high appreciation from the target group. The implementation and evaluation plan were described in steps five and six.

IM proved to be a useful approach for translating an existing intervention to a new target group. The use of this systematic approach in the intervention development increases the likelihood of OncoActive still being effective in increasing PA behavior and meeting the needs and preference of the new target group (Bartholomew et al., 2016). Major strengths of using IM include the possibility to retain the core elements of the original, proven effective (Peels, Bolman, et al., 2013b; van Stralen et al., 2011) intervention and the use of behavioral change theories and scientific literature. The involvement of prostate and colorectal CPS, at three time points (i.e., interviews, pretest and pilot test), and health care professionals was also regarded as a strength in the development of the OncoActive intervention. As a result, the intervention content is assumed to fit the needs and preferences of the target group. This was preliminarily confirmed by the findings of the small scale pilot study in which the intervention as a whole and its elements received positive evaluations from the target group. In particular, the newly added pedometer was identified as useful. Pre-posttest analyses even revealed an increase in PA behavior.

One of the major challenges in adapting an existing intervention to a new target group was to constrain the amount of information provided to the participants. By adding cancer-specific content to the already existing content, texts inevitably become longer. A lot of written information might particularly be a problem for lower educated participants (Verkissen et al., 2014). To avoid an overload of information, we decided to give preference to cancer-specific information as mentioned in step four. Additionally, intervention texts were edited and shortened by a professional editor. Furthermore, participants were able to revisit the website as many times as they wanted during the intervention period and as they received a printed version of their advice, they could easily stop and return or re-read the information.

Strengths of the OncoActive intervention itself include the fact that CPS can participate from their own home and at their own preferred time, as was indicated as a preference of CPS in previous research (McGowan et al., 2013; Murnane et al., 2012; Szymlek-Gay et al., 2011). Therefore, the intervention is regarded as easily accessible for the target group. Additionally, as both an online version and printed materials are provided, CPS can choose which delivery channel they prefer, which is suggested to increase the reach of the OncoActive intervention (Peels, Bolman, et al., 2012). As the OncoActive intervention is based on the concept of computer-tailoring, the information regarding PA could be made more personally relevant. Information perceived as personally relevant is assumed to be read more often and processed more thoughtfully, increasing the likelihood of behavior change or maintenance (De Vries & Brug, 1999; Noar et al., 2007). With time and place not being an issue, and the use of an automated process like computer tailoring, the OncoActive intervention has the potential to reach a large group of CPS with minimal resources in terms of personnel, and can thus be offered at low costs once it has been developed.

Notwithstanding the potential strengths, a RCT should still provide further insight into the effectiveness of the OncoActive intervention. This RCT will also provide insight into the question of whether a systematically adapted version of an effective intervention is still effective for a different target group. If the OncoActive intervention indeed proves to be effective in increasing PA, an implementation study for future nationwide implementation would be the next logical step. Information on optimal conditions (hindering and facilitating factors) for implementation will be derived from interviews with representatives of organizations relevant for implementation. Furthermore, if proven effective, the content of the OncoActive intervention can be extended to the cancer-specific determinants of other cancer types.

4

A WEB-BASED AND PRINT-BASED COMPUTER-TAILORED PHYSICAL ACTIVITY INTERVENTION FOR PROSTATE AND COLORECTAL CANCER SURVIVORS: AN EVALUATION OF USER CHARACTERISTICS AND INTERVENTION USE

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ABSTRACT

Background

Physical activity (PA) is beneficial in improving negative physical and psychological effects of cancer. The rapidly increasing number of cancer survivors, resulting from aging and improved cancer care, emphasizes the importance to develop and provide low cost, easy accessible PA programs. Such programs could be provided through the internet, but that could result in the exclusion of cancer survivors not familiar with the internet. Therefore, we developed a computer-tailored PA intervention for prostate and colorectal cancer survivors in which both web-based and print materials are provided, and participants can choose their own preferred delivery mode.

Objective

The aim of this study was to assess participants' characteristics related to delivery mode and use of intervention materials.

Methods

We studied characteristics of participants using web-based and printed intervention materials in a randomized controlled trial. Prostate and colorectal cancer survivors recruited from hospitals were randomized to OncoActive (computer-tailored PA intervention) or a usual-care control group. OncoActive participants received both web-based and printed materials. Participants were classified into initial print- or web-based participants based on their preferred mode of completion of the first questionnaire, which was needed for the computer-tailored PA advice. Intervention material use during the remainder of the intervention was compared for initial print- or web-based participants. Additionally, participants were classified into those using only print materials and those using web-based materials. Differences in participant characteristics and intervention material use were studied through analysis of variance, chi-square tests, and logistic regressions.

Results

The majority of the participants in the intervention group were classified as initial web-based participants (170/249, 68.3%), and 84.9% (191/249) used web-based intervention materials. Dropout was low (15/249, 6.0%) and differed between initial

web-based (4/170, 2.4%) and print-based (11/79, 14%) participants. Participants were less likely to start web-based with higher age (odds ratio [OR]=0.93), longer time since last treatment (OR=0.87), and higher fatigue (OR=0.96), and more likely with higher education (OR=4.08) and having completed treatments (OR=5.58). Those who were older (OR=0.93) and post treatment for a longer time (OR=0.86) were less likely to use web-based intervention materials. Initial print-based participants predominantly used print-based materials, whereas initial web-based participants used both print- and web-based materials.

Conclusions

To our knowledge, this is one of the first studies that assessed participant characteristics related to delivery mode in an intervention in which participants had a free choice of delivery modes. Use of print-based materials among the initial web-based participants was substantial, indicating the importance of print-based materials. According to our findings, it may be important to offer Web- and print-based materials alongside each other. Providing web-based materials only may exclude older, less educated, more fatigued, or currently treated participants; these groups are especially more vulnerable and could benefit most from PA interventions.

INTRODUCTION

Cancer and cancer treatment coincide with short- and long-term effects on both physical and mental health, eventually decreasing quality of life of cancer patients and survivors (CPS) (Bourke et al., 2015; Denlinger & Barsevick, 2009; El-Shami et al., 2015; Harrington et al., 2010; Skolarus et al., 2014; Wu & Harden, 2015). A healthy lifestyle, and especially physical activity (PA), is known to be beneficial for cancer survivors in improving treatment-related side effects and thereby health-related quality of life (HRQoL) (Buffart et al., 2017; Cormie et al., 2017; Schmitz et al., 2005; Szymlek-Gay et al., 2011). Additionally, PA is a preventive factor for the development of other chronic diseases and comorbidities for which cancer survivors are at risk (e.g., obesity, coronary heart disease, and diabetes), as well as for secondary or new cancer or cancer recurrence (Denlinger & Engstrom, 2011; Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; Schmitz et al., 2010; Speck et al., 2010; Szymlek-Gay et al., 2011). Therefore, effective PA programs for CPS are of major importance, especially since studies regarding supportive care needs have shown that CPS themselves express a substantial need for healthy lifestyle information and programs including PA (Jansen et al., 2015; Playdon et al., 2016; Willems et al., 2016).

In light of the rapidly growing population living with or after cancer, because of advances in early detection and treatment (Meulepas & Kiemeney, 2011; Siesling et al., 2014), there is a clear need for easily accessible and affordable programs aimed at self-management. web-based interventions may be a cost-effective method since they have a large potential reach for low cost and have proven to be effective in increasing PA in both healthy and diseased populations (Davies, Spence, Vandelanotte, Caperchione, & Mummery, 2012; Joseph, Durant, Benitez, & Pekmezi, 2014; Vandelanotte et al., 2016; Webb et al., 2010). A frequently used and proven effective method for web-based interventions is computer-tailoring (Davies et al., 2012; Krebs et al., 2010; Lustria et al., 2013; Vandelanotte et al., 2016): participants receive personalized feedback generated automatically using computer-based data-driven decision rules and data collected from questionnaires (e.g., individual characteristics, beliefs, and behavior, etc.) (Kreuter & Skinner, 2000).

With rapid increases in internet access in recent years, preconditions for the use of web-based interventions have improved substantially. In 2016, 94% of the Dutch population had internet access and electronic health (eHealth) applications were increasingly used, especially by adults aged over 65 years and adults with a chronic disease (Centraal Bureau voor de Statistiek (CBS) [Statistics Netherlands], 2017;

Krijgsman et al., 2016). Therefore, with a median age of 65 years at diagnosis (Miller et al., 2016) use of eHealth for CPS seems promising. However, internet access decreases substantially from the age of 75 years (60% compared with 90% among those aged 65-75 years in 2016), and frequency of internet use is also substantially lower with increasing age (Centraal Bureau voor de Statistiek (CBS) [Statistics Netherlands], 2017). eHealth literacy, that is, the ability to seek, find, understand, and appraise health information from electronic resources and apply that knowledge to solving a health problem or making a health-related decision (Norman & Skinner, 2006), is important for eHealth interventions to be successful. Studies showed that older age and lower socioeconomic status (SES) are related to lower eHealth literacy (Neter & Brainin, 2012) and that older adults may lack skills and knowledge for the use of eHealth interventions (Choi & Dinitto, 2013). Interventions that are only provided through the internet may therefore be less useful in a population of CPS (who are generally older aged) and may even exclude the elderly or those of lower SES from its benefits.

Alternatively, computer-tailored interventions can be delivered both through the internet and in print. A web-based version and a print-based version were offered alongside each other in the OncoActive intervention, a computer-tailored PA program to stimulate and maintain PA in prostate and colorectal CPS. As a result, CPS could choose their preferred delivery mode: every participant received log-in details for the OncoActive website to fill out the assessment questionnaire, as well as an additional (identical) paper-and-pencil version. After completion of the questionnaire of their own choice, participants received their tailored advice both web-based and by normal mail, enabling them to use either one or both. Providing the ability to use the preferred method for accessing intervention materials can increase intervention reach and adherence and may eventually result in larger behavior change effects in the target population. Therefore, it is important to determine which participant characteristics (e.g., demographics, disease related-factors, and health-related factors) are associated with the preference for a certain delivery mode and with the use of intervention materials. As providing the printed delivery mode alongside the web-based intervention is associated with higher costs, it is also important to gain insight into the actual use of these materials.

Research relating participant characteristics to delivery mode preference is scarce. To our knowledge, there is only one study in which participants from a general adult population could freely choose between print-based and web-based intervention materials. Factors associated with choosing printed materials were being older, less educated, and of poorer health status (Greaney et al., 2014). Another study examining participant characteristics of adults aged over 50 years cluster-randomized to either a print- or web-based PA intervention found that there was a higher percentage of males in the web-based intervention and that participants in the web-based intervention were younger, had a higher body mass index (BMI), and a lower intention to be physically active (Peels, Bolman, et al., 2012). A study from Short, Vandelanotte, and Duncan (2014) regarding PA intervention preferences of the general adult population (comparing face-to-face, group-, print-, and web-based delivery mode) revealed that factors positively associated with preference for a web-based intervention were being middle aged, living in a rural area, and high internet use. web-based preference was negatively associated with female gender, obesity, and high PA participation. Preference for a print-based intervention was positively associated with older age and negatively associated with female gender and obesity (Short et al., 2014). A positive attitude toward eHealth interventions in a population of cancer survivors was associated with lower age, higher income, higher quality of life, having completed cancer treatment, and having prostate cancer (Jansen et al., 2015).

The aim of this study was to provide insight into the characteristics of participants who initially chose to participate web-based versus those who initially chose to participate in the print-delivered intervention. As participants could use both web-based and printed materials or a combination after the initial choice, we also examined intervention material use and participant characteristics related to this. On the basis of findings in previous studies, we expected that age and education would be important predictors of initial web-based participation and using web-based intervention materials. Analyses with regard to PA and disease-related factors were exploratory.

Information regarding participant characteristics related to the initial choice for a delivery mode and the delivery mode and material use during the complete intervention would aid further implementation, as it could provide insight into the feasibility of using web-based interventions in a population of CPS, which often is elderly. This information could also help future researchers to choose the appropriate delivery mode for their audience and provide insight in which persons may be hard to reach when providing only a web-based intervention.

METHODS

Study Design

This study is part of a randomized controlled trial (RCT) in which participants were randomized to either the OncoActive intervention group or a usual-care waiting-list control group to assess the effectiveness. Since this study only examines the intervention delivery mode, control group participants were excluded from the analyses. The RCT was approved by the Medical Ethics Committee of the Zuyderland hospital (NL47678.096.14) and is registered in the Dutch Trial Register (NTR4296). All participants provided written informed consent.

Participants

CPS (≥18 years) diagnosed with colorectal or prostate cancer could participate in the trial if they were undergoing treatment with a curative intent or if they successfully completed primary treatment (surgery, chemotherapy, or radiation) up to 1 year ago. There was no restriction for patients currently undergoing hormonal therapy. By selecting only two cancer types, we could better fine-tune the intervention to the specific needs and capabilities in relation to cancer type. Prostate cancer and colorectal cancer were selected because they are among the most common cancer types in the Netherlands. Furthermore, survival rates are good, indicating a large population possibly benefiting from a PA intervention (Comprehensive Cancer Center of the Netherlands (IKNL), 2015; Miller et al., 2016).

Participants should have had surgery at least 6 weeks before the start of the study. Those suffering from severe medical, psychiatric, or cognitive illnesses (e.g., Alzheimer disease and mobility limitations) that could interfere with participation in a PA program were not invited to participate. Proficient Dutch reading and speaking skills were required for completing questionnaires and reading the tailored advice. Lack of internet access and internet skills were not a reason for exclusion.

Procedure

Prostate and colorectal CPS were recruited from the urology or oncology departments of 17 hospitals in 2015 and 2016. Eligible CPS were identified by hospital staff, verbally informed (either in person or by telephone) about the study, and invited to participate. Written information was handed over or sent by mail if the patient agreed to receive an information package. Additionally, CPS were recruited via other channels (e.g., calls in local newspapers, on relevant websites, discussion groups, and flyers in hospitals). Participants responding to these messages were informed by the researchers and were also sent an information package by mail.

The information package included a letter with information, a time schedule, an informed consent form, and a prepaid return envelope. If there was no response to the initial information package, 3 weeks later one postal reminder was sent. CPS who agreed to participate were randomized into either the intervention group or the control group. Subsequently, all participants wore an accelerometer (ActiGraph GT3X-BT, ActiGraph, Pensacola, FL) to objectively assess PA. Immediately after wearing the accelerometer for 7 days, every participant received an email with log-in details for the OncoActive website together with an invitation to fill out the web-based questionnaire and an identical paper-and-pencil version of the questionnaire by normal mail, enabling them to fill out the version of their preference. After completing this baseline questionnaire (T0), the intervention group received the OncoActive intervention that is outlined below. Both groups had to fill out follow-up questionnaires at three time points: 3 (T1), 6 (T2), and 12 (T3) months after baseline. At each time point, participants could choose whether they wanted to fill out the questionnaire on the website or on paper. The T1 questionnaire was used to provide ipsative feedback in the form of tailored advice (see below). The questionnaires at 6 and 12 months were administered for efficacy and process evaluation purposes and were thus not considered part of the intervention. The T3 questionnaire is not part of this study.

The OncoActive Intervention

The OncoActive intervention is a computer-tailored intervention aimed at awareness, initiation, and maintenance of PA behavior in prostate and colorectal CPS. The intervention was based on a proven effective, evidence-based intervention to stimulate PA in adults over 50 years (Peels, Bolman, et al., 2013a; van Stralen et al., 2011) and adapted for prostate and colorectal CPS using the intervention mapping protocol (Golsteijn, Bolman, Volders, et al., 2017).

Participants in the intervention group received tailored PA advice at three time points. The content of the first and second tailored advice was based on information gathered with the baseline questionnaire. Both the baseline (T0) and the second questionnaire (T1) provided input for the third tailored advice and allowed for the provision of ipsative feedback. The content of the advice is based on behavior change theories and targets pre-motivational constructs (e.g., awareness and knowledge), motivational constructs (e.g., self-efficacy, attitude, and intrinsic motivation), and post-motivational constructs (e.g., goal setting, action and coping planning, and self-regulation) (Golsteijn, Bolman, Volders, et al., 2017; Peels, van Stralen, et al., 2012; van Stralen et al., 2008). In addition to the tailored advice, every participant received a pedometer and access to interactive content on the website (e.g., role model videos, home exercise instruction videos, a module for goal setting using a pedometer, the option to consult a physical therapist, and additional information). A more detailed description of the intervention content can be found elsewhere (Golsteijn, Bolman, Volders, et al., 2017).

As previously mentioned, every participant received the first questionnaire web-based and on paper. After completion of the questionnaire of their own choice, participants received their tailored advice. If the questionnaire was completed on the website, advice was immediately available on the website, and participants were made aware that they would receive a printed version of their advice within 3 days. If participants completed the paper-and-pencil questionnaire, the advice text was available (web-based and print-based) within 2 weeks after receiving the questionnaire, after uploading participant data by research staff. Participants were emailed (if they provided their email address) that their advice was available on the website and that they would receive a printed version of the advice within 3 days. The tailored text was exactly the same for both modalities, but the web-based version contained more interactive content (e.g., videos). All participants were made aware that they could find additional interactive content on the website. The tailored advice was displayed on a distinct section of the website.

For the second provision of advice (2 months after the start), participants received an email to notify them that their advice was available on the website and that they would receive a printed version within a few days. For the third provision of advice (within 2 weeks of completing the T1 questionnaire), participants again received 2 versions (Web and print) of a questionnaire, with a procedure similar to the first advice.

Measurements

Several demographic variables, cancer-related characteristics, PA behavior, PA determinants, and health-related outcomes were measured in the baseline questionnaire of the RCT (Golsteijn, Bolman, Volders, et al., 2017). For this study, we used the following demographic variables: age, gender, height, weight, highest educational level, and household income. Educational level was categorized into low (i.e., primary, basic vocational, or lower general school), moderate (i.e., medium vocational school, higher general secondary education, and preparatory academic education), or high (i.e., higher vocational school or university level) according to the Dutch educational system. Height and weight were used to calculate BMI (i.e., weight in kilograms divided by height in meters squared). Participants were classified as being overweight (BMI >24.9 kg/m^2) or not. Cancer-related characteristics included type of cancer, which was either prostate or colorectal in this study; treatment status; and date of their last treatment.

PA was measured in two ways. Self-reported PA was measured using the validated Short Questionnaire to Assess Health Enhancing Physical Activity (SQUASH) (Wendel-Vos et al., 2003) assessing activities regarding commuting, household, occupation and leisure time. Total minutes of PA were classified into light (Metabolic Equivalent (MET) < 3.0), moderate (MET 3.0 – 5.9) and vigorous (MET > 6) (Haskell et al., 2007). Minutes of moderate-to-vigorous PA (MVPA) were calculated by adding up total time in moderate and vigorous PA. The SQUASH questionnaire has shown to have reasonable reliability (rho = 0.58) and validity against an accelerometer (rho = 0.45) (Wendel-Vos et al., 2003).

Additionally, objective PA was measured using the ActiGraph GT3X-BT. Participants wore the accelerometer on an elastic belt on their right hip for seven days. Data were downloaded and analyzed using ActiLife software (ActiGraph, Pensacola, FL). Measurements were considered valid if there were at least 3 days with at least 10 hours of wear time (Broderick et al., 2014; Hart, Swartz, Cashin, & Strath, 2011; Skender et al., 2015). Non-wear periods were excluded from the analyses and were identified according to Choi et al. (2012): intervals of at least 90 consecutive minutes of zero counts with allowance of a maximum of 2 minutes of nonzero counts during a non-wear interval. MVPA was calculated using Freedson-VM cut-off points based on 60 second epochs (Sasaki et al., 2011).

Intention to be sufficiently physically active was assessed using a scale of three items (alpha=.91) on a 10-point scale (e.g., “To what extent do you intend to be sufficiently physically active?”) (Peels, Bolman, et al., 2012; van Stralen et al., 2011). The score of the three items was averaged, resulting in a total score ranging from 1 to 10, with a high score indicating a high intention to be physically active.

HRQoL was measured using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC QLQ-C30) (Aaronson et al., 1993). The questionnaire comprises several scales, with the global health status scale providing an overview of general quality of life. Global health status was measured with two items (alpha=.85) on a 7-point scale. Scores were converted to scores ranging from 0 to 100, with a high score indicating a high HRQoL.

Fatigue was assessed using the Checklist Individual Strength (CIS) (Vercoulen et al., 1994). The subjective fatigue subscale assesses the experience of fatigue of participants. The eight items (alpha=.89) of the subscale are scored on a scale from 1 to 7, resulting in a total score in the range of 8 to 56.

Intervention material use was assessed with two questions per advice specifically aimed at the tailored advice: "Did you read your advice on paper?" and "Did you read your advice on the website?"; participants could identify whether they read the advice "completely," "partly," or "not."

Statistical Analysis

Dropout Analysis

Multiple logistic regression was performed to determine whether participants' characteristics were predictors of dropout during the intervention (i.e., at the 3-month follow-up questionnaire). Choice for the initial delivery mode was added as a variable to identify if one of the groups was more likely to drop out of the intervention. All predictors were forced into the model simultaneously (method Enter in Statistical Package for the Social Sciences [SPSS]).

Initial Choice Intervention Delivery Mode

For the analysis regarding the choice of the initial intervention delivery mode, we analyzed data from all participants who completed the baseline questionnaire. Classification into groups for the initial preferred intervention delivery mode was based on the way participants chose to complete the baseline questionnaire. In the accompanying information letter, participants were informed that they would immediately receive their first PA advice on the website if they completed the baseline questionnaire (used for the tailored advice) through the internet. Participants completing the first questionnaire on the website were therefore classified as "initial web-based participants," and participants completing the first questionnaire on paper were classified as "initial print-based participants."

Descriptive statistics on demographic factors (i.e., age, sex, educational level, and household income), cancer-related factors (i.e., type of cancer, treatment phase, and time since last treatment), PA-related factors (i.e., self-reported and objective PA behavior and intention to be physically active), and health-related factors (i.e., BMI, HRQoL, and fatigue) were calculated for the complete intervention group and split for "initial web-based participants" and "initial print-based participants."

Univariate one-way analysis of variance (ANOVA) and chi-square tests were used to determine significant differences between both groups. Multiple logistic regression (Enter method) was performed to determine differences in participant characteristics for initial intervention delivery mode choice.

Both educational level and household income are regarded as indicators of SES. We decided to include only educational level in the logistic regression as a previous study showed that compared with household income, education was more consistently predictive of eHealth use (Kontos, Blake, Chou, & Prestin, 2014).

Linking Delivery Preference to Intervention Use

Use of the different tailored advice texts was assessed with self-report questions. Chi-square tests were performed to determine differences between the "initial web-based participants" and the "initial print-based participants" with regard to the use of tailored advice. Additionally, differences regarding mode of completion of the second questionnaire (T1), which was part of the intervention, were assessed.

Continued Intervention Use Delivery Mode

On the basis of self-report regarding the use of the three sets of advice, participants were classified as "exclusively print-based participants," "participants who used both web-based and print-based materials," and "exclusively web-based participants." As there were only 2 participants classified as "exclusively web-based participants," we chose to dichotomize this classification into "exclusively print-based participants" and "participants using web-based materials."

Multiple logistic regression (Enter method) was performed to determine differences in participant characteristics between both groups.

All analyses were performed using SPSS version 22 (IBM Corp., Armonk, NY). To check for the influence of uneven groups in the multivariate logistic regression analyses, nonparametric bootstrapping with 5000 replications was applied.

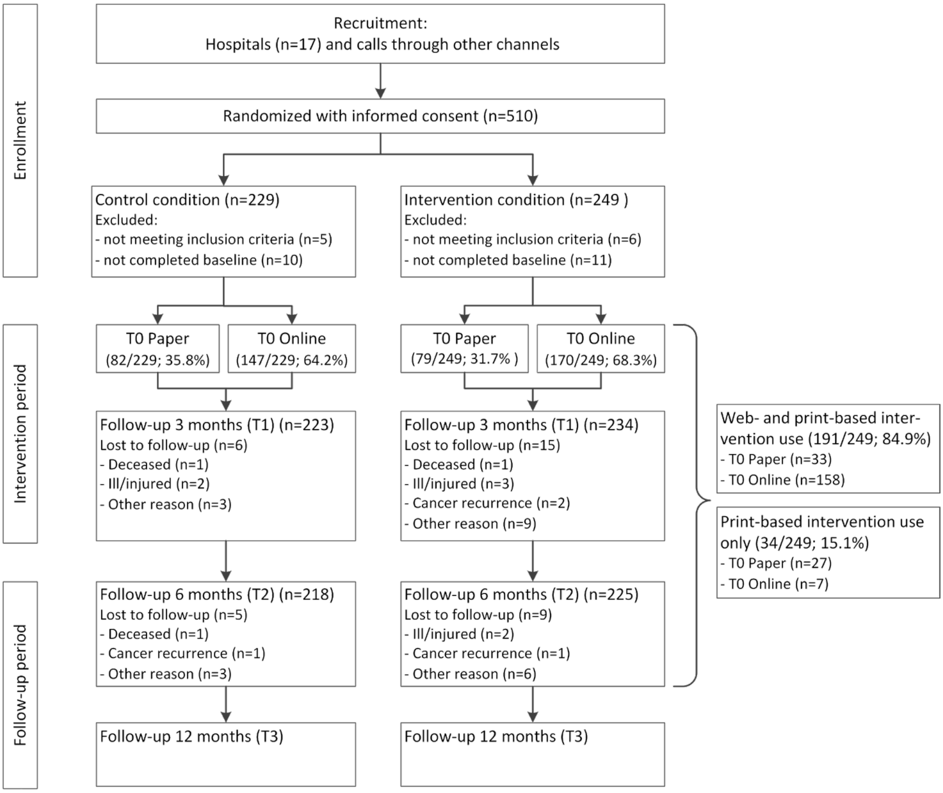

Figure 1 Flow diagram of the study

Note: The control condition was not included in the current study

RESULTS

Dropout Analysis

Within the intervention group, 232 participants out of the 249 enrolled at baseline completed the second questionnaire and received their final advice. Two participants who did not complete the second questionnaire missed just one questionnaire, whereas 15 participants opted out of the study, resulting in a dropout rate of 6.0%. Although dropout was limited, logistic regression analyses revealed that initial print-based participants were more likely to drop out (odds ratio [OR] 4.32, 95% CI 1.15 -16.25). Among the initial web-based participants, the dropout rate was 2.4% (4/170), and among the initial print-based participants, the dropout rate was 14% (11/79).

Table 1 *Baseline participant characteristics of the total intervention group and split for the initial web-based participants and the initial print-based participants*

	Total inter-vention (n = 249)	Initial web-based participants (n=170)	Initial print-based participants (n = 79)	*P* value
Demographic factors				
Mean age in years (SD)	66.38 (8.22)	65.08 (8.22)	69.18 (8.37)	.000
Gender (%)				.346
Male	85.4	86.8	82.3	
Female	14.6	13.2	17.7	
Education (%)				.002
Low	43.3	36.5	57.7	
Middle	28.6	29.3	26.9	
High	28.2	34.1	15.4	
Household income				.003
Low	11.8	7.4	23.2	
Middle	38.7	37.8	41.1	
High	49.5	54.7	35.7	
Cancer related factors				
Type of cancer (%)				.084
Prostate	59.8	63.5	51.9	
Colorectal	40.2	36.5	48.1	
Treatment phase				.046
During treatment	7.7	5.4	12.7	
After treatment	92.3	94.6	87.3	
Time since last treatment in months (SD)	5,64 (3,84)	5.42 (3.65)	6.13 (4.22)	.176
PA related factors				
MVPA SQUASH (SD)	798 (721)	831 (765)	727 (617)	.288
MVPA ActiGraph (SD)	270 (211)	280 (199)	249 (233)	.301
PA intention (SD)	7.60 (1.35)	7.71 (1.26)	7.38 (1.52)	.073
Health related factors				
BMI category (%)				.472
Normal weight	36.2	34.7	39.5	
Overweight	63.8	65.3	60.5	
General HRQoL (SD)	80.01 (16.81)	80.34 (16.53)	79.28 (17.50)	.647
Fatigue (SD)	24.00 (11.58)	23.04 (11.22)	26.48 (12.18)	.039

Participant Characteristics and Initial Choice Intervention Delivery Mode

In total, 510 prostate and colorectal CPS provided informed consent and were randomized into the intervention or the control group. For this study, we only used the data from the intervention condition, as this study aims to identify individual predictors of intervention delivery mode. In total, 249 participants were randomized into the intervention condition (Figure 1). Baseline characteristics for the complete intervention group are shown in Table 1.

The majority of the participants in the intervention group (n=249) were classified as initial web-based participants (170/249, 68.3%). Significant differences between the initial web-based participants and the initial print-based participants were found. Initial web-based participants were significantly younger (*P*<.001) and higher educated (*P*=.002). Furthermore, initial web-based participants had a higher income (*P*=.003), were more often post cancer treatment (*P*=.046), and were less fatigued (*P*=.04) (see Table 1).

Multiple logistic regression (see Table 2) revealed that participants were less likely to initially start web-based with higher age (OR=0.93, 95% CI 0.89-0.98), longer time since last treatment (OR=0.87, 95% CI 0.79-0.96), and higher levels of fatigue (OR=0.96, 95% CI 0.93-1.0). Although time since last treatment is negatively associated with initially participating web-based, participants who had completed cancer treatment were more likely to participate web-based than those who were still under active treatment (OR=5.58, 95% CI 1.36-22.82). Furthermore, those with a high level of education were more likely to initially participate web-based compared with those with a low level of education (OR=4.08, 95% CI 1.58-10.56).

Linking Delivery Preference to Intervention Use

When examining intervention material use in relation to the initial choice for delivery mode (see Table 3), it can be noticed that a significantly higher percentage of initial print-based participants did not read (all three) web-based advice (advice 1 and 2: *P*<.001; advice 3: *P*=.005). Furthermore, initial print-based participants were very consistent in their intervention material use throughout the intervention: 95% to 98% (partly) read the print-based advice and 56% to 62% did not read the web-based advice (see Table 3). web-based participants were more variable in the way they read their advice: completeness per advice decreases from the first advice to the final advice, with the final print-based advice being read significantly less completely (*P*<.001) by initial web-based participants compared with initial print-based participants. Additional analyses showed that intervention completeness considering both versions of the advice was not lower for the initial web-based participants. Percentages of participants reporting not having read any advice completely ranged from 0.9% (2/223) to 5.8% (13/225) per advice with no statistical differences between both groups.

With regard to completion of the second questionnaire (T1), it was noticed that the majority chose the same delivery mode for this questionnaire: 89.0% (146/164) of the initial web-based participants completed the questionnaire on the website, and 86.8% (59/68) of the initial print-based participants completed the questionnaire on paper.

Table 2 *Logistic regression to study relation between participant characteristics and the initial choice to participate online*[1] *(Nagelkerke R^2 = .25)*

	Odds Ratio (95% CI)	***P* Value**
Demographic factors		
Age (years)	0.93 (0.89-0.98)	.005
Female (male = Ref)	1.62 (0.52-5.03)	.403
Education (low = Ref)		
Middle	0.95 (0.42-2.15)	.899
High	4.08 (1.58, 10.56)	.004
Cancer-related factors		
Type of cancer (prostate = Ref)	0.55 (0.26-1.18)	.127
Treatment phase (during treatment = Ref)	5.58 (1.36-22.82)	.017
Time since last treatment (months)	0.87 (0.79-0.96)	.007
PA related factors		
PA intention	1.08 (0.80-1.44)	.624
MVPA ActiGraph	0.99 (1.0-1.0)	.330
Health-related factors		
BMI (normal weight = Ref)	1.48 (0.73-3.03)	.279
General HRQoL	1.00 (0.97-1.03)	.985
Fatigue	0.96 (0.93-1.00)	.035

[1] *initial web-based participation coded as 1.*

Note: additional nonparametric bootstrap analysis led to similar results

Table 3 *Intervention material use and completeness compared for initial web-based and print-based participants*

	Initial web-based participants (n = 170)	**Initial print-based participants (n = 79)**	***P* value**
Advice 1 Print-based Read			.356
Completely	72.0	79.7	
Partly	23.2	18.8	
Not	4.9	1.6	
Advice 1 Web-based Read			.000
Completely	58.9	22.6	
Partly	27.0	18.9	
Not	14.1	58.5	
Advice 2 Print-based Read			.057
Completely	62.2	76.9	
Partly	23.8	18.5	
Not	14.0	4.6	
Advice 2 Web-based Read			.000
Completely	51.2	21.2	
Partly	24.7	17.3	
Not	24.1	61.5	
Advice 3 Print-based Read			.000
Completely	48.1	78.3	
Partly	37.7	16.7	
Not	14.3	5.0	
Advice 3 Web-based Read			.005
Completely	42.2	24.0	
Partly	27.3	20.0	
Not	30.5	56.0	

Continued intervention use delivery mode

With regard to the selected delivery mode for using the intervention materials, we noticed that the majority (n = 191; 84.9%) used web-based most often in combination with print-based materials (see Figure 1). Results of the logistic regression identifying participant characteristics concerning the delivery mode for the use of intervention materials (print-only vs. using web-based materials; see Table 4) were similar to the results for initial choice of delivery mode for age (OR .93; 95% CI .86 – 1.00) and time since last treatment (OR .86; 95% CI .75 - .98). Highly educated participants were not significantly more likely to use web-based intervention materials than less educated participants, but the odds ratio (OR 3.52) and its 95% CI (.98 – 12.61), indicate that educational level may still be an important predictor. Fatigue and treatment phase were not identified as predictors for using web-based materials (or a combination) instead of using only print-based materials.

Table 4 *Logistic regression to study relation between participant characteristics and the continued use of web-based intervention materials*[1] *(Nagelkerke R^2 = .21)*

	Odds Ratio (OR)	***P* Value**
Demographic factors		
Age (years)	0.93 (0.86-1.0)	.041
Female (male = Ref)	0.82 (0.18-3.63)	.789
Education (low = Ref)		
Middle	1.22 (0.39-3.79)	.729
High	3.52 (0.98-12.61)	.054
Cancer-related factors		
Type of cancer (prostate = Ref)	0.98 (0.33-2.87)	.964
Treatment phase (during treatment = Ref)	0.99 (0.08-12.77)	.993
Time since last treatment (months)	0.86 (0.75-0.98)	.020
PA related factors		
PA intention	1.13 (0.78-1.65)	.508
MVPA ActiGraph	1.00 (1.0-1.0)	.525
Health-related factors		
BMI (normal weight = Ref)	2.34 (0.92-5.95)	.075
General HRQoL	1.00 (0.97-1.04)	.763
Fatigue	0.98 (0.93-1.03)	.431

[1] *Use of web-based materials coded as 1.*

Note: additional nonparametric bootstrap analysis led to similar results

DISCUSSION

This study was aimed at investigating participant characteristics in relation to initial choice of intervention delivery mode in a population of prostate and colorectal CPS. Additionally, intervention material use and participant characteristics in relation to intervention delivery mode were examined. Analyses provide insight into the feasibility of web-based interventions in an older population of cancer patients and thereby aid further implementation of the intervention.

Participant Characteristics and Delivery Mode

Age and education level were two participant characteristics which were consistently related to intervention delivery mode both for initial choice and follow-up delivery mode (i.e., web-based vs print-based). Higher age was associated with a lower likelihood of using web-based intervention materials. A lower educational level, although not significant in all analyses, was also associated with lower web-based participation. This corresponds with our expectations. Previous studies also revealed that eHealth literacy is lower for older adults and those with lower education (Choi & Dinitto, 2013; Tennant et al., 2015). Kontos et al. (2014) found younger age and higher education to be predictors for searching health information through the internet and using websites for diet, weight, and PA. In addition, participants in an adult population selecting print-based materials were older and had a lower level of education than those selecting web-based materials (Greaney et al., 2014).

This finding may imply that when implementing web-based interventions in a population of prostate and colorectal CPS, but probably also in a general older population (i.e., 61% of colorectal and 64% of prostate cancer patients is aged over 70 years at the time of diagnosis (Miller et al., 2016)), those who are older and those with a lower level of education may not be reached. Statistics in the Netherlands showed that internet access and frequency of internet use decrease substantially from the age of 75 years and are also lower among those with a lower educational level (Centraal Bureau voor de Statistiek (CBS) [Statistics Netherlands], 2017). Thus, besides lower internet access, older and less educated participants may also have lower internet experience and self-efficacy. As a result, they may choose to use the print-based materials, requiring less effort in comparison with the web-based materials. This is acknowledged by the unified theory of acceptance and use of technology (UTAUT) by Venkatesh. This theory states that use of technology is influenced by (among others) facilitating conditions and performance and effort expectancy, which are moderated by age and experience (Venkatesh, Morris, Davis, & Davis, 2003). Additionally, a study among colorectal CPS revealed that older patients do perceive web-based health information tools as highly useful and indicate a willingness to use such tools but are not always able to use them optimally (Bolle et al., 2016). It may be recommended to provide both web-based and print-based materials, especially among those aged over 75 years, to prevent exclusion of a vulnerable group of older or less educated participants and to have the most optimal use of the intervention .

Besides age and education, time since treatment was also consistently related to participating in the web-based intervention. CPS who finished their treatment longer ago were less likely to participate through the internet. CPS who received their most recent treatment longer ago are probably already further in their recovery process, may perceive less need for PA advice and may be less committed to becoming physically active. As a result, they probably chose the delivery mode for which they needed the least effort. Using print-based materials may be perceived as easier, as all materials are delivered at home and can be completed at any time. Although accessing web-based materials was made as easy as possible (e.g., emails linked participants to the website without log-in), for web-based participation, it is still necessary to start up a computer or tablet and go on the Web before being able to complete questionnaires (Kroeze, Oenema, Campbell, & Brug, 2008). Our results suggest that it may be important to provide print-based materials to also include those who completed their treatment longer ago. However, no other studies considered time since treatment, and therefore, additional research is necessary to explore the role of time since treatment.

Having finished treatment and lower levels of fatigue predicted the initial choice to participate Web-based but did not predict the use of web-based intervention materials. Possibly, participants' internet frequency decreases during treatments and while feeling fatigued. Going on the Web to start the intervention may be perceived as more effortful and may explain the initial choice to participate in the print-based intervention. During the course of the intervention, treatments may be finished and fatigue may decrease. As a result, CPS may decide to visit the web-based content of the intervention during continued use. It may be important to provide both delivery modes at invitation for those who are still undergoing treatment or suffering from fatigue, a group that may benefit most from the intervention. Future research needs to confirm these findings.

In this study, gender was not predictive for intervention delivery mode. The precise role of gender differences regarding internet access, eHealth use, and delivery mode has been ambiguous: whereas some studies found a link with gender (Kontos et al., 2014; Peels, Bolman, et al., 2012; Short et al., 2014), others did not find differences between males and females (Greaney et al., 2014; Kerr et al., 2010; Martin et al., 2016; Neter & Brainin, 2012). Additionally, it should be noted that there was only a small portion of women in this study, as a result of part of the intended target population being prostate CPS, which may have influenced the power to detect differences. Future research should provide more insight regarding the influence of gender on delivery mode.

It is also interesting that PA behavior and intention to be physically active are not related to intervention delivery mode preference. PA behavior has proven to be a predictor of delivery mode preference according to studies examining self-reported intervention modality preference. Studies in the general population and in a cancer population found that those with lower PA levels may have a preference for web-based or computer-based interventions (Martin et al., 2016; Short et al., 2014). Others argued that those with a risk behavior (e.g., low PA behavior) may prefer the instant availability and interactivity of web-based materials (Greaney et al., 2014). However, both in this study as well as in the study of Greaney et al. (2014) actual choice of delivery mode was not predicted by PA behavior. Possibly, reporting a certain preference is different from the actual choice. Therefore, additional research is necessary to examine the role of health behavior in intervention delivery mode.

Intervention Material Use

It is promising that in an older population (i.e., mean age of 66 years), approximately two-thirds of the participants initially chose to participate through the internet and that even a larger proportion (i.e., almost 85%, 191/225) used the web-based intervention content. This indicates that for a large part of our population, going on the Web was not a barrier.

Since the web-based content of the OncoActive intervention could be accessed using a computer or tablet, participants were able to visit the website in the manner they were most familiar with (e.g., computer or tablet). Providing OncoActive through different platforms may have increased the usage of the web-based intervention materials (Granger et al., 2016).

We also examined whether intervention material use differed between initial print-based participants and initial web-based participants. The majority of initial print-based participants predominantly used the print-based tailored advice. Significantly less participants in this group used the web-based advice (i.e., 38%-44%, Table 3), compared with the initial web-based participants (i.e., 69.5%-85.9%, Table 3). Additionally, the majority (i.e., 87%, 59/68) of the initial print-based participants also completed the second questionnaire (which was part of the intervention) on paper. These findings indicate that it may be important to provide print-based intervention materials for participants who start the intervention print-based. However, since web-based materials can be provided without additional costs, it is recommended to provide both.

The majority of the initial web-based participants also completed the second questionnaire on the website (i.e., 89.0%, 146/164) and used both web-based (i.e., 69.5%-85.9%, Table 3) and print-based (i.e., 85.8%-95.2%, Table 3) intervention materials, indicating that initial web-based participants used a mixture of both advice texts and that providing print-based tailored advice in addition to the web-based advice may be advantageous. Studies among elderly found similar results, indicating that even among those using the internet, a preference for print-based or non-digital information persists (Choi & Dinitto, 2013; Gordon & Hornbrook, 2016). Although this may be a temporary phenomenon (e.g., rapid technology development and aging of adults more familiar with the internet), Vandelanotte et al. (2016) also suggested that having access to web-based material might not be sufficient in itself. Therefore, future research should also focus on reasons for not using web-based materials or why there is a preference for print-based materials.

As mentioned, information regarding use of print-based materials is important, as offering web-based and print-based materials alongside each other is associated with higher costs. A version that is only web-based would be less costly. With regard to the questionnaires, it was noticed that a majority started the intervention with a web-based questionnaire and also continued to complete additional questionnaires on the website. Consequently, it may be feasible to initially invite participants to complete the questionnaires on the website, while explicitly explaining that it is also possible to participate in the intervention if they do not have internet access or are not able or willing to participate through the internet. Print-based questionnaires can then be provided on request or with a reminder. Nevertheless, it may be advisable to offer both delivery modes with the invitation for those who are older or for those still undergoing treatment, as these participant characteristics are easy to administer at intake, and results of this study showed that they are predictors of initial print-based participation.

With regard to the computer-tailored advice, the majority used a combination of both web-based and printed materials. Although providing print-based materials complementary to the web-based advice is associated with higher costs (e.g., printing and postage costs), it may be best to provide both, as print materials are used by all participants. Providing both delivery modes alongside each other may be more costly than providing the intervention in a singular delivery mode. Additionally, intervention efficacy in relation to delivery mode should also be considered, as information processing may depend on the delivery mode (Smit, Linn, & Van Weert, 2015). Therefore, future research should also focus on the relation between delivery mode and (cost)effectiveness.

Strengths and Limitations of This Study

Providing participants with the ability to select their own preferred intervention delivery mode is regarded as a strength of this study. As indicated by previous studies, this may enlarge intervention engagement and thereby the impact of the intervention (Greaney et al., 2014). Additionally, this study had a very low dropout rate. Only 6.0% (15/249) of the participants opted out of the study during the intervention period. This is a remarkable finding, as high dropout rates are common in web-based interventions (Eysenbach, 2005; Kohl, Crutzen, & de Vries, 2013). Providing a combination of web-based and print-based materials might have prevented participants from dropping out of the study. If a specific delivery mode did not meet participants' expectations, they were able to use only the materials that were most appealing to them.

As described in the methods, the preferred initial delivery mode was based on completion of the first questionnaire, as it contained the questions to build the tailored advice. However, it should be acknowledged that because of the evaluation of the intervention in an RCT, the questionnaire was longer than the actual questionnaire needed for tailoring. As a result, the current findings may reflect the preference for completing a research survey rather than the actual intervention delivery mode. Future implementation without the research component would be necessary to confirm the current findings.

In this study, we did not collect any information regarding internet access and previous experience with the internet. This information might have been valuable, as other studies found those factors to be predictors of using web-based intervention materials (Choi & Dinitto, 2013; Greaney et al., 2014; Kontos et al., 2014).

Participants in this study were offered both web-based and print-based materials complementary to each other. Therefore, we were not able to discriminate whether offering only one delivery mode would yield the same results. This could be studied in future research.

In our study, recall bias was possible. The use of tailored advice was self-reported, and evaluation took place up to 3 months after participants received advice. For future studies, it is recommended to incorporate some evaluation regarding the use of web-based material immediately after providing the materials and preferably objective usage data. Objective usage data is not available in a print-based version and incorporating an additional questionnaire immediately after provision is more complicated and burdensome for the print-based material. However, objective usage data for web-based material can be used to validate self-report items to assess the probability of recall bias in future studies.

Conclusions

Intervention reach may be better, and interventions may possibly even be more effective if participants are able to use their own preferred delivery mode (Greaney et al., 2014). Information regarding participant characteristics related to intervention delivery mode can provide important cues for implementing computer-tailored interventions. To our knowledge, this is one of the first studies that assessed the relationship between participant characteristics and choice of delivery mode in an intervention in which both delivery modes were offered alongside each other, thereby providing participants a free choice of delivery mode.

Use of print-based materials among the initial web-based participants was substantial, indicating that print-based materials are also important for those using web-based materials. In contrast, by using only print-based materials, the intervention may be less attractive and useful for younger CPS, as it is known that younger CPS frequently use the internet with regard to finding health-related information (Chou et al., 2011). This study provides indications that web-based and print-based materials could best be offered alongside each other. Providing web-based materials only would exclude some of those who are older, less educated, more fatigued, or are currently undergoing treatment. Especially these participants are often more vulnerable and could benefit most from PA interventions.

5

SHORT-TERM EFFICACY OF A COMPUTER-TAILORED PHYSICAL ACTIVITY INTERVENTION FOR PROSTATE AND COLORECTAL CANCER PATIENTS AND SURVIVORS: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background

Physical activity (PA) is beneficial in improving negative physical and psychological effects of cancer and cancer treatment, but adherence to PA guidelines is low. Computer-tailored PA interventions can reach large populations with little resources. They match with patients' preference for home-based, unsupervised PA programs and are thus promising for the growing population of cancer survivors. The current study assessed the efficacy of a computer-tailored PA intervention in (four subgroups of) prostate and colorectal cancer survivors.

Methods

Prostate and colorectal cancer patients and survivors were randomized to the OncoActive intervention group (N=249), or a usual-care waiting-list control group (N=229). OncoActive participants received a pedometer and computer-tailored PA advice, both web-based via an interactive website and with printed materials. Minutes moderate-to-vigorous PA (MVPA) and days ≥ 30 min PA were assessed with an accelerometer (ActiGraph) at baseline and 6 months. Further, questionnaires were used to assess self-reported PA, fatigue, distress, and quality of life at baseline, 3 and 6 months. Differences between both groups were assessed using linear regression analyses (complete cases and intention-to-treat). In addition, efficacy in relation to age, gender, education, type of cancer, and time since treatment was examined.

Results

Three months after baseline OncoActive participants significantly increased their self-reported PA (PA days: d=0.46; MVPA: d=0.23). Physical functioning (d=0.23) and fatigue (d=-0.21) also improved significantly after three months. Six months after baseline, self-reported PA (PA days: d=0.51; MVPA: d=0.37) and ActiGraph MVPA (d=0.27) increased significantly, and ActiGraph days (d=0.16) increased borderline significantly (p=.05; d=0.16). Furthermore, OncoActive participants reported significantly improvements in physical functioning (d=0.14), fatigue (d=-0.23) and depression (d=-0.32). Similar results were found for intention-to-treat analyses. Higher increases in PA were found for colorectal cancer participants at 3 months, and for medium and highly educated participants' PA at 6 months. Health outcomes at 6 months were more prominent in colorectal cancer participants and in women.

Conclusions

The OncoActive intervention was effective at increasing PA in prostate and colorectal cancer patients and survivors. Health-related effects were especially apparent in colorectal cancer participants. The intervention provides opportunities to accelerate cancer recovery. Long-term follow-up should examine further sustainability of these effects.

BACKGROUND

Physical activity (PA) has numerous benefits for cancer patients and survivors. Positive effects have been reported for physical and psychological variables, such as cardiorespiratory fitness, muscle strength, fatigue, anxiety, depression, pain, physical functioning and thereby health-related quality of life (HRQoL) (Bourke et al., 2016; Buffart et al., 2017; Cormie et al., 2017; Menichetti et al., 2016; Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; Moug et al., 2017; Szymlek-Gay et al., 2011). PA is also a preventive factor for other chronic diseases (e.g., cardiovascular disease, diabetes, osteoporosis) for which cancer survivors have an increased risk (Denlinger & Engstrom, 2011; Roberts et al., 2017; Schmitz et al., 2010; Speck et al., 2010; Szymlek-Gay et al., 2011). Research has provided indications that PA is inversely associated with cancer-recurrence, development of secondary cancer and cancer mortality as well as overall mortality (Cormie et al., 2017; Kenfield et al., 2011; Meyerhardt, Heseltine, et al., 2006).

Despite all these benefits, the majority of cancer survivors do not meet PA guidelines, with self-reported rates ranging from 30-47% (Blanchard et al., 2008; LeMasters et al., 2014), and accelerometer-measured rates being even lower (Golsteijn, Berendsen, Bolman, Volders, & Lechner, 2018; Roberts et al., 2017; Vassbakk-Brovold et al., 2016). Moreover, PA behavior declines during treatment, does not reach pre-treatment levels after completing treatment and is lower for cancer survivors in comparison to the general population (Chung et al., 2013; Szymlek-Gay et al., 2011; Wang, McLoone, & Morrison, 2015). In combination with cancer survivors' need for healthy lifestyle information (Jansen et al., 2015; Playdon et al., 2016; Willems et al., 2016), this emphasizes the importance of developing effective programs to increase PA in cancer survivorship.

In 2012, over 14 million people were newly diagnosed with cancer worldwide (Ferlay et al., 2015) and this is expected to rise in the upcoming decades as a result of aging and advances in early detection (Ferlay et al., 2015; Meulepas & Kiemeney, 2011). With advances in cancer treatment and early diagnosis, survival rates are improving and will result in an increasing population living after, and thus with the negative sequelae of cancer (Siesling et al., 2014). Thus, broad-reaching (i.e., non-face-to-face) PA programs, aimed at self-management, which can be provided in a cost-effective way, are especially important.

Evidence for the efficacy of PA interventions in improving cancer outcomes and treatment related side effects (e.g., fatigue, depression) and HRQoL (Bourke et al., 2016; Davies et al., 2011; Kanera, Bolman, Willems, et al., 2016; Kanera et al., 2017; Schmitz et al., 2010; Speck et al., 2010; Stout et al., 2017) is extensive, but mostly originates from interventions delivered face-to-face in a clinical or exercise setting. Such programs often report larger effect sizes compared to non-face-to-face interventions, but also come with considerable costs and it may be more difficult to implement them on a large scale. Few of such programs, however, examined effects with regard to PA behavior (Courneya et al., 2012; Stout et al., 2017). Possibly, because they are not aimed at integrating PA into daily life and may lack real world application after ending the program (Lahart et al., 2016; Stacey et al., 2017). In addition, cancer survivors have a preference for home-based programs (Hardcastle & Cohen, 2017; McGowan et al., 2013; Murnane et al., 2012). Hence, it is promising that reviews regarding interventions using non-face-to-face modalities (e.g., telephone, (tailored) print materials or internet) in general (Goode, Lawler, Brakenridge, Reeves, & Eakin, 2015) and digital interventions explicitly (Roberts et al., 2017) reported increases in PA and decreases in fatigue. Such interventions are much easier scalable to large settings and thus have the potential to reach large populations at relatively low costs.

Considering the advantages in terms of resources required, both for patients (time and travel) and care providers and the scalability, eHealth in particular, can provide important efforts in providing easily accessible PA interventions. Especially, since internet access and use are increasing in developed countries. In addition, perceived relevance can be increased by personalizing PA information through computer-tailoring, resulting in increased efficacy of such interventions (Lustria et al., 2013; Webb et al., 2010). Nevertheless, we found that providing interventions only through the internet may exclude vulnerable sub-groups in a cancer population, such as those who are older, less educated, more fatigued or undergoing treatments (Golsteijn, Bolman, Peels, et al., 2017). Providing print-based tailored materials in addition to the online materials can be considered a solution to include these subgroups.

Accordingly, the OncoActive (OncoActief in Dutch) intervention was developed: a computer-tailored PA program providing PA advice online and with printed materials. Participants received automatically generated personalised feedback regarding PA and psychosocial determinants of PA at three time points. The content is aimed at the stimulating PA in daily life. To increase the probability of behavior change, the intervention is based on behavioral change theories (Golsteijn, Bolman, Volders, et al., 2017; Gourlan et al., 2016; Stacey et al., 2015) and on a demonstrated effective intervention for adults aged over fifty years (Peels, Bolman, et al., 2013a; van Stralen et al., 2011). The aim of this study is to gain insight into the efficacy of the OncoActive intervention to increase PA.

Since the majority of evidence of PA interventions is currently based on trials conducted in breast cancer populations, there is need for interventions targeting other common cancer types (Goode et al., 2015) in order to improve cancer care in all cancer types. Therefore, the intervention was targeted at prostate and colorectal cancer, as these have a high incidence and good survival rates (Comprehensive Cancer Center of the Netherlands (IKNL), 2015; Miller et al., 2016). By selecting only these two cancer types, we could better fine-tune the intervention to the specific PA needs and capabilities of the target group.

The purpose of the current study was to evaluate the efficacy of the OncoActive intervention at 3 months (during the intervention) and at 6 months (2 months after the intervention ended). As the intervention was aimed at increasing PA, the primary outcome is change in PA, assessed both for self-reported and accelerometer-measured PA. It was hypothesized that the intervention group would increase their PA more compared to the usual care group. As PA is also related to health-related outcomes of cancer patients and survivors (Denlinger & Engstrom, 2011) it was also hypothesized that the intervention group would decrease their fatigue, anxiety and depression and increase their physical functioning and overall HRQoL. Although the intervention was individually tailored, it might be that not all subgroups of participants respond similarly to the intervention. Therefore, we exploratively examined whether the efficacy differed for age, gender, education level, cancer type (i.e., prostate and colorectal) and time since treatment.

METHODS

Study design

A parallel-group, randomized controlled trial (RCT), in which participants were allocated to either the OncoActive intervention group or a usual care waiting list control group (ratio 1:1) was conducted. Randomization was automatically performed by means of a digital randomizer after centralized registration of participants (OverNite Software Europe, 2015). Due to the nature of the study, it was not possible or necessary to blind participants or the researchers. The RCT was approved by the Medical Ethics Committee of the Zuyderland hospital (NL47678.096.14) and is registered in the Dutch Trial Register (NTR4296). All participants provided written informed consent.

Participants

Cancer patients and survivors (≥18 years) diagnosed with colorectal or prostate cancer could participate in the trial if they were undergoing treatment with a curative intent, or if they successfully completed primary treatment (surgery, chemotherapy or radiation) up to one year ago. They had to be at least 6 weeks post-surgery and there were no restrictions regarding patients undergoing hormonal therapy. Participants with severe medical, psychiatric or cognitive illness (e.g., Alzheimer's disease, severe mobility limitations) were excluded from participation. Proficient Dutch reading and speaking skills were required for the questionnaires and for reading the tailored PA advice.

Procedure

Over 12 months (in 2015 and 2016) prostate and colorectal cancer patients and survivors were recruited from the urology and/or oncology departments of seventeen hospitals throughout the Netherlands. Eligible participants were identified by hospital staff, verbally informed (either in person or by telephone) about the study, and invited to receive an information package. This written information was handed over or sent by mail. Additionally, cancer patients and survivors were invited via other channels (e.g., calls in local newspapers, on relevant websites, discussion groups, and flyers in hospitals). The researchers informed the interested participants, checked their eligibility, and provided them with an information package by mail.

The information package contained an information letter with a timeline of the study, an informed-consent form and a pre-paid return envelope. One postal reminder was sent after three weeks if there was no response to the information package. Cancer patients and survivors who agreed to participate were randomized into either the intervention group or the control group (usual care). Subsequently, baseline PA was assessed with an accelerometer (ActiGraph GT3X-BT). Afterwards, participants received an online and paper-based questionnaire with the choice to fill out their preferred format. The intervention group received the OncoActive intervention after completing this baseline questionnaire (T0). Both groups filled-out follow-up questionnaires at three time points: 3 (T1), 6 (T2) and 12 (T3) months after baseline.

Accelerometer PA measurements were conducted in the week prior to the T2 and T3 questionnaires. The usual care control group received the OncoActive intervention after completing the last measurement (T3).

The OncoActive intervention

The OncoActive intervention is a computer-tailored intervention aimed at increasing awareness, initiation and maintenance of PA in prostate and colorectal cancer patients and survivors. The intervention was based on a demonstrated effective intervention to stimulate PA in adults over age fifty (Peels, Bolman, et al., 2013a; van Stralen et al., 2011) and adapted for prostate and colorectal cancer patients and survivors of all ages using the Intervention Mapping protocol (Golsteijn, Bolman, Volders, et al., 2017). The content was structured in line with behavioral change theories such as the I-Change Model (De Vries et al., 2006; De Vries et al., 2005; De Vries et al., 2003), Social Cognitive Theory (Bandura, 1986), Transtheoretical Model (Prochaska & DiClemente, 1983), Health Belief model (Janz & Becker, 1984), goal setting theories (Gollwitzer & Schaal, 1998; Locke & Latham, 1990), Health Action Process Approach (Schwarzer, 2008, 2009), theories of self-regulation (Baumeister & Vohs, 2004; Boekaerts et al., 2001; Zimmerman, 2000) and the Precaution Adoption Process Model (Weinstein, 1988).

Participants in the intervention group received computer-tailored PA advice at three time points (at baseline, after 2 months and after 3 months) both online on a secured website and on paper (by mail). The advice was generated automatically using a message library, questonnaire data and computer-based data-driven decision rules. The content of the first and second tailored advice was based on information gathered with the baseline questionnaire. Both the baseline (T0) and the second questionnaire (T1) provided input for the third tailored advice and allowed for the provision of ipsative feedback. The content of the advice was based on behavior change theories and targets pre-motivational constructs (e.g., awareness, knowledge), motivational constructs (e.g., self-efficacy, attitude, intrinsic motivation), and post-motivational constructs (e.g., goal setting, action and coping planning, self-regulation) (Golsteijn, Bolman, Volders, et al., 2017; Peels, van Stralen, et al., 2012; van Stralen et al., 2008). In addition to the tailored advice, every participant received a pedometer and access to interactive content on the website (e.g., role model videos, home exercise instruction videos, a module for goal setting using a pedometer, the option to consult a physical therapist and additional information). A more detailed description of the intervention content can be found elsewhere (Golsteijn, Bolman, Volders, et al., 2017). Use of the advice was examined through self-report. Percentages of participants reporting not having read any advice ranged from 0.6 to 6.1% time point (Golsteijn, Bolman, Peels, et al., 2017).

Measurements

As it was the main goal of the OncoActive intervention to improve PA, the primary outcome is PA behavior. Health-outcomes including fatigue, distress and HRQoL are examined as secondary outcomes.

PA outcomes

As PA comprises a complex behavior consisting of type of activity, duration, frequency, and intensity, PA was measured both with questionnaires and accelerometers (Blikman, Stevens, Bulstra, van den Akker-Scheek, & Reininga, 2013). Although self-report questionnaires are known for their overestimation of MVPA, they measure different constructs than accelerometers (Golsteijn, Berendsen, et al., 2018; Kelly et al., 2016). Therefore, a combination of both might present the most complete insight in PA.

Self-reported PA was measured using the validated Short Questionnaire to Assess Health Enhancing Physical Activity (SQUASH) (Wendel-Vos et al., 2003), assessing activities regarding commuting, household, occupation, and leisure time. Total minutes of PA were classified into light (metabolic equivalent [MET] <3.0), moderate (MET 3.0-5.9), and vigorous (MET >6) (Haskell et al., 2007). Minutes of moderate to vigorous PA (MVPA) were calculated by adding up total time in moderate and vigorous PA. Participants with extreme values (i.e., >6720 min PA/week), were excluded in accordance with the SQUASH scoring manual. The SQUASH questionnaire also contains a single-item measure assessing the number of days in the past week, on which one is at least moderately physically active for 30 minutes or more. The SQUASH questionnaire has reasonable reliability (ρ=.58) and validity against an accelerometer (ρ=.45) (Wendel-Vos et al., 2003).

Additionally, PA was measured using the ActiGraph GT3X-BT (ActiGraph, Pensacola, FL). Participants wore the accelerometer on an elastic belt on their right hip for 7 days. Data were downloaded and analyzed using ActiLife software (ActiGraph, Pensacola, FL). Measurements were considered valid if there were at least 4 days with at least 10 hours of wear time per day (Migueles et al., 2017). Non-wear periods were excluded from the analyses and were identified in accordance with Choi et al. (2012): intervals of at least 90 consecutive min of zero counts with allowance of a maximum of 2 min of nonzero counts during a non-wear interval. MVPA was calculated using 3 axes based on 60 s epochs. Freedson-VM cut-off points (developed by Sasaki et al. (2011)) and the cut-off point developed by Aguilar-Farias et al. (2014) to distinguish between light, moderate and vigorous PA.

Health-related outcomes

Health-related outcomes assessed in the current study included fatigue, distress and HRQoL. Fatigue was measured with the Checklist Individual Strength (CIS) (Vercoulen et al., 1994). The questionnaire consists of 20 items which are scored on a scale from 1 to 7, resulting in a total score ranging from 20-140 (alpha=.919), with a higher score indicating more fatigue. The CIS contains 4 subscales (subjective fatigue, concentration, motivation, and activity), but the total score, which was used in the current study, provides an overall indication of fatigue (Bultmann et al., 2000). Missing items were imputed with the mean of the subscale and were limited to 1 item per subscale.

Distress was assessed with the 14-item Hospital Anxiety and Depression Scale (HADS) (Bjelland et al., 2002; Zigmond & Snaith, 1983). The questionnaire consists of two scales, each one comprising 7 items with a 4-point scale, measuring anxiety (alpha=.799) and depression (alpha=.798.). Scale scores range from 0 to 21. A maximum of 1 missing item per scale was imputed with the mean of the respective subscale (Bell, Fairclough, Fiero, & Butow, 2016).

HRQoL was measured with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC QLQ-C30) (Aaronson et al., 1993). In the current study, we assessed global health status (2 items (alpha=.837) on a 7-point scale) and physical functioning (4 item (alpha=.683) on a 5-point scale) as these have the strongest relation with PA (Sweegers et al., 2018). Scores were converted to scores ranging from 0 to 100, with a high score indicating a high HRQoL.

Other relevant measures

Demographic and cancer-related characteristics including age, gender, body mass index (BMI), educational level, type of cancer, type of treatment (e.g., surgery, chemo therapy, radiotherapy and hormonal treatment), treatment phase (during or after) and elapsed time since final treatment were assessed in the baseline questionnaire. Educational level was categorized into low (i.e., primary, basic vocational, or lower general school), moderate (i.e., medium vocational school, higher general secondary education, and preparatory academic education), or high (i.e., higher vocational school or university level) according to the Dutch educational system. Participants were classified as being overweight (BMI >24.9 kg/m^2) or not. Cancer-related characteristics included type of cancer, which was either prostate or colorectal in the current study, and date of their last treatment. In addition, the presence of a chronic disease (yes or no) and the intention to be physically active (3 items on a scale from 1-10 (alpha =0.91), (Peels, Bolman, et al., 2012; van Stralen et al., 2008)) were assessed at baseline.

Timing of assessments

PA assessments with the ActiGraph were carried out at baseline and 6 months thereafter. Both self-reported PA and health-related outcomes were assessed using questionnaires at baseline (T0), 3 months (T1) and 6 months (T2; 2 months after the end of the intervention). At baseline all outcome measures were assessed. In the T1 questionnaire, which was conducted during the intervention period, we tried to limit the burden for participants by including only questions which were necessary to generate computer tailored advice for the intervention group (although the control group completed the same questionnaire). These included the SQUASH (self-reported MVPA & days ≥ 30 min PA), CIS (fatigue), and the physical functioning and general HRQoL subscales of the EORTC QLQ-C30. At T2 in addition, accelerometer-measured PA (ActiGraph) and the HADS (anxiety and depression) were assessed.

Sample size

Sample size calculations were based on the PA outcomes of predecessors of the intervention in adults aged fifty years or older (Peels, Bolman, et al., 2013a; van Stralen et al., 2011). These studies found an effect size of 0.3 with regard to PA (primary outcome) and effects were assumed to be comparable in cancer patients and survivors. Power calculations showed that approximately 300 participants were needed in total for the current study based on this effect size, a power of .80 with an alpha of .05 and a correction for multilevel analyses (intracluster correlation coefficient (ICC) =.005, design effect = 1.15). Drop-out was expected to be around 30% during the study (Kanera et al., 2017; Peels, Bolman, et al., 2013a; van Stralen et al., 2011), thus in total 428 participants were needed for enrollment at baseline.

Statistical analyses

Baseline differences regarding demographics, cancer-related, health-related, and PA-related characteristics between both conditions were assessed with independent t-tests and chi-square test. Group assignment, demographics, cancer and health-related characteristics and baseline values of the outcome measures were assessed as predictors of dropout at 3 and 6 months using logistic regression.

Multilevel linear regressions (linear mixed models) were conducted to analyze the results. With patients originating from different hospitals, it was expected that their data was clustered. In order to adjust for this clustering, we applied multilevel linear regression with participants nested in hospitals. However, these analyses revealed that the ICC was almost zero (i.e., $1.09e^{-13}$) and correction for clustering was not necessary. In addition, with multiple time points there is also a possibility of interdependence between the measurements within a person. Therefore, time, group and the interaction between time and group (to study differences between both groups over time) were added to the mixed models providing the opportunity to assess intervention efficacy over time. The models were fitted using the maximum likelihood procedure and an independent covariance structure. For all analyses age, gender, educational level, type of cancer, treatment phase, time since last treatment, BMI, comorbidity, PA intention and the baseline values of the outcome measure were added as covariates. Raw means of primary and secondary outcomes at all time points were presented. In addition Cohen's d effect sizes were calculated for all outcomes, with effect sizes of 0.20, 0.50, and 0.80 indicating small, medium, and large effects respectively (Cohen, 1988).

Although drop out was limited, we applied intention-to-treat (ITT) analyses in addition to the complete case analysis. With multiple imputations (20 times) missing data at 3 and 6 months was imputed including all covariates, the independent variable, and the outcome measure as predictors.

Intervention effectiveness was also assessed in different subgroups of participants. Therefore, interaction terms for age, gender, educational level, type of cancer and time since treatment were added to the regression. To test the moderation effects, 3 and 6 month measurements were analyzed separately. When an interaction term was significant, subgroup effects were examined. Since interaction terms have less power, the significance levels were set to $p < .10$ (Twisk, 2006). Significance levels for other analyses were set to $p < .05$. All analyses were conducted using STATA version 13.1.

RESULTS

STUDY POPULATION

An overview of the number of participants who are enrolled in the intervention and participated in the 3 and 6 months follow-up measurements is provided in Figure 1.

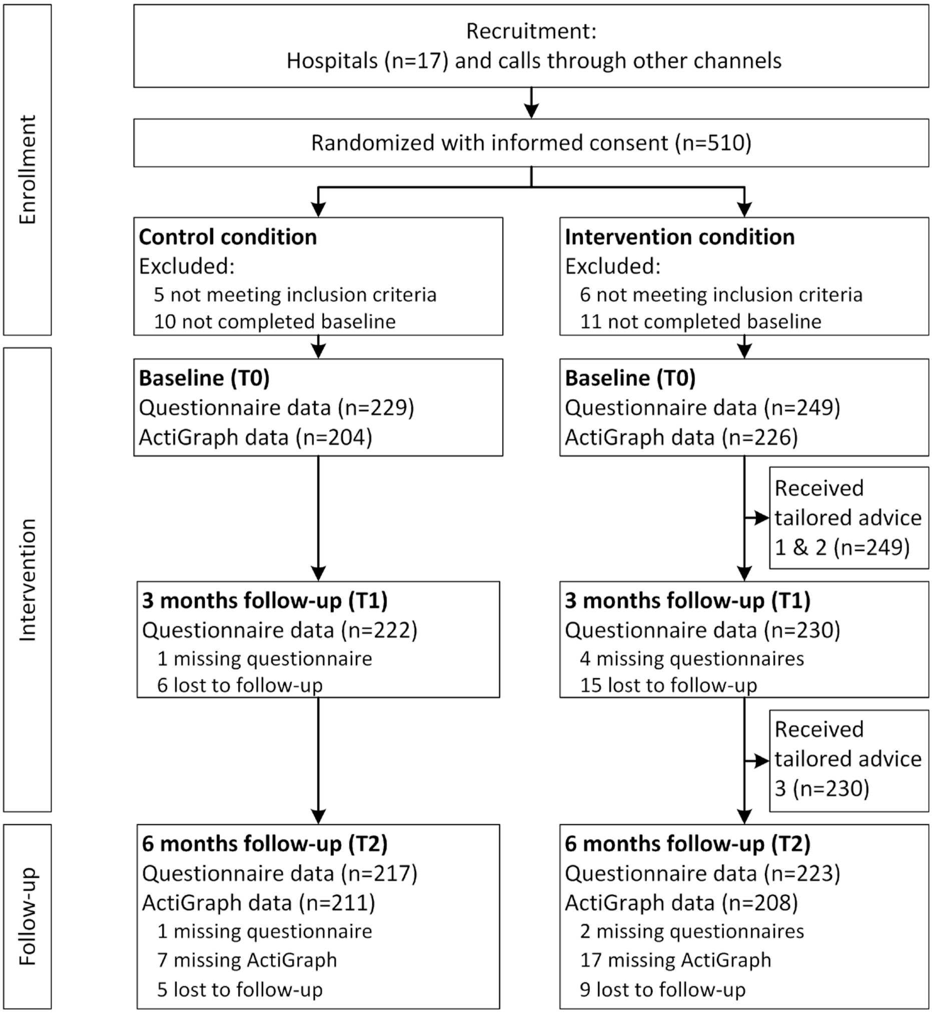


Figure 1 Flow diagram of the study

Drop-out rates were very low with 4.4% (21/478) of the participants dropping out at the 3 months follow-up and 7.3% (35/478) dropping out at the 6 months follow-up. Attrition analyses showed that at 3 months participants in the intervention group (B=1.43, 95%CI = 0.02 – 2.84, p=.047) and participants with a lower intention to be physically active (B=0.53, 95%CI = 0.01 – 1.05, p=.047) were more likely to drop out of the study. At 6 months, colorectal cancer patients were more likely to dropout (B=1.05, 95%CI = 0.06 – 2.04, p=.034).

Participant characteristics of both groups are shown in Table 1. The mean age was 66.5, the majority of the participants were male (87%) and the proportion of prostate cancer was 61% compared to 39% colorectal cancer. The control group and intervention group differed on the depression score, with a significantly higher baseline score for the intervention group (p = .01).

Table 1 *Baseline participant characteristics of the intervention group and the control group*

	Intervention group (n =249)	**Control group (n = 229)**	***P* value**
Demographic characteristics			
Age in years, mean (SD)	66.55 (7.07)	66.38 (8.21)	.81
Gender, n (%)			.20
Male	212 (85.1)	204 (89.1)	
Female	37 (14.9)	25 (10.9)	
Education, n (%)			.15
Low	109 (44.0)	114 (50.0)	
Middle	70 (28.2)	47 (20.6)	
High	69 (27.8)	67 (29.4)	
Cancer related characteristics			
Type of cancer, n (%)			.34
Prostate	149 (59.8)	143 (62.5)	
Colorectal	100 (40.2)	86 (37.5)	
Treatment phase			.42
During treatment	19 (7.6)	14 (6.1)	
After treatment	230 (92.4)	215 (93.9)	
Time since last treatment in months (SD)	5.64 (3.84)	5.17 (3.49	.16
Type or treatment, n (%)			
Surgery	186 (81.2)	192 (77.1)	.27
Chemo	41 (17.9)	44 (17.7)	.95

table continues

	Intervention group (n =249)	Control group (n = 229)	*P* value
Radiotherapy	63 (27.5)	80 (32.1)	.27
Hormonal treatment	8 (3.5)	10 (4.0)	.76
Health related characteristics			
BMI, mean (SD)	26.39 (3.38)	26.74 (4.41)	.32
Comorbidities yes, n (%)	87 (35.2)	86 (38.2)	.46
Fatigue, mean (SD)	58.95 (23.31)	57.54 (24.25)	.52
Anxiety, mean (SD)	3.75 (3.22)	3.37 (2.95)	.18
Depression, mean (SD)	3.54 (3.54)	2.80 (2.91)	.01
General HRQoL (SD)	80.01 (16.81)	82.06 (14.15)	.15
Physical Functioning, mean (SD)	86.57 (14.39)	86.58 (14.80)	.99
PA characteristics			
MVPA SQUASH (SD)	798 (721)	873 (764)	.27
MVPA ActiGraph (SD)	271 (211)	293 (230)	.30
Days ≥ 30 min PA SQUASH	3.67 (2.05)	3.86 (2.07)	.34
Days ≥ 30 min PA ActiGraph	3.23 (2.46)	3.38 (2.38)	.52
PA intention, mean (SD)	7.61 (1.35)	7.74 (1.48)	.32

Intervention effects at 3 month follow-up

Raw means at baseline and at 3 month follow-up (still during the intervention period) for both conditions are shown in Table 2. These raw scores indicated improvements in PA, fatigue and physical functioning, but not in general HRQoL. To test for significance additional statistical analyses were performed. The results are shown in Table 3. Participants in the OncoActive group improved their PA significantly in terms of both MVPA (B = 133.55, p=.04) and days with at least 30 minutes of PA (B = 0.86, p < .001). With regard to the secondary outcomes, we found decreased fatigue (B = -3.57, p = .02) and improved physical functioning (B= 2.61, p = .003) for participants of the OncoActive intervention. No significant differences were found with regard to overall HRQoL (B = 0.18, p = .82). ITT analyses showed similar results for all outcomes.

Intervention effects at 6 month follow-up

Raw means for the 6 month follow-up assessment are shown in Table 2 indicating further improvements in PA, fatigue and physical functioning. Depression scores also improved in the intervention group. Further statistical analyses were performed to examine the efficacy after finishing the intervention (6 month follow-up) (Table 4). Results indicate significant improvements in PA assessed through the SQUASH questionnaire (MVPA: B = 267.17, $p < .001$; Days ≥ 30 min PA: B = 0.98, $p < .001$). ActiGraph assessed MVPA also increased significantly (MVPA: B = 44.60, p = .006), whereas the increase in ActiGraph assessed days ≥ 30 min PA was borderline significant (B = 0.38, p = .05).

There were also significant improvements in health-related outcomes. In comparison to the control group, a decrease in fatigue (B = -4.16, p = .009) and depression (B = -0.64, p = .005), and an improvement in physical functioning (B = 1.86, p = .04) were observed for the OncoActive group. No significant differences were found for anxiety (B = 0.14, p = .54) and overall HRQoL (B = 1.09, p = .37). Similar results were found in the ITT analyses, except for physical functioning which did not improve significantly in the ITT analysis.

Moderation of effects

To further explore the efficacy of the intervention, analyses for subgroups were performed. These exploratory analyses showed that the intervention effect on PA was moderated by education level and type of cancer. The 3 month effect on MVPA as reported by the SQUASH questionnaire was moderated by cancer type (p = .02): The intervention was effective at increasing PA in colorectal cancer participants (B = 355.23, p = .001, ES = 0.53), but not in prostate cancer participants (B = 20.33, p = .81, ES = 0.07). MVPA assessed with the ActiGraph at 6 months was moderated by education level (p = .06). OncoActive resulted in a significant increase in MVPA in participants with a medium education level (B = 106.85, p = .001, ES = 0.59), in a borderline significant increase for highly educated participants (B = 56.33, p = .06, ES = 0.42) and no increase for those with a low education (B = -0.11, p = .99, ES = .03).

Health outcomes were moderated by gender and type of cancer. At the 3 month follow-up fatigue was moderated by type of cancer (p = .04). Fatigue levels of colorectal cancer participants significantly decreased (B = -6.88, p = .02, ES = -0.31), whereas no significant decrease was found for prostate cancer participants (B = -1.69, p = .34, ES = -0.14). Physical functioning at 3 months was also moderated by type of cancer (p = .003). Again, significant improvements were found for colorectal cancer participants (B = 6.32, $p <.001$, ES = 0.45), but not for prostate cancer participants (B = 0.77, p = .45, ES = 0.06).

Table 2 *Raw means of primary and secondary outcomes at all time points*

	OncoActive						Usual Care					
	T0		T1		T2		T0		T1		T2	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Primary outcomes												
SQUASH MVPA	246	780 (721)	230	1060 (771)	222	1145 (883)	229	873 (764)	221	962 (833)	213	943 (769)
SQUASH Days ≥ 30 min PA	246	3.70 (2.06)	226	4.81 (1.89)	218	5.18 (1.65)	226	3.86 (2.07)	222	4.02 (2.06)	210	4.31 (1.93)
ActiGraph MVPA[1]	226	271 (211)	-	-	208	331 (234)	204	293 (229)	-	-	211	301 (219)
ActiGraph Days ≥ 30 min PA ActiGraph[1]	226	3.35 (2.54)	-	-	208	3.96 (2.38)	204	3.46 (2.40)	-	-	211	3.71 (2.38)
Secondary outcomes												
Fatigue	241	58.9 (23.3)	227	54.5 (22.5)	221	51.6 (23.9)	223	57.5 (24.3)	217	56.7 (23.4)	214	55.1 (23.7)
Physical functioning	246	86.6 (14.0)	230	89.6 (13.0)	223	89.7 (13.6)	229	86.6 (14.8)	222	87.4 (14.1)	216	88.4 (13.0)
General HRQoL	246	80.0 (16.8)	229	79.8 (16.3)	223	83.8 (15.6)	229	82.1 (14.2)	222	80.7 (14.8)	216	83.7 (13.7)
Anxiety[1]	248	3.75 (3.21)	-	-	223	3.52 (3.39)	227	3.37 (2.95)	-	-	216	3.49 (3.17)
Depression[1]	248	3.54 (3.54)	-	-	223	3.09 (3.34)	227	2.80 (2.91)	-	-	216	3.31 (3.08)

[1] Outcomes assessed only at T2 measurement to limit participant burden at T1; see methods section for explanation

Table 3 *Outcomes at 3 months follow-up*

	Complete case analyses				Intention to treat analysis		
	N	B (95% CI)	p	ES[1]	N	B (95% CI)	p
Primary outcomes							
MVPA SQUASH	437	133.55 (3.70 – 263.40)	.04	0.23	462	139 (9.41 – 268.97)	.04
Days ≥ 30 min PA SQUASH	433	0.86 (0.55 – 1.18)	<.001	0.46	461	0.82 (0.52 – 1.13)	<.001
Secondary outcomes							
Fatigue	425	-3.57 (-6.68 – -0.46)	.02	-0.21	453	-3.66 (-6.78 – -0.54)	.02
Physical functioning	440	2.61 (0.86 – 4.36)	.003	0.23	464	2.33 (0.54 – 4.12)	.01
General HRQoL	439	0.18 (-2.19 – 2.55)	.88	0.09	464	-0.02 (-2.39 – 2.35)	.99

[1] Based on mean difference between T0 and T1

Table 4 *Outcomes at 6 months follow-up*

	Complete case analyses				Intention to treat analyses		
	N	B (95% CI)	p	ES[1]	N	B (95% CI)	p
Primary outcomes							
MVPA							
SQUASH	421	267.17 (135.12 – 399.22)	<.001	0.37	462	275 (141.14 – 408.59)	<.001
ActiGraph	373	44.60 (12.57 – 76.63)	.006	0.27	420	45.9 (13.51 – 78.30)	.006
Days ≥ 30 min PA							
SQUASH	415	0.98 (0.66 – 1.30)	<.001	0.51	461	0.93 (0.62 – 1.24)	<.001
ActiGraph	373	0.38 (-0.01 – 0.77)	.05	0.16	420	0.37 (-0.01 – 0.75)	.06
Secondary outcomes							
Fatigue	416	-4.16 (-7.30 – -1.02)	.009	-0.23	453	-3.88 (-7.02 – -0.74)	.015
Physical functioning	427	1.86 (0.09 – 3.63)	.04	0.14	464	1.31 (-0.48 – 3.10)	.15
General HRQoL	427	1.09 (-1.30 – 3.49)	.37	0.13	464	0.69 (-1.71 – 3.06)	.58
Anxiety	427	-0.14 (-0.59 – 0.30)	.54	-0.11	464	-0.15 (-0.60 – 0.29)	.51
Depression	427	-0.64 (-1.09 – - 0.19)	.005	-0.32	464	-0.61 (-1.06 – -0.16)	.008

[1] Based on mean difference between T0 and T2

At 6 month follow-up, fatigue was moderated by gender (p = .02). OncoActive resulted in a significant decrease in fatigue in women (B = -12.70, p = .007, ES = -0.76), but not in men (B = -2.14, p = .21, ES = -0.15). Type of cancer moderated the effects on depression (p = .07) and physical functioning (p = .03). Depression decreased significantly in colorectal cancer participants (B = -1.17, p = .004, ES = -0.37), but not in prostate cancer participants (B = -0.44, p = .10, ES = -0.30). Similar results were found for physical functioning, with significant improvements in colorectal cancer participants (B = 4.27, p = .01, ES = 0.35), but not in prostate cancer participants (B = 0.31, p = .73, ES = -0.004).

DISCUSSION

The current study assessed the efficacy of the computer-tailored OncoActive intervention at increasing PA and in improving fatigue, HRQoL and distress (i.e., anxiety and depression) in prostate and colorectal. In addition, efficacy in specific subgroups of cancer patients was explored.

PA outcomes

The hypothesis that the intervention group would increase their PA, was confirmed by the finding that OncoActive participants increased both in MVPA and in the number of days on which they were physically active for at least 30 minutes. As mentioned, PA was measured both with an accelerometer and with a self-report questionnaire as both measures have strengths and weaknesses (Blikman et al., 2013; Golsteijn, Berendsen, et al., 2018). With regard to MVPA, it was noted that although the absolute increase was substantially higher for self-reported PA compared to PA assessed by the ActiGraph, findings were clearly in the same direction (Appendix 1). Absolute increases of 280 (3 months) and 365 (6 months) minutes MVPA per week for self-reported PA and 60 minutes (6 months) MVPA for ActiGraph PA (based on raw scores; Table 2) were found in the intervention group. In comparison increases of 89, 70, and 8 minutes respectively were found in the control group. As a meta-analysis regarding digital PA interventions in cancer patients found an average increase of 40 minutes MVPA based on self-report PA (Roberts et al., 2017), the OncoActive intervention thus seems to be highly effective in increasing PA. Intervention studies using accelerometer-measured PA as outcome variables are lacking (Roberts et al., 2017), therefore it is recommended to include them in future studies.

Several explanations can be provided for the substantial differences between both PA measures. Self-report questionnaires are known for their probability of over-reporting, whereas accelerometers are not able to measure certain activities properly (e.g., swimming, cycling, upper body movement), and they cannot assess the type of PA (e.g., leisure time PA, PA for transportation, occupational PA) (Warren et al., 2010). In addition, ActiGraph outcomes regarding light, moderate and vigorous PA are based on cut-points developed for healthy adults (Freene, Waddington, Chesworth, Davey, & Cochrane, 2014; Lewis et al., 2017; Sasaki et al., 2011). However, as cancer patients and survivors may have decreased physical fitness they possibly perceive certain activities as moderately intensive, whereas the ActiGraph classifies them as light activities (Golsteijn, Berendsen, et al., 2018).

Effect sizes for MVPA were small (0.23-0.37), yet comparable to other studies. Effect sizes for the Active Plus intervention (healthy adults aged over fifty), from which the OncoActive intervention was developed, also ranged from 0.23 to 0.35 (Peels et al., 2014). Meta-analyses regarding computer-tailored and web-based PA interventions for healthy and diseased adult populations found average Cohen's *d* of 0.14 (Davies et al., 2012) and Hedge's *g* of 0.16 (Krebs et al., 2010). Kanera, Bolman, Willems, et al. (2016) also found a comparable Cohen's *d* of 0.25 for moderate PA in a multiple lifestyle eHealth intervention for cancer survivors. A review regarding broad-reach modality PA interventions for cancer survivors found effect sizes for MVPA outcomes in the same range as the current study (Goode et al., 2015).

Besides MVPA, days on which participants were physically active for at least 30 minutes were also examined. Significant increases were found for self-report at 3 and 6 months, but the ActiGraph measured outcome at 6 months was only borderline significant ($p = .05$). Again, this can possibly be explained by the nature of the two measurements. Besides the earlier mentioned discrepancies in classifying light and moderate intensity PA, it might also be difficult to exactly estimate time in self-report. If someone is physically active for 25 minutes, one might experience this as being physically active for at least 30 minutes and thus report it accordingly. Since the ActiGraph measures and classifies every single minute, such a day would not be included in the ActiGraph measure for days with ≥ 30 min PA, resulting in a discrepancy between both measures.

Health-related outcomes

Besides being effective in increasing PA, it was also hypothesized that the OncoActive intervention would improve health-related outcomes such as fatigue, HRQoL and distress. This hypothesis was partially confirmed by the findings of the current study as significant improvements were found for fatigue, depression and physical functioning, but not for anxiety and general HRQoL.

Fatigue levels of OncoActive participants decreased significantly during the intervention period and decreased even further during the second part of the intervention period, resulting in significantly less fatigue two months after the last tailored advice. This is in accordance with findings in several systematic reviews on health outcomes such as fatigue among cancer patients (Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; Mustian et al., 2017). However, most of the studies in these reviews are supervised exercise trials with a health outcome like fatigue as the primary outcome measure. Such trials are often aimed at improving health outcomes instead of improving PA (Courneya, 2010). The main aim of the current study, which would be classified as a behavior change trial by Courneya (2010), was to improve PA, with fatigue and other health outcomes being secondary outcomes. As a meta-analysis regarding digital behavior change interventions in cancer survivors only found a non-significant trend towards decreased fatigue (Roberts et al., 2017), it is very promising that the OncoActive intervention was able to improve fatigue.

Reviews from Mishra, Scherer, Geigle, et al. (2012), Mishra, Scherer, Snyder, et al. (2012) and Sweegers et al. (2018) found that exercise interventions are able to establish significant benefits with regard to general HRQoL. However, for the OncoActive intervention no improvement in overall HRQoL was observed. Similarly, Roberts et al. (2017) also did not find improvements in HRQoL for digital behavior change interventions. A possible explanation for not finding any effects regarding HRQoL could be the high baseline scores of our study population. Both the intervention group and the control group had general HRQoL baseline scores above 80 (on a 0-100 scale). With such high baseline scores, it may be difficult to improve further. Also, baseline scores in our study were higher than in other studies that did find significant improvements in HRQoL (Kampshoff et al., 2015).

Nevertheless, physical functioning did improve significantly in OncoActive participants both during and after the intervention period, indicating that OncoActive may accelerate cancer recovery, especially since the effects were more apparent during the first 3 months of the intervention. The absence of a similar improvement for 3 to 6 months after baseline, may be due to ceiling effects, as the levels of physical functioning were already high at the 3 month measurement (i.e., 89.6 on a scale from 0-100 in the intervention group). A systematic review also reported improvements in physical functioning through home- and community-based PA programs with effect sizes ranging from .17 to .45, with larger effect sizes for community-based programs with group meetings (Swartz et al., 2017). Thus, it can be concluded that effect sizes found for the OncoActive intervention (0.23 at 3 months and 0.14 at 6 months) are in the same range of home-based PA programs without group meetings.

Findings in the literature regarding anxiety and depression are mixed. Some reviews and studies reported improvements in anxiety, whereas others reported improvements in depression (Craft et al., 2012; Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; Roberts et al., 2017). For the OncoActive intervention, no significant improvements were found regarding anxiety. For depression we found a significant improvement in the intervention group. However, even though we corrected for baseline differences in depression symptoms, this finding should be interpreted with caution as the intervention group had a significant higher depression score at baseline. As a result, regression to the mean might have influenced our results.

In general, it is promising that a computer-tailored intervention, which can be provided to a relatively large population at relatively low costs, is able to improve treatment-related side effects and thereby cancer recovery. Future research should focus on reaching and assessing long term maintenance of intervention effects.

Efficacy in subgroups

In the current study effects in specific subgroups of cancer patients and survivors were studied exploratory. Results showed that during the first part of the intervention, PA only increased in colorectal cancer participants. However, two months after completing the intervention, OncoActive was equally effective in increasing PA for both cancer types. As the intervention is tailored to cancer type, future research could extend the intervention to other types of cancer.

The explorative moderation analyses also showed that the intervention was effective in increasing PA in those with a medium and high education level, but not in those with a low education level. Possibly, receiving information about behavior change may have decreased lower educated participants' self-efficacy to be able to change their PA and may have resulted in perceiving the recommendations as less feasible (Reinwand et al., 2015). Another explanation can be found in the structure of the OncoActive intervention. Intervention materials were provided both print- and web-based alongside each other. In a previous study regarding the OncoActive intervention, a lower educational level was associated with a lower probability of using web-based materials (Golsteijn, Bolman, Peels, et al., 2017). Although this previous study also showed that tailored advice was read by most of them, those with a lower education may have had a less comprehensive experience with the intervention as they may not have viewed video incorporated in the web-based tailored PA advice or used other interactive (web-based) components of the intervention. For future studies implementation adaptations, like less written texts, should be made to improve efficacy in cancer patients and survivors with a lower educational level.

With regard to health-related outcomes, it was noted that the intervention in general was more effective for colorectal cancer participants than for prostate cancer participants. At 3 months effects on fatigue and physical functioning, and at 6 months effects on depression and physical functioning were stronger among colorectal cancer participants. In addition, at 6 months we found a larger effect on fatigue for women compared to men. Since, women can only be diagnosed with colorectal cancer this might also be linked to cancer type. As health effects do take some time to occur, a possible explanation for better health effects in colorectal cancer participants might be that PA did not increase in the first 3 months of the intervention in prostate cancer participants. Another explanation may be the fact additional in depth analyses showed that raw baseline scores for prostate cancer participants were higher in comparison to colorectal cancer participants, resulting in less room for improvement. Nevertheless, since PA did improve significantly after the intervention, evaluation at 12 month follow-up should prove whether there will be further improvements in health-related outcomes in prostate cancer participants on the longer term. Furthermore, if the increase in PA can be maintained, eventually cancer survivors may develop a healthier lifestyle (Stacey et al., 2017) and possibly benefit from improved survival (Kenfield et al., 2011; Meyerhardt, Heseltine, et al., 2006).

Strengths and limitations

The current study has a strong research design (RCT) in which both self-reported and accelerometer-measured PA were assessed. In addition, a very low dropout rate of only 7% was observed in the current study. Such a low dropout rate is exceptional in digital interventions (Eysenbach, 2005) and in the same range of supervised exercise programs (Kampshoff et al., 2015; Steins Bisschop et al., 2015; van Waart et al., 2015). Although promising results were found regarding the efficacy of the OncoActive intervention, there are also some limitations that should be acknowledged.

In the current study, the proportion of participants who had adjuvant treatment is relatively small. This can partly be attributed to the current treatment preferences for the types of cancer in the target group. Currently prostate cancer is most often treated with surgery or brachytherapy, which might be less invasive than external radiotherapy. Furthermore, in 2014 a screening program for colorectal cancer was introduced in the Netherlands. Due to this increased early detection, patients may be diagnosed in the early stage of the disease. Consequently, there are fewer patients that need to undergo adjuvant chemotherapy and thus experience fewer treatment-related side effects. As a result, the effect found in the current study may not be representative for patients undergoing more burdensome (adjuvant) treatments.
Although participant dropout was very low, it was related to cancer type, intention to be physically active and group assignment. Although this may affect findings, it is expected that the influence of selective dropout is negligible due to the very low dropout numbers.

With regard to the health-related outcomes, it should be noted that these analyses may have been less optimal powered, since the power calculation was based on the primary outcome PA. However, since we were able to include (and retain) a large number of patients, we expect that under-powering is limited. A post-hoc power calculation for example for fatigue at 3 months (ES = -0.21), with an alpha of .05, showed to have a power of 0.74.

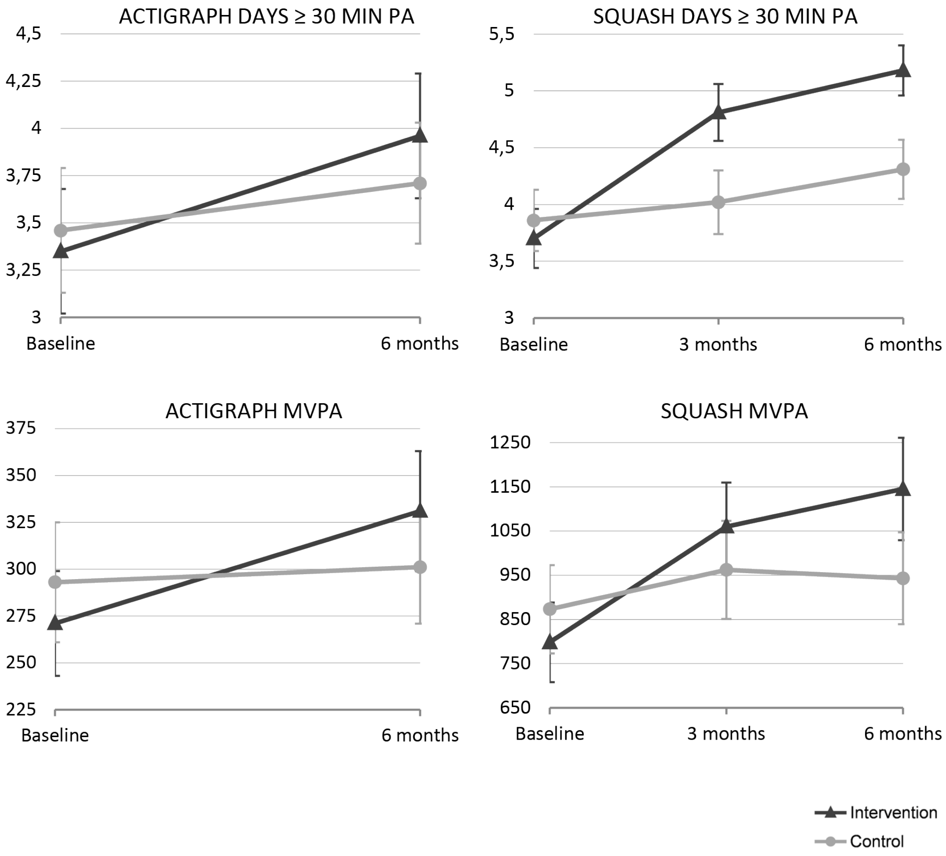
Conclusion

The OncoActive intervention was effective at increasing PA in prostate and colorectal cancer patients and survivors both during and after primary cancer treatment. Health-related effects, such as improved fatigue, depression and physical functioning were mainly found in colorectal cancer participants, which also had lower baseline levels. Although long-term maintenance of these effects should be studied, it can be concluded that the intervention provides opportunities to accelerate cancer recovery. In addition, as PA increased in both populations this might have preventive effects for future health status.

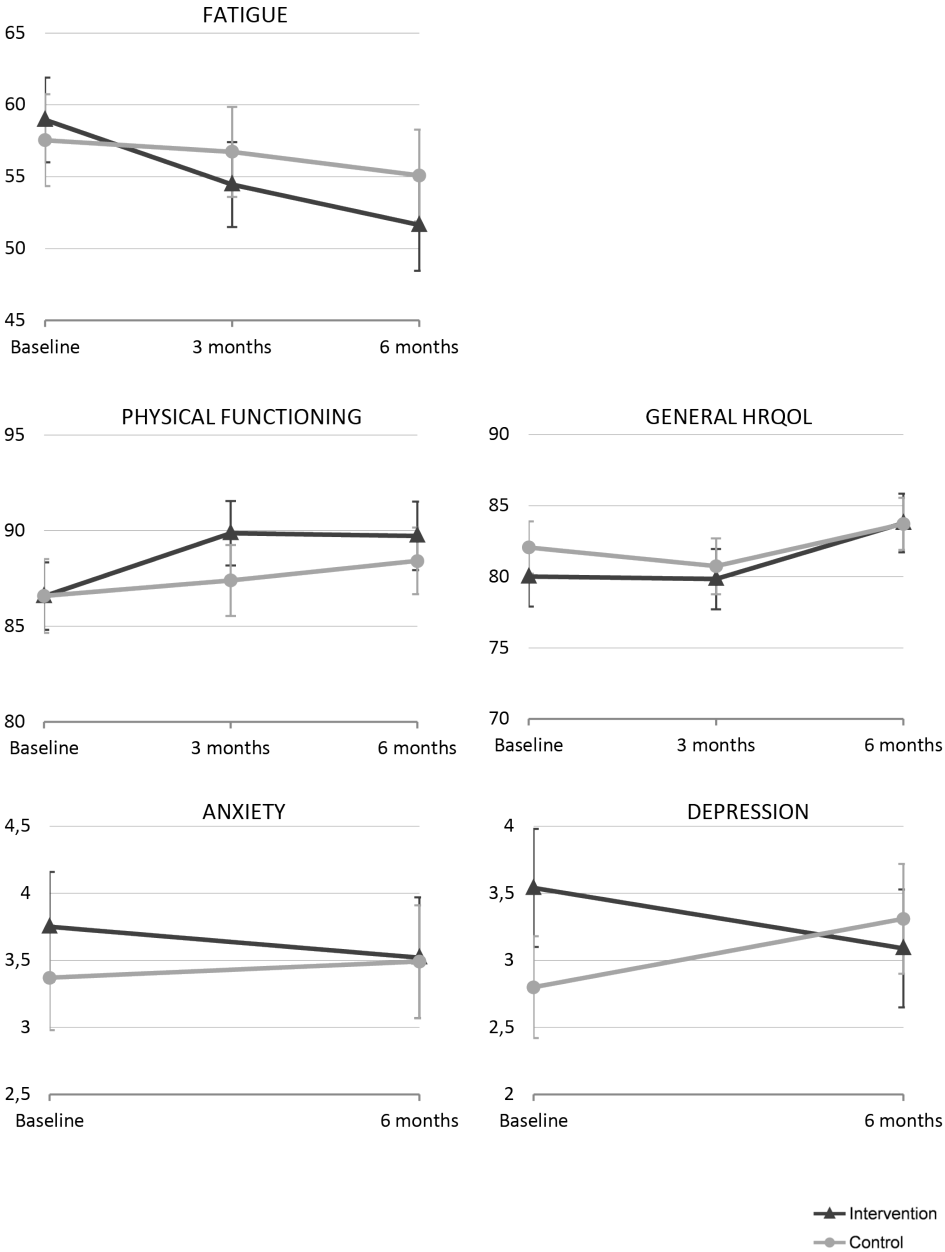
Although previous research has suggested that supervised programs result in larger effect sizes, it should also be noted that in view of costs, resources and access, those programs may not be available to everyone (Goode et al., 2015; Lahart et al., 2016). eHealth interventions can be provided at relatively low costs, are more in line with cancer survivors' preference of home-based PA programs (McGowan et al., 2013; Murnane et al., 2012) and may also be able to reach those who are not motivated enough to participate in intensive, facility-based programs (Hardcastle & Cohen, 2017). Therefore, the results of the current study provide valuable support for the use of the OncoActive intervention to increase PA and improve cancer recovery.

APPENDIX 1

Line graphs physical activity outcomes



Line graphs health-related outcomes



6

A COMPUTER-TAILORED PHYSICAL ACTIVITY INTERVENTION FOR PROSTATE AND COLORECTAL CANCER PATIENTS AND SURVIVORS: LONG-TERM FINDINGS OF THE ONCOACTIVE RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Purpose

Physical activity (PA) can improve physical and psychological health of cancer survivors. PA maintenance is necessary for long-term health benefits. We evaluated the long-term effects of OncoActive, a web-based intervention in which prostate and colorectal cancer patients and survivors receive automatically generated, personalized feedback aimed at integrating PA into daily life.

Patients and methods

Prostate or colorectal cancer patients and survivors were randomly assigned to OncoActive (N=249) or a usual care, waitlist group (N=229). OncoActive participants received PA advice (printed and web-based) and a pedometer. Primary (i.e., ActiGraph and self-report PA) and secondary outcomes (i.e., fatigue, depression, physical functioning) were assessed at baseline, 6 and 12 months. Differences between groups and changes over time were assessed with multilevel linear regressions.

Results

At 12 months, self-report days with PA improved significantly in OncoActive, but other PA outcomes lacked significant differences. Within the OncoActive group, PA changed significantly from baseline to 12 months; the 6-month PA effects in OncoActive were maintained at 12 months. However, differences with the usual care group declined due to a (non-significant) natural recovery from 6 to 12 months. At 12 months, fatigue was significantly lower in OncoActive. No significant differences were found for depression and physical functioning. Change from 6 to 12 months follow-up in health outcomes was not different between groups.

Conclusion

OncoActive was effective in maintaining PA, but because of natural improvement differences with the usual care group diminished at 12 months. Fatigue was significantly lower in OncoActive compared to usual care. OncoActive may give participants an early start to recovery and potentially contributes to improving long-term health as improvements in PA were maintained.

INTRODUCTION

Cancer and cancer treatment may have detrimental effects on both physical and psychological health of cancer patients and survivors (CPS), including changes in cardiorespiratory fitness, physical functioning, fatigue, anxiety and depression, resulting in a lower health-related quality of life (HRQoL) (El-Shami et al., 2015; Harrington et al., 2010; Skolarus et al., 2014; Wu & Harden, 2015). Problems can persist for years and may even have a delayed onset. Additionally, CPS are at risk for developing comorbidities like cardiovascular disease, diabetes, and osteoporosis (Denlinger & Engstrom, 2011; Rock et al., 2012; Schmitz et al., 2010; Speck et al., 2010), as well as for cancer recurrence, second primary cancers, and premature mortality (Cormie et al., 2017; El-Shami et al., 2015; Skolarus et al., 2014).

Increasingly, research shows positive effects of physical activity (PA) for CPS. Improvements in physical fitness, fatigue, physical functioning, anxiety, depression, and general HRQoL have been reported for various cancers, although the main body of evidence is still provided by breast cancer studies (Bourke et al., 2016; Fong et al., 2012; Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; Moug et al., 2017; Speck et al., 2010). PA is also assumed to be inversely associated with cancer recurrence and mortality (Cormie et al., 2017).

Maintenance of PA is necessary to establish long-term health benefits and occurs at least 6 months after initial behavior change (Howlett, Trivedi, Troop, & Chater, 2019; Spark, Reeves, Fjeldsoe, & Eakin, 2013). Currently, most studies have only reported short-term effects and included supervised programs in a clinical or exercise setting aimed at improving health outcomes rather than changing PA behavior (Aaronson et al., 2014; Courneya, 2010; Stacey et al., 2017). Notwithstanding positive outcomes of such interventions, behavior change and maintenance may be difficult to achieve, because participants may not continue PA in daily life after ending the program (Courneya et al., 2012; Lahart et al., 2016). This suggests a need for studies with longer follow-up periods. According to Hardcastle and Cohen (2017), home-based, unsupervised PA interventions that are tailored to cancer survivors' needs and preferences may be needed to achieve sustained behavior change. A growing population of cancer survivors also highlights the importance of such interventions being cost-effective, feasible, and scalable (Goode et al., 2015).

OncoActive, a print- and web-based, computer-tailored PA program for prostate and colorectal CPS may have important advantages in these respects. This theory-based intervention provides participants with automatically generated, personalized feedback aimed at integrating PA into daily life (Golsteijn, Bolman, Volders, et al., 2017). Significant short-term effects (i.e., 6 months after baseline) in PA (e.g., Moderate-to-vigourous PA (MVPA), days with sufficient PA) and health-related outcomes (e.g., depression, fatigue, physical functioning) were reported previously (Golsteijn, Bolman, et al., 2018). Although these findings are valuable, maintenance of PA and health-related outcomes is necessary to establish long-term effects. PA maintenance can be defined as the extent to which an intial change in behavior is sustained for 6 or more months (Glasgow, Klesges, Dzewaltowski, Estabrooks, & Vogt, 2006; Kwasnicka, Dombrowski, White, & Sniehotta, 2016).

Hence, this study aims to assess long-term efficacy and maintenance of the previously found effects of OncoActive with regard to PA (primary outcome) and health-related (secondary) outcomes including fatigue, HRQoL and distress (Golsteijn, Bolman, et al., 2018). Effects at 12 months follow-up and changes from 6 to 12 months follow-up were examined. It was hypothesized that the OncoActive group would maintain their increased PA and be more physically active one year after the start than the usual care group that would not increase their PA. Additionally, OncoActive participants were expected to perform better with respect to fatigue, depression, and physical functioning.

METHODS

Study design and participants

A randomized controlled trial (RCT) was conducted, allocating participants (digital randomizer with ratio 1:1 (OverNite Software Europe, 2015)) to either OncoActive or a usual care, waitlist group. Eligible participants were prostate or colorectal CPS (aged ≥18 years) who were at least 6 weeks post-surgery and were undergoing intentionally curative treatment or had successfully completed primary treatment (surgery, chemotherapy, or radiation) up to one year ago, without constraints for hormonal therapy. Participants with severe comorbidities (e.g., Alzheimer's disease, severe mobility limitations) were excluded. The nature of OncoActive required proficient Dutch reading and speaking. All participants provided written informed consent. The RCT was registered (Dutch Trial Register; NTR4296) and ethically approved (Medical Ethics Committee Zuyderland; NL47678.096.14).

In order to find a significant effect size of .30 (Peels, Bolman, et al., 2013a; van Stralen et al., 2011) with a power of .80 and =.05 (ICC=.005, design effect=1.15), and a drop-out rate of 30% (Kanera et al., 2017; Peels, Bolman, et al., 2013a; van Stralen et al., 2011), 428 particpants needed to be enrolled at baseline.

Procedure

During 12 months (2015-2016) staff from urology, surgery and oncology departments of seventeen Dutch hospitals recruited prostate and colorectal CPS. After being verbally informed, patients were invited to receive an information package and an informed consent form, with one postal reminder after three weeks. Similarly, additional participants were recruited through other sources (e.g., local newspapers, relevant websites, discussion groups, flyers).

After assessing baseline PA (ActiGraph GT3X-BT, Pensacola, FL), participants chose to complete either an online or paper-based questionnaire (Golsteijn, Bolman, Peels, et al., 2017). Subsequently, OncoActive was provided to the intervention group. After the final measurement, the usual care group received OncoActive.

OncoActive

A detailed description of OncoActive was published previously (Golsteijn et al., 2014). Briefly, OncoActive aims to increase awareness, initiation, and maintenance of PA in prostate and colorectal CPS via computer-tailored PA advice. Advice is generated automatically from a message library, questonnaire data, and computer-based data-driven decision rules. The content was based on a demonstrably effective intervention (Peels, Bolman, et al., 2013a; van Stralen et al., 2011) applying behavioral change theories (Bandura, 1986; Baumeister & Vohs, 2004; Boekaerts et al., 2001; De Vries et al., 2003; Gollwitzer & Schaal, 1998; Janz & Becker, 1984; Locke & Latham, 1990; Prochaska & DiClemente, 1983; Schwarzer, 2008; Zimmerman, 2000) and targeting pre-motivational constructs (e.g., awareness, knowledge), motivational constructs (e.g., self-efficacy, attitude, intrinsic motivation), and post-motivational constructs (e.g., goal-setting, action and coping planning, self-regulation) (Golsteijn, Bolman, Volders, et al., 2017; Peels, van Stralen, et al., 2012; van Stralen et al., 2008).
Participants received computer-tailored PA advice from a secure website and on paper (by mail) on three occasions (baseline, after 2 and 3 months). Participants also received a pedometer and access to interactive web-based content (e.g., role model videos, home exercise videos, pedometer goal-setting, possibility to consult

a physical therapist, additional information). Intervention materials were read by a majority of the participants (Golsteijn, Bolman, Peels, et al., 2017).

Measurements

PA, the primary outcome, comprises a complex behavior consisting of type of activity, duration, frequency, and intensity. Overestimation of PA is common with self-report questionnaires, but they measure different constructs than accelerometers do (Kelly et al., 2016; Vassbakk-Brovold et al., 2016). Therefore, a combination of measures was used (Blikman et al., 2013). The number of days with at least 30 min of MVPA, and MVPA based on commuting, household, occupation, and leisure time PA were assessed with the Short Questionnaire to Assess Health Enhancing Physical Activity (SQUASH) (Wendel-Vos et al., 2003). PA was also assessed during 7 days with a right-sided, hip-worn ActiGraph GT3X-BT (ActiGraph, Pensacola, FL) using ActiLife software (ActiGraph, Pensacola, FL) for data processing.

Secondary outcomes included fatigue (Checklist Individual Strength, CIS (Vercoulen et al., 1994)), depression (Hospital Anxiety and Depression Scale, HADS (Zigmond & Snaith, 1983)), and physical functioning (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30, EORTC QLQ-C30 (Aaronson et al., 1993)) because significant short-term effects of OncoActive were found previously (Golsteijn, Bolman, et al., 2018).

Outcomes were assessed at baseline, 6, and 12 months. Other measures (e.g., demographics, cancer-related characteristics) were assessed at baseline. Table 1 shows details for all measures.

Statistical analyses

Baseline differences between conditions were assessed with independent t-tests and chi-square tests. To assess predictors of dropout, logistic regression with condition, baseline outcome measures, demographics, cancer- and health-related characteristics was performed.

Multilevel linear regressions using the maximum likelihood procedure and an independent covariance structure were conducted to assess between-group differences. Time, group, and interaction between time and group (for differences between groups over time) were added to the mixed models. Changes from 6 to 12

Table 1 *Outcome measures*

Concept	Measurement Instrument	Measure/Scale used	N items	Item range	Scoring/missing items	Scoring range	α/ρ	Higher score indicates
Primary outcome measures								
Accelro-meter PA	ActiGraph GT3X-BT	MVPA & Days ≥ 30 min MVPA per week	n.a.	n.a.	Valid if worn 4 days during 10 hours or more; Non-wear definition by algorithm of Choi et al.; PA scoring by Freedson-VM cut-off points[1]	0-6720 min 0-7 days	n.a.	More PA
Self-report PA	SQUASH	MVPA & Days ≥ 30 min MVPA per week	12[a]	n.a.	According to manual; light PA <3.0 MET; moderate PA 3.0-5.9 MET; vigorous PA > 6 MET[2]	0-6720 min 0-7 days	ρ=.45[2]	More PA
Secondary outcome measures								
Fatigue	CIS	Total score[3]	20	1-7	Sum score; subscale mean imputation; max 1 item	20-140	α=.92[b]	Higher fatigue
Distress	HADS	Depression	7	0-3	Sum score; Subscale mean imputation; max 1 item[4]	0-21	α=.80[b]	More depression
HRQoL	EORTC QLQ C-30	Physical functioning	5	1-4	According to manual[5]	0-100	α=.68[b]	Better functioning
Other measures								
Age, gender, BMI, comorbidity (yes, no), education level (low, moderate, high), type of cancer (prostate, colorectal), type of treatment (surgery, chemo therapy, radiotherapy (incl. brachytherapy), hormonal therapy), treatment phase (during, after), time since treatment, intention for PA (3 items on a scale from 1 to 10; α=0.91).								

Abbreviations: PA, physical activity; MVPA, moderate-to-vigorous physical activity per week; SQUASH, short questionnaire to assess health-enhancing physical activity; MET, metabolic equivalent; CIS, checklist individual strength; HADS, hospital anxiety and depression scale; EORTC QLQ-C30, European organization for research and treatment of cancer quality of life questionnaire C30; BMI, body mass index.

[a] *twelve major items with 0-3 sub-items each, such as frequency, duration, and intensity*

[b] *based on current study sample*

[1] *Migueles et al. (2017); Choi et al. (2012); Sasaki et al. (2011)*

[2] *Wendel-Vos and Schuit (2004); Haskell et al. (2007)*

[3] *Bultmann et al. (2000)*

[4] *Bell et al. (2016)*

[5] *Fayers et al. (2001)*

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months follow-up were examined to assess maintenance. Measurements over time were clustered in participants, but participants were not clustered within hospitals (ICC=1.09e^{-13}). Age, gender, education, type of cancer, treatment phase, time since last treatment, BMI, comorbidity, PA intention and baseline value of the dependent were added as covariates. Changes from baseline to 12 months within groups were reported through unadjusted means and assessed with multilevel linear regression including all three measurements. Cohen's d effect sizes for change scores were calculated. Effect sizes of 0.20, 0.50, and 0.80 indicate relevant small, medium, and large effects, respectively (Cohen, 1988). Intention-to-treat (ITT) analyses using multiple imputations (20 times) were conducted in addition to the complete case analyses.

Exploratory, differences regarding intervention efficacy were assessed for age, gender, educational level, type of cancer and time since treatment with p <.10 for the interaction term (Twisk, 2006). Significance levels for other analyses were set to p < .05. All analyses were conducted using STATA version 13.1.

RESULTS

In total 510 participants provided informed consent for the study. Eleven of them did not meet inclusion criteria and 21 others did not complete baseline measurement, resulting in 478 participants successfully entering the study (Figure 1). Their mean age was 66.5 (SD=7.7), with the majority being male (87%), 47% being low-educated (i.e., primary, basic vocational, or lower general school), and a ratio of 61% prostate and 39% colorectal cancer diagnoses. As shown in Table 2 no significant baseline differences were found, except for depression ($M_{OncoActive}$=3.54 SD=3.54; $M_{usual\ care}$=2.80 SD=2.91; p=.01).

The drop-out rate was 7.3% (35/478) at 6 months and 11.1% (53/478) at 12 months. Drop-out was more likely for colorectal CPS at 6 months (B=1.10, 95%CI=0.13; 2.07, p=.026), and for intervention participants at 12 months (B=1.16, 95%CI=0.36; 1.96, p=.005).

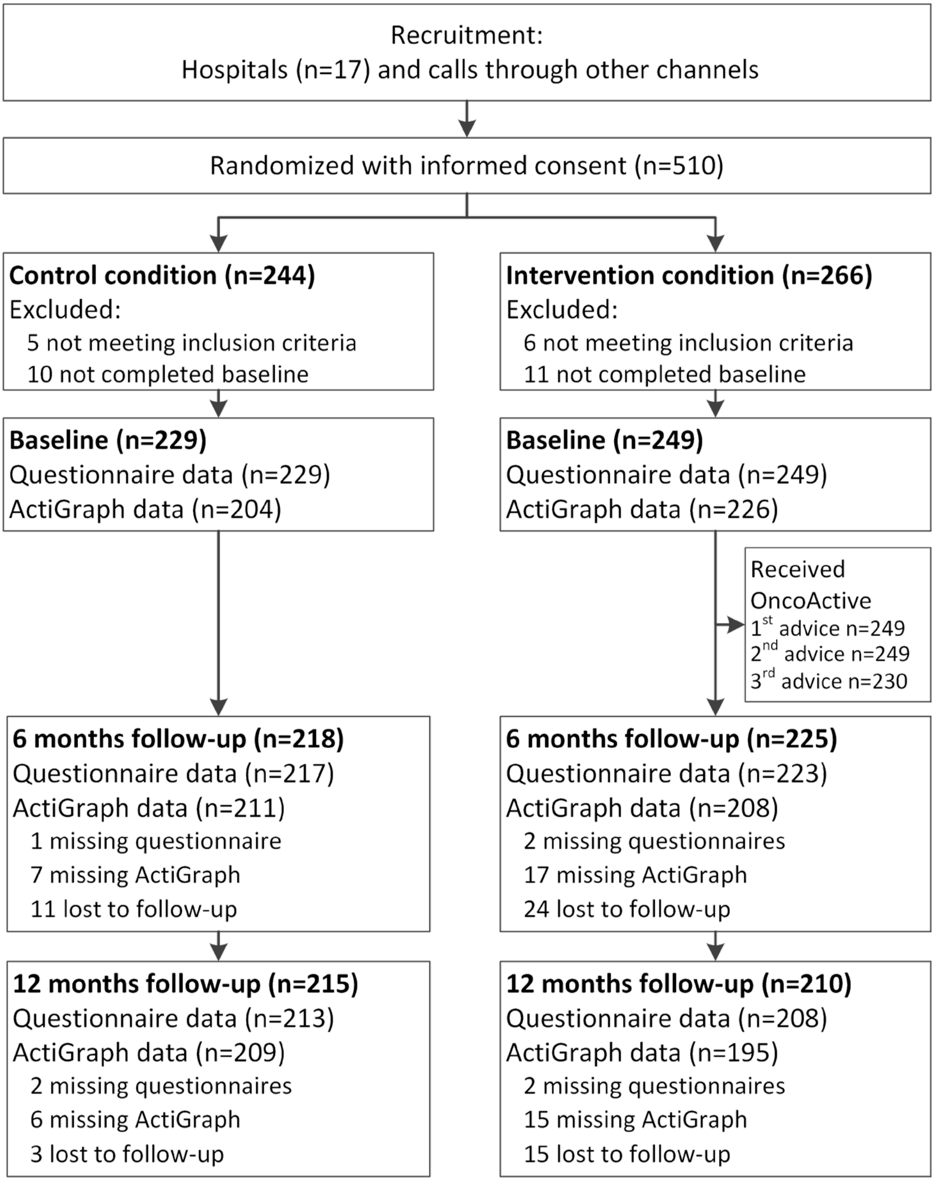

Figure 1 Flow diagram of the study

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Table 2 *Baseline participant characteristics of the intervention group and the usual care group*

	OncoActive (n =249)	Usual Care (n = 229)	*P* value
Demographic characteristics			
Age in years, mean (SD)	66.55 (7.07)	66.38 (8.21)	.81
Gender, n (%)			.20
Male	212 (85.1)	204 (89.1)	
Female	37 (14.9)	25 (10.9)	
Education, n (%)			.15
Low	109 (44.0)	114 (50.0)	
Middle	70 (28.2)	47 (20.6)	
High	69 (27.8)	67 (29.4)	
Cancer related characteristics			
Type of cancer, n (%)			.34
Prostate	149 (59.8)	143 (62.5)	
Colorectal	100 (40.2)	86 (37.5)	
Treatment phase			.42
During treatment	19 (7.6)	14 (6.1)	
After treatment	230 (92.4)	215 (93.9)	
Time since last treatment in months (SD)	5.64 (3.84)	5.17 (3.49	.16
Type or treatment, n (%)			
Surgery	186 (81.2)	192 (77.1)	.27
Chemo	41 (17.9)	44 (17.7)	.95
Radiotherapy	63 (27.5)	80 (32.1)	.27
Hormonal treatment	8 (3.5)	10 (4.0)	.76
Health related characteristics			
BMI, mean (SD)	26.39 (3.38)	26.74 (4.41)	.32
Comorbidities yes, n (%)	87 (35.2)	86 (38.2)	.46
Fatigue, mean (SD)	58.95 (23.31)	57.54 (24.25)	.52
Anxiety, mean (SD)	3.75 (3.22)	3.37 (2.95)	.18
Depression, mean (SD)	3.54 (3.54)	2.80 (2.91)	**.01**
General HRQoL (SD)	80.01 (16.81)	82.06 (14.15)	.15
Physical Functioning, mean (SD)	86.57 (14.39)	86.58 (14.80)	.99
PA characteristics			
MVPA SQUASH (SD)	798 (721)	873 (764)	.27
MVPA ActiGraph (SD)	271 (211)	293 (230)	.30
Days ≥ 30 min PA SQUASH	3.67 (2.05)	3.86 (2.07)	.34
Days ≥ 30 min PA ActiGraph	3.23 (2.46)	3.38 (2.38)	.52
PA intention, mean (SD)	7.61 (1.35)	7.74 (1.48)	.32

Abbreviations: SD, standard deviation; BMI, body mass index; HRQoL, health related quality of life; MVPA, moderate-to-vigorous physical activity per week; SQUASH, short questionnaire to assess health-enhancing physical activity; PA, physical activity.

Physical Activity

Comparisons between both groups at 12-month follow-up showed significantly more self-report days with PA (B=0.39, 95%CI=0.07; 0.70) in OncoActive compared to usual care, but no significant differences for ActiGraph MVPA (B=12, 95%CI=-19;43), and ActiGraph days with PA (B=0.16, 95%CI=-0.22;0.55). Self-report MVPA (B=132, 95%CI=-12;275) was borderline significant (*p*=.07).

To assess whether previously found improvements in PA at 6-month follow-up were maintained, differences in change over time (i.e., from 6 to 12 months) between both groups were examined. Self-reported days with PA decreased significantly in OncoActive, but did not decrease in the usual care group as indicated by a significant interaction between time and condition (B=-0.61, 95%CI=-0.95; -0.26). Interactions between time and condition for self-report MVPA (B=-122, 95%CI=-287; 44), ActiGraph MVPA (B=-27, 95%CI=-63; 9), and ActiGraph days with PA (B=-0.16, 95%CI=-0.56;0.26) were not significant, indicating that changes from 6 months to 12 months were not significantly different between groups. In both groups PA, did not change significantly from 6 to 12 months (Table 3; Figure 2).

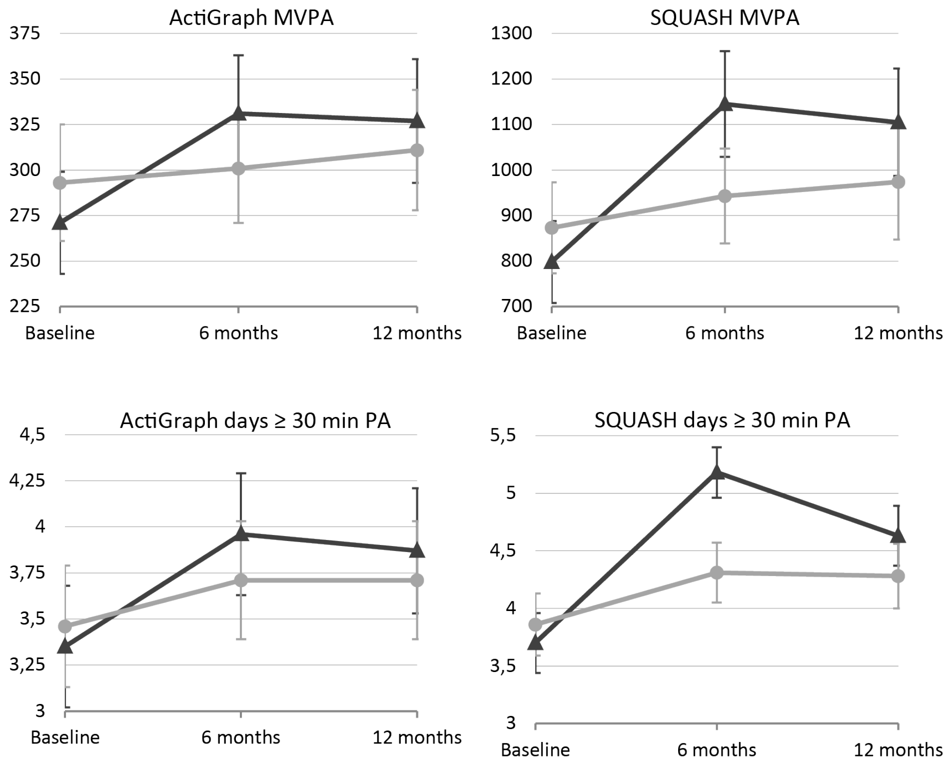
Nevertheless, OncoActive PA improved significantly from baseline to 12 months, whereas changes in PA from baseline to 12 months in the usual care group were not significant, except for self-report days with PA (Table 4).

Health outcomes

At 12 months, fatigue was significantly lower in the OncoActive group than the usual care group (B=-3.75, 95%CI= -7.04; -0.45). There were no differences in depression (B=-0.26, 95%CI= -0.68; 0.16) and physical functioning (B=0.35, 95%CI=-1.53; 2.24).

Changes from 6 months to 12 months were not different between the groups as indicated by non-significant interactions between time and condition for fatigue (B=0.14; 95%CI= -3.44; 3.71), depression (B=0.42; 95%CI= -0.04; 0.88), and physical functioning (B=-1.45, 95%CI= -3.27; 0.37). From short- to long-term follow-up, fatigue remained the same and depression did not change significantly for both groups. Physical functioning decreased significantly only in the OncoActive group (Table 3; Figure 2).

Yet, within the OncoActive group compared to baseline, physical functioning at 12-month follow-up was still significantly higher, whereas changes in physical functioning from baseline to 12 months in usual care were not significant. Changes in fatigue from baseline to 12 months were also significant in OncoActive but not in usual care. Depression did not change significantly from baseline to 12 months in OncoActive, whereas in usual care, a significant increase in depression from baseline to 12 months was observed (Table 4).



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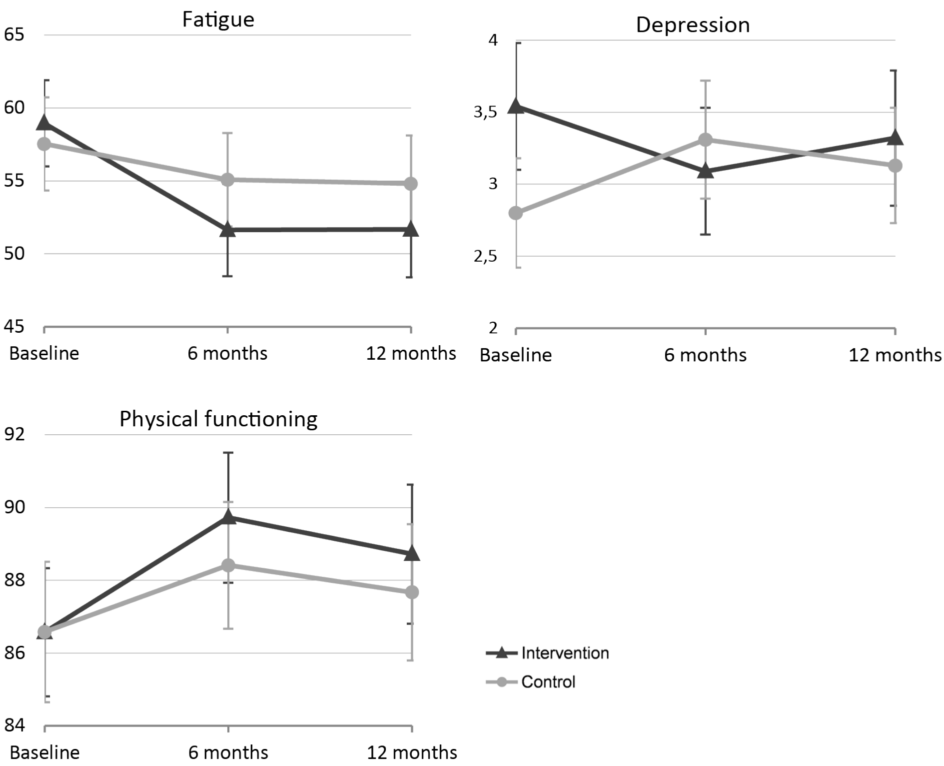

Figure 2 Line graphs of outcomes at baseline, 6 and 12 months (mean and 95%CI)

Table 3 *Between-group differences at 6- and 12-month follow-up*

	N	OncoActive vs UC $_{6\ months}$			OncoActive vs UC $_{12\ months}$			Δ Time OncoActive[c]		Δ Time UC[c]	
		β (95% CI)	**P**	**ES[a]**	**β (95% CI)**	**P**	**ES[b]**	**β (95% CI)**	**P**	**β (95% CI)**	**P**
Complete Cases											
Primary outcomes											
MVPA											
ActiGraph	388	**39 (8; 69)**	**.01**	**0.28**	12 (-19; 43)	.45	0.13	-15 (-41; 11)	.26	12 (-13; 37)	.36
SQUASH	428	**253 (112; 395)**	**<.001**	**0.37**	132 (-12; 275)	.07	0.20	-65 (-182; 53)	.28	57 (-60; 174)	.34
Days ≥ 30 min PA											
ActiGraph	388	0.33 (-0.05; 0.71)	.09	0.16	0.16 (-0.22; 0.55)	.40	0.10	-0.17 (-0.48; 0.13)	.26	-0.01 (-0.31; 0.29)	.95
SQUASH	425	**1.00 (0.69; 1.31)**	**<.001**	**0.50**	**0.39 (0.07; 0.70)**	**.02**	**0.20**	**-0.59 (-0.82; -0.34)**	**<.001**	0.02 (-0.22; 0.27)	.85
Secondary outcomes											
Fatigue	421	**-3.89 (-7.14; -0.64)**	**.02**	**-0.23**	**-3.75 (-7.04;-0.45)**	**.03**	**-0.20**	-0.01 (-2.51; 2.51)	.99	-0.14 (-2.68; 2.39)	.91
Depression	430	**-0.68 (-1.09; -0.27)**	**.001**	**-0.33**	-0.26 (-0.68; 0.16)	.23	-0.15	0.23 (-0.10; 0.55)	.17	-0.19 (-0.52; 0.13)	.25
Physical functioning	430	1.80 (-0.06; 3.66)	.057	0.14	0.35 (-1.53; 2.24)	.71	0.07	**-1.91 (-3.20; -0.62)**	**.004**	-0.46 (-1.74; 0.83)	.49
Intention-to-treat (imputed data)											
Primary outcomes											
MVPA											
ActiGraph	420	**41 (10; 71)**	**.009**	**0.27**	16 (-15; 47)	.31	0.14	-11 (-39; 16)	.42	13 (-13; 40)	.32
SQUASH	462	**252 (109; 395)**	**.001**	**0.33**	136 (-11; 283)	.07	0.18	-61 (-197; 75)	.38	55 (-65; 175)	.37
Days ≥ 30 min PA											
ActiGraph	420	0.35 (-0.02; 0.72)	.07	0.17	0.18 (-0.18; 0.55)	.33	0.08	-0.15 (-0.45; 0.15)	.33	0.01 (-0.29; 0.32)	.93
SQUASH	459	**0.96 (0.66; 1.27)**	**<.001**	**0.48**	**0.36 (0.05; 0.68)**	**.02**	**0.20**	**-0.57 (-0.83; -0.31)**	**<.001**	0.02 (-0.23; 0.27)	.86

table continues

	N	OncoActive vs UC 6 months			OncoActive vs UC 12 months			Δ Time OncoActive[c]		Δ Time UC[c]	
		β (95% CI)	P	ES[a]	β (95% CI)	P	ES[b]	β (95% CI)	P	β (95% CI)	P
Secondary outcomes											
Fatigue	453	**-3.83 (-7.06; -0.60)**	**.02**	**-0.25**	**-3.61 (-6.98;-0.25)**	**.04**	**-0.20**	-0.09 (-2.92; 2.75)	.95	-0.30 (-3.00; 2.39)	.83
Depression	464	**-0.67 (-1.09; -0.24)**	**.002**	**-0.31**	-0.19 (-0.62; 0.24)	.39	-0.15	0.25 (-0.13; 0.64)	.20	-0.23 (-0.57; 0.12)	.20
Physical functioning	464	1.32 (-0.53; 3.18)	.16	0.09	0.31 (-1.59; 2.22)	.75	0.03	**-1.79 (-3.30; -0.27)**	**.02**	-0.78 (-2.22; 0.66)	.29

Abbreviations: UC, usual care; ES, effect size; 95% CI, 95% confidence interval; MVPA, moderate-to-vigorous physical activity per week; SQUASH, short questionnaire to assess health-enhancing physical activity; PA, physical activity.

[a] Based on mean difference between baseline and 6 months

[b] Based on mean difference between baseline and 12 months

[c] Difference between 6 months and 12 months

Table 4 *Unadjusted means and adjusted changes of primary and secondary outcomes within groups*

	Raw Means						Within group effects					
	Baseline		6 months		12 months		Δ 6 months			Δ 12 months		
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	β (95% CI)	P	ES[a]	β (95% CI)	P	ES[b]
OncoActive												
Primary outcomes												
MVPA												
ActiGraph	226	271 (211)	208	331 (234)	195	327 (238)	**51 (28; 74)**	**<.001**	**0.23**	**38 (14; 61)**	**.002**	**0.17**
SQUASH	246	780 (721)	222	1145 (883)	206	1105 (857)	**342 (234; 448)**	**<.001**	**0.44**	**283 (174; 392)**	**<.001**	**0.37**
Days ≥ 30 min PA												
ActiGraph	226	3.35 (2.54)	208	3.96 (2.38)	195	3.87 (2.38)	**0.53 (0.24; 0.82)**	**<.001**	**0.23**	**0.35 (0.06; 0.65)**	**.02**	**0.15**
SQUASH	246	3.70 (2.06)	218	5.18 (1.65)	207	4.63 (1.87)	**1.44 (1.20; 1.68)**	**<.001**	**0.75**	**0.85 (0.61; 1.09)**	**<.001**	**0.41**

table continues

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	Raw Means						Within group effects					
	Baseline		6 months		12 months		Δ 6 months			Δ 12 months		
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	β (95% CI)	P	ES[a]	β (95% CI)	P	ES[b]
Secondary outcomes												
Fatigue	241	58.9 (23.3)	221	51.6 (23.9)	208	51.7 (24.0)	**-6.7 (-9.1; -4.3)**	**<.001**	**-0.27**	**-6.6 (-9.0; -4.1)**	**<.001**	**-0.27**
Depression	248	3.54 (3.54)	223	3.09 (3.34)	207	3.32 (3.44)	**-0.35 (-0.69; -0.01)**	**.045**	**-0.08**	-0.11 (-0.46; 0.23)	.52	-0.02
Physical functioning	246	86.6 (14.0)	223	89.7 (13.6)	207	88.7 (13.9)	**3.3 (1.9; 4.8)**	**<.001**	**0.23**	**1.6 (0.1; 3.0)**	**.04**	**0.13**
Usual Care												
Primary outcomes												
MVPA												
ActiGraph	204	293 (229)	211	301 (219)	209	311 (237)	5 (-21; 30)	.72	0.01	13 (-12; 39)	.30	0.05
SQUASH	229	873 (764)	213	943 (769)	213	974 (943)	47 (-72; 165)	.44	0.07	101 (-17; 220)	.09	0.13
Days ≥ 30 min PA												
ActiGraph	204	3.46 (2.40)	211	3.71 (2.38)	209	3.71 (2.38)	0.21 (-0.09; 0.51)	.17	0.08	0.18 (-0.12; 0.48)	.24	0.07
SQUASH	226	3.86 (2.07)	210	4.31 (1.93)	209	4.28 (2.04)	**0.39 (0.12; 0.67)**	**.005**	**0.20**	**0.41 (0.13; 0.68)**	**.004**	**0.20**
Secondary outcomes												
Fatigue	223	57.5 (24.3)	214	55.1 (23.7)	212	54.8 (24.5)	-2.0 (-4.6; 0.7)	.14	-0.10	-2.5 (-5.2; 0.1)	.06	-0.09
Depression	227	2.80 (2.91)	216	3.31 (3.08)	214	3.13 (3.00)	**0.56 (0.23; 0.89)**	**.001**	**0.19**	**0.34 (0.01; 0.67)**	**.045**	**-0.10**
Physical functioning	229	86.6 (14.8)	216	88.4 (13.0)	212	87.7 (13.8)	**1.6 (0.1; 3.1)**	**.03**	**0.11**	1.13 (-0.4; 2.6)	.14	-0.07

Abbreviations: SD, standard deviation; ES, effect size; 95% CI, 95% confidence interval; MVPA, moderate-to-vigorous physical activity per week; SQUASH, short questionnaire to assess health-enhancing physical activity; PA, physical activity.

[a] Based on group means at baseline and 6 months

[b] Based on group means at baseline and 12 months

Moderation of effects

Exploratory sub-group analyses at 12 months showed that self-report days with PA were moderated by gender (B=1.05, 95%CI= 0.01; 2.10) and age (B=-0.04, 95%CI= -0.09; 0.00). OncoActive was only effective for females (B=1.33, 95%CI= 0.36; 2.31, ES=1.03) and younger CPS (median split (B=0.45, 95%CI= 0.01; 0.90, ES=0.19)). The effect on fatigue was moderated by age (B=0.64, 95%CI= 0.15; 1.12), with a significant decrease for younger CPS (median split: B=-6.32, 95%CI= -11.12; -1.52, ES=-0.35).

DISCUSSION

The current study examined the long-term efficacy and behavior change maintenance of OncoActive. Results showed that at 12 months only self-report days with PA were significantly higher for OncoActive compared to usual care. However, previously reported PA improvements at 6 months (Golsteijn, Bolman, et al., 2018) did not decrease significantly between 6 and 12 months, indicating that behavior was maintained. The usual care group showed a small absolute increase in PA during follow-up that was not significant. This combination of small, non-significant changes resulted in non-significant between-group differences after 12 months. Small improvements in the usual care group are seen more often for PA and health-related outcomes, suggesting natural improvement over time and contamination (Grimmett et al., 2019; Osei, Lee, Modest, & Pothier, 2013; Ottenbacher et al., 2012; Pinto, Stein, & Dunsiger, 2015; Rogers et al., 2015; van den Berg et al., 2015; Willems, Mesters, Lechner, Kanera, & Bolman, 2017); usual care participants may increase their PA because of the cancer diagnosis (i.e., teachable moment) and increased awareness due to PA measurements (Basen-Engquist, Carmack, et al., 2012; Blaney et al., 2013; Demark-Wahnefried et al., 2007).

As mentioned, exercise studies often only report findings shortly after the end of an intervention, and studies examining long-term effects or maintenance of PA are limited (Aaronson et al., 2014; Stacey et al., 2017). Our analyses showed that despite a small, non-significant decline, OncoActive participants maintained their increased PA from 6- to 12-month follow-up. Single studies also reported successful maintenance of PA in CPS, but reviews showed mixed findings that may partly be due to differences in operationalization of PA maintenance (Demark-Wahnefried et al., 2007; Finlay et al., 2018; Grimmett et al., 2019; Hawkes et al., 2013; Jankowski et al., 2014; Kahlert, 2015; Kanera et al., 2017; Mutrie et al., 2012; Pinto et al., 2013;

Pinto et al., 2008; Pinto et al., 2015; Spark et al., 2013). Very few digital and distance-based interventions reported long-term outcomes, and PA maintenance was limited (Goode et al., 2015; Haberlin et al., 2018; Roberts et al., 2017). Reviews in the general population also showed some decline in effects with longer follow-ups (Davies et al., 2012; Krebs et al., 2010). OncoActive effect sizes for PA at 12 months were in the same range (i.e., 0.13-0.20) as these reviews, but differences were no longer significant; thus, statistical power may be an issue. The home-based nature and aim of integrating PA into daily life may have contributed to sustained PA after ending OncoActive (Hardcastle & Cohen, 2017; Lahart et al., 2016). Moreover, using behavior change techniques associated with PA maintenance (e.g., action planning, graded tasks (with pedometers), goal-setting, self-monitoring) may have contributed to PA maintenance (Finlay et al., 2018; Grimmett et al., 2019; Howlett et al., 2019; Samdal, Eide, Barth, Williams, & Meland, 2017).

While between-group differences were not significant, OncoActive participants increased their MVPA from baseline to 12 months significantly with 38 (ActiGraph MVPA) to 283 minutes per week (self-report MVPA). Meta-analyses showed post-intervention increases of 49 and 30 minutes self-report MVPA between and within groups, respectively, for distance-based and digital PA interventions in CPS, and long-term increases of 65 minutes self-report MVPA for all kinds of interventions (including supervised) (Grimmett et al., 2019; Groen et al., 2018; Roberts et al., 2017). As OncoActive showed similar increases in ActiGraph MVPA it seems thus to perform very reasonable.

Although a 38 minutes increase of weekly MVPA may seem marginal, PA guidelines indicated that even small increases can provide relevant health benefits (Piercy et al., 2018; Thompson & Eijsvogels, 2018; Weggemans et al., 2018). Moreover, few studies assessed PA with accelerometers. Therefore, most of the evidence for health effects and recommendations regarding PA is based on self-report PA (Smith et al., 2019; Vassbakk-Brovold et al., 2016). As self-report PA is often substantially higher than ActiGraph PA (e.g., 38 vs 283 min MVPA), health effects could possibly be obtained with even smaller increases in PA. Future studies should further validate this concept (Smith et al., 2019).

Fatigue at 12 months was significantly lower in OncoActive and remained the same between 6- and 12 months. Improved fatigue is reported in several systematic reviews, but mainly for supervised exercise trials (Kessels, Husson, & van der Feltz-Cornelis, 2018; Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; Mustian et al., 2017; Vashistha et al., 2016). Although psychological eHealth interventions are effective in decreasing fatigue, a meta-analysis regarding digital PA interventions only found a non-significant trend towards decreased fatigue (Roberts et al., 2017; Seiler, Klaas, Troster, & Fagundes, 2017). The finding that OncoActive improved long-term fatigue is therefore very promising. Significantly higher PA in OncoActive at 6 months may have induced sustained long-term effects on fatigue. Mediation analyses should provide more insight in these processes.

Moderation analyses showed that effects on fatigue were especially apparent in younger participants, similar to findings from a multi-behavior eHealth intervention for cancer survivors (Willems et al., 2017). A possible explanation could be that younger cancer survivors experience more fatigue, leaving more room for improvement (Husson et al., 2015).

At long-term follow-up no significant improvements were found for depression. Although Craft et al. (2012) found significant improvement in depression with exercise, this was especially true for facility-based and supervised programs. Moreover, Roberts et al. (2017) did not find any effect for depression in their review of digital PA interventions. In addition, depressive symptoms are likely to change over time (Aaronson et al., 2014). Additional research is necessary to assess the influence of PA on depressive symptoms.

Physical functioning did improve significantly from baseline to 12 months in the OncoActive group, but it did not differ significantly from the usual care group. Previously published results showed improvements early after starting OncoActive (Golsteijn, Bolman, et al., 2018), which also indicated that the usual care group naturally improved over time (Willems et al., 2017). Baseline levels for physical functioning were already high and response-shift bias may be an issue (Gerlich et al., 2016).

Some strengths and limitations of the current study should be noted. The current study has a strong research design (RCT) assessing both self-reported and accelerometer-measured PA (Haskell et al., 2007). Although both measures vary substantially in absolute values, they show a similar trajectory (Figure 2). Both measures have their strengths and weaknesses. Self-report questionnaires are known for over-reporting, whereas accelerometers do not measure certain activities properly (e.g., cycling, swimming), and cannot discriminate between different domains of PA (e.g., leisure time PA, occupational PA) (Warren et al., 2010). By examining effects in both group separately, we provided insights into the probability of type II error (i.e., rejecting intervention efficacy despite large improvements in PA) (Grimmett et al., 2019). The study contributes to increasing the knowledge base for cancer types other than breast cancer, which currently constitutes the main body of evidence (Fong et al., 2012). A dropout of 11% at long-term follow-up is exceptionally low for a (partly) digital intervention and falls within the lower range for studies assessing maintenance (Eysenbach, 2005; Jankowski et al., 2014; Steins Bisschop et al., 2015).

Limitations were a relatively healthy population, selective dropout and statistical power for secondary outcomes. The introduction of a national colorectal cancer screening program in 2014, may have resulted in more early stage diagnoses not requiring adjuvant chemotherapy. In the Netherlands, surgery or brachytherapy are the primary treatments for prostate cancer and might be less invasive than external-beam radiotherapy; thus, generalizability to populations undergoing more burdensome treatments may be limited. Although selective dropout (i.e., cancer type and group assignment) may affect findings, this is expected to be negligible because of the very low dropout. As the power calculation was based on PA (primary outcome), moderator and health-related outcomes analyses may have been underpowered. Large inclusion numbers and a low dropout rate may have limited this potential problem.

In conclusion, our findings indicated that PA in OncoActive was not significantly higher at 12 months. Although between-group differences for PA were not sustained at 12-month follow-up, OncoActive participants were able to maintain their increased PA long-term. Participants became physically active earlier in their recovery and thereby experienced health benefits sooner. Improvements regarding fatigue were sustained long-term and fatigue was significantly lower for the OncoActive group. Supervised programs may result in larger effect sizes, but it may not be possible to provide them to everyone, because of costs, resources, and accessibility (Goode et al., 2015; Lahart et al., 2016). As it is argued that PA should be part of routine cancer care (Cormie et al., 2018), OncoActive is an easily accessible option to improve cancer recovery and sustain behavior change that meets patients preferences (Hardcastle & Cohen, 2017) and can potentially reach large populations.

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GENERAL DISCUSSION

This thesis aimed to promote PA in prostate and colorectal cancer patients and survivors (CPS). The main objectives were: (1) to compare self-report PA and accelerometer-measured PA in prostate and colorectal CPS, (2) to provide insight in the development of a computer-tailored PA intervention called OncoActive, (3) to evaluate characteristics of use of OncoActive, and (4) to study the efficacy of OncoActive regarding PA and health-related outcomes after six and 12 months. In this general discussion, main findings are presented and discussed, methodological strengths and limitations are considered, and implications for future research and practice are presented. Concluding remarks are provided at the end.

MAIN FINDINGS AND DISCUSSION

Physical activity measurement

As discussed in **chapter 1**, valid and reliable measurement of PA is important. Therefore, we compared accelerometer-measured PA (ActiGraph GT3X-BT) with a frequently used self-report PA questionnaire in the Netherlands (i.e., the Short Questionnaire to assess health-enhancing PA (SQUASH); see **chapter 2**) in prostate and colorectal CPS. Correlation and agreement were moderate, yet comparable to other studies regarding the SQUASH in healthy and diseased populations (Arends et al., 2013; Nicolaou et al., 2016; Wagenmakers et al., 2008; Wendel-Vos et al., 2003), and other self-report questionnaires in the general population (Chinapaw, Slootmaker, Schuit, van Zuidam, & van Mechelen, 2009; Cleland et al., 2014; Helmerhorst et al., 2012; Hoos et al., 2012; Skender et al., 2016; Wanner et al., 2016), and cancer populations (Boyle et al., 2015; Lewis et al., 2017; Liu et al., 2011; Pinto et al., 2013; Su et al., 2014; Ungar, Sieverding, et al., 2016).

Absolute PA values from self-report measures were substantially higher than accelerometer-measured PA as shown in **chapter 2, 5 and 6**, suggesting that overestimation of PA might occur when using self-report measures, a finding that is in agreement with other studies (Limb et al., 2019; Roberts et al., 2017; Smith et al., 2019; Vassbakk-Brovold et al., 2016; Watson et al., 2017). Self-reported PA may be appropriate for ranking individual participation in PA and comparing groups, but may not provide accurate absolute values of duration and intensity of PA (Van Blarigan & Meyerhardt, 2015). Although absolute PA values from accelerometers may be more reliable, accelerometers also have some limitations. Accelerometers do not provide information on the activity domain and are limited in the measurement of swimming/water-based activities (due to not always being waterproof), cycling, step/inclined activity, or strength exercises (Broderick et al., 2014; Freene et al., 2014; Helmerhorst et al., 2012; Peddle-McIntyre et al., 2018). Consequently, PA may be underestimated when using accelerometers. In addition, algorithms to define light, moderate and vigorous PA are not specifically developed for cancer populations (Migueles et al., 2017; Peddle-McIntyre et al., 2018). Due to a decreased cardiorespiratory fitness associated with cancer and cancer treatment, the amount of moderate and vigorous PA may be underestimated because activity is incorrectly classified as light activity. For example, Smith et al. (2019) found that self-report MVPA in prostate CPS had a stronger correlation with accelerometer-measured light PA than with accelerometer-measured MVPA.

The self-report SQUASH performed poorly in classifying change in individuals as shown by the low kappa values when comparing to classification according to the ActiGraph. Responsiveness of the SQUASH to assess PA change at group level was reasonable, but improved when questionnaire and accelerometer were assessed during the exact same week. Yet, it was noted that PA changes for self-report and ActiGraph PA showed a similar trajectory during the intervention study (see **chapter 6**), possibly indicating that both measures are indeed reasonably valid to assess group level change. As the ability to detect PA change is critical for intervention studies (Reeves, Marshall, Owen, Winkler, & Eakin, 2010), additional research with strict protocols (i.e., both measurements capturing the exact same week) is necessary, especially since the few studies that assessed responsiveness showed mixed findings (Cleland et al., 2014; Hoos et al., 2012; Nicaise et al., 2014; Ungar, Sieverding, et al., 2016; Vandelanotte et al., 2019) .

As mentioned in **chapter 1**, it is difficult to assess a complex behavior like PA that reflects type of activity, duration, frequency, and intensity (Caspersen et al., 1985). Questionnaires and accelerometers measure different dimensions of this behavior and it is therefore suggested that they may measure different underlying constructs (Kelly et al., 2016; Migueles et al., 2017). Taking all issues into consideration, it is recommended to include both measures in future studies to have the most complete insight into PA behavior (Broderick et al., 2014; Peddle-McIntyre et al., 2018; Rogers, 2010; Van Blarigan & Meyerhardt, 2015), as done when examining the efficacy of the OncoActive intervention.

Intervention development

Interventions grounded in theory and using behavior change techniques are necessary to achieve behavior change (Bluethmann et al., 2017; Gourlan et al., 2016). The Intervention Mapping protocol is often used to develop theory and evidence-based interventions (Bartholomew et al., 2016). In our study this protocol demonstrated to be very useful for finding a balance between the retention of core elements and yet improving relevance for the new target population, while adapting the Active Plus intervention into OncoActive (see **chapter 3**).

In accordance with the Intervention Mapping protocol we involved prostate and colorectal CPS and several care providers which could be involved in stimulating a physically active lifestyle in a cancer population (i.e., oncologist, physical therapist, oncology nurses, exercise physiologists) early in the development process by conducting interviews (Bartholomew et al., 2016). Although a literature search showed that determinants based on theoretical models for behavior change (i.e., constructs from social cognitive theory (SCT), trans-theoretical model (TTM), theory of planned behavior (TPB)/Reasoned Action Approach (RAA)) were similar for the original target group consisting of older adults and the new target group of prostate and colorectal CPS, operationalization of these determinants differed for example in terms of important beliefs and perceived barriers (Courneya, 2014; Husebo et al., 2013; Romero-Elias et al., 2017; Thorsen et al., 2008). Interviews provided important additional information regarding benefits of PA and barriers to PA specifically for prostate and colorectal CPS (Golsteijn et al., 2014).

By using computer-tailoring we were able to tailor the intervention to the specific interests, abilities, opportunities and preferences of prostate and colorectal CPS, as recommended from previous research (Blaney et al., 2013; Buffart et al., 2014; Hardcastle & Cohen, 2017; Szymlek-Gay et al., 2011). In addition a review showed that methods using individual and interactive elements tailored to the individual needs are most successful in improving PA uptake (IJsbrandy et al., 2018). With literature showing that pedometers may stimulate self-monitoring and goal-setting in cancer populations (Beg, Gupta, Stewart, & Rethorst, 2017; De Cocker et al., 2015; Knols et al., 2010; Vallance et al., 2008), we integrated them into the intervention to improve self-regulation. Additional analyses regarding use and appreciation of intervention materials showed that the pedometers was the most frequently used and highest appreciated intervention component (Bolman et al., 2019) and may thus have provided a major contribution to the intervention efficacy.

Print-based and web-based intervention materials were offered alongside each other, as findings from the literature and in-depth analyses of the Active Plus intervention showed that optimal intervention effects are more likely to be obtained if participants can choose themselves whether they prefer online or print intervention materials (Ekman et al., 2006; Kongsved et al., 2007; Peels, Bolman, et al., 2012). Characteristics related to delivery mode were examined afterwards as described in **chapters 4** and are discussed in more detail below.

Based on a pretest of new intervention materials, a small scale pilot-test of the modified intervention among prostate and colorectal CPS, and a review by healthcare professionals, minor adaptations were made to finalize the intervention for evaluation in a randomized controlled trial (RCT). **Chapter 3** provides an overview of the protocol for this RCT.

Intervention evaluation

Delivery channel and use

Chapter 4 showed that a vast majority of participants used a combination of printed and web-based materials when both delivery modes were offered alongside each other. Although it is promising that in an older population (i.e., mean age of 66 years) almost 85% of the participants used web-based materials to some extent, it cannot be ignored that printed-materials were used as well. This is in line with other studies that also indicated that even among internet users, a preference for print-based or non-digital information persists (Choi & Dinitto, 2013; Corbett et al., 2018; Gordon & Hornbrook, 2016; Heiman, Keinki, & Huebner, 2018; Sanders, Conroy, Schmitz, & Gusani, 2018). Yet, a review showed that cancer survivors often considered web-based interventions superior to offline comparators (Corbett et al., 2018). Therefore, we concluded that it is preferable to offer print- and web-based materials alongside each other.

Only providing web-based materials would potentially exclude some vulnerable sub-groups. Older, less educated, more fatigued participants or participants that still received active treatment were less likely to use web-based materials. Such characteristics are also associated with lower digital skills and eHealth literacy (Latulippe, Hamel, & Giroux, 2017; Plantinga & Kaal, 2018). To the best of our knowledge, only one other study examined factors that were associated with an actual choice for print- or web-based intervention materials. Findings from our study were comparable to what they found: being older, less educated and a poorer health status were associated with the choice for print materials (Greaney et al., 2014).

Furthermore, those who used web-based materials, predominantly used a combination of print- and web-based materials. As a result these participants may have read their advice more often and may have used interactive content more extensively, which may have resulted in a higher engagement with the intervention (Greaney et al., 2014). Additional analyses indeed showed that participants that read all web-based content, showed higher use of intervention components than those who did not read all web-based content (Bolman et al., 2019). According to a review in cancer survivors, higher engagement with web-based interventions resulted in more benefits regarding the aimed outcomes (Corbett et al., 2018). Therefore, using a combination of materials may have influenced intervention efficacy.

Efficacy regarding PA

Results showed that OncoActive was effective in increasing self-report PA at three months (i.e., during the intervention) and six months (i.e., two months after the intervention) for minutes of moderate-to-vigorous PA (MVPA) per week and the number of days on which a person was at least moderately physically active for at least 30 minutes (days with PA). At 6 months, significant improvements in favor of OncoActive were also found for ActiGraph MVPA (not measured at 3-month follow-up). ActiGraph days with PA improved borderline significantly (**Chapter 5**).

Positive effects of OncoActive can possibly be assigned to the high numbers of participants that (at least partly) read their PA advice: participants not having read any advice varied from only 1 to 6% per advice, as shown in **chapter 4**. The teachable moment of a cancer diagnosis may have increased the motivation of participants to receive and read information regarding PA. According to the Elaboration Likelihood Model (Petty, Barden, & Wheeler, 2009), a high motivation to receive information leads to more elaborate processing of information and thus to a higher likelihood of change in attitude regarding PA. With the information in the OncoActive intervention targeting determinants of PA in line with behavior change theories (see **chapter 3**), this may have resulted in improved PA. Numbers of participants not having read any advice in OncoActive were substantially lower than in a comparable intervention in which older adults were assigned to either a web-based or a print-based delivery mode (Peels, de Vries, et al., 2013). In a completely web-based cancer aftercare intervention, 13% of the participants did not read any advice (Kanera, Willems, et al., 2016). A free choice of delivery channel (i.e., web-based vs. print-based) may have enlarged engagement and may have given participants the possibility to process the information at their own pace (Abraham & Kools, 2011; Smit et al., 2015) and thereby may have contributed to intervention efficacy. In addition, 80% of intervention participants used the provided pedometer, which may have increased effects of the intervention even further (Bolman et al., 2019). A study in men also identified that using a pedometer fostered motivation to increase PA (Donnachie et al., 2017).

At 3 months, self-report MVPA increased significantly in OncoActive participants with colorectal cancer but not in participants with prostate cancer. As colorectal cancer is associated with more invasive treatments, colorectal CPS are more likely to perceive their general health as poor and to report activity limitations compared to prostate CPS (Cabilan & Hines, 2017; LeMasters, Madhavan, Sambamoorthi, & Kurian, 2013). Therefore, colorectal CPS may have perceived a higher need to improve their lifestyle and thus improved their PA more rapidly. A moderating effect of educational level was found for ActiGraph MVPA at 6 months: MVPA increased significantly in participants with a medium education level, borderline significantly in highly educated participants, but not in low educated participants. As shown in **chapter 4**, lower educated participants were also less likely to use web-based materials. Therefore, they may not have viewed video content, used interactive web-based components and only read the print-based advice, resulting in a less comprehensive intervention experience as already discussed above. This may have resulted in a lower efficacy in those with a lower education. Another explanation may be that, although lower educated participants aimed to improve their PA, receiving information about behavior change may have decreased self-efficacy of lower educated participants to eventually change their PA. Subsequently, this may have resulted in perceiving recommendations as less feasible and thereby hindering behavior change (Reinwand et al., 2015). Yet, at long-term follow-up PA was no longer moderated by educational level (see **chapter 6**).

The effect sizes for OncoActive shortly after the end of the intervention (i.e., 0.28-0.37; **chapter 5**) are slightly higher than those reported in a meta-analysis including distance-based interventions in cancer survivors (i.e., 0.21), yet effect sizes in both studies were small (Groen et al., 2018). Distance-based interventions include non-face-to-face interventions like, telephone, print-, and web-based interventions. Based on self-report measures Groen et al. (2018) reported an absolute increase of 49 minutes MVPA, which is comparable to ActiGraph MVPA found in our study (i.e., 45 min MVPA), but substantially lower than our findings regarding self-report (i.e., 267 min MVPA). A meta-analysis of digital behavior change interventions in cancer survivors reported absolute values of self-report MVPA similar to Groen et al. (2018): 49 minutes of MVPA for RCTs and 30 minutes for pre-post studies (Roberts et al., 2017). Although such short-term findings are promising, sustained behavior change is necessary to achieve long-term health benefits (Grimmett et al., 2019; Spark et al., 2013)

Long-term finding showed that self-report days with sufficient PA were still significantly higher for OncoActive participants compared to the control group at 12-month follow-up (i.e., 8 months after the end of the intervention). Self-report MVPA improved borderline significant. No significant differences between OncoActive and the usual care control group were found for ActiGraph days with PA and MVPA. Nevertheless, it was noted that both self-report and ActiGraph PA did not decrease significantly between 6-and 12-month follow-up, indicating that OncoActive participants were able to maintain their improved PA (Glasgow et al., 2006; Kwasnicka et al., 2016). In addition, OncoActive participants improved their PA significantly from baseline to 12-month follow-up: pre-post differences of 38 minutes ActiGraph MVPA and 283 minutes self-report MVPA. The lack of finding significant differences between the OncoActive group and the control group at 12 months can be attributed to a small, but non-significant improvement of PA in the control group: pre-post differences of 13 minutes ActiGraph MVPA and 101 minutes self-report MVPA (see **chapter 6**).

Such small improvements in control groups are seen more often studies regarding cancer populations (Grimmett et al., 2019; Osei et al., 2013; Ottenbacher et al., 2012; Pinto et al., 2015; Rogers et al., 2015; Spark et al., 2013; van den Berg et al., 2015; Willems et al., 2017). A systematic review and meta-analysis assessing PA maintenance in cancer survivors even revealed that in 35% of the included studies, control groups showed significant improvements in PA (Grimmett et al., 2019). Firstly, improvements of PA in control groups may emerge from natural improvements in health status and cardiorespiratory fitness over time. Studies in breast and prostate cancer have shown that while PA levels decline during treatment, PA improves during 1-3 year follow-up after treatment without any intervention (Cabilan & Hines, 2017; De Groef et al., 2018; Gal et al., 2019; Smith et al., 2019). Secondly, control group participants may also adopt PA, a common phenomenon in PA and exercise studies in cancer populations which is called contamination (Courneya, Friedenreich, Sela, Quinney, & Rhodes, 2002). Although contamination is often defined as the unintentional transfer of intervention materials to the control group, several studies regarding exercise in cancer also defined PA adoption of control group participants (without cross-over of intervention materials) as contamination (Grimmett et al., 2019; Steins Bisschop et al., 2015). A review study of Steins Bisschop et al. (2015) reported contamination in 75% of the studies they included. Furthermore, as previously mentioned, a cancer diagnosis is regarded as a teachable moment (Basen-Engquist, Carmack, et al., 2012; Blaney et al., 2013; Demark-Wahnefried et al., 2007) and CPS who were randomized to the control group knew that the study was aimed at improving PA and that being physically active was beneficial. Therefore, control group participants were probably to some extend motivated to improve their PA. Thirdly, PA measurements may have raised awareness of PA and the necessity of improvement, resulting in control group participants increasing their PA. The latter phenomenon is called reactivity, and is well known for PA measurement (Sylvia, Bernstein, Hubbard, Keating, & Anderson, 2014). In conclusion, by only looking at differences between the intervention and control group, the effects of natural improvement and contamination are ignored, resulting in small effect sizes and a possibility of type II error. Consequently, interventions are regarded ineffective in spite of large improvements in PA in the intervention group (Grimmett et al., 2019). Therefore we examined both between-group differences and pre-post differences within the intervention group.

Between-group MVPA effect sizes for OncoActive (i.e., 0.13-0.20) were slightly lower than the effect size of 0.25 that was reported in a meta-analysis examining maintenance of PA in cancer survivors (Grimmett et al., 2019). The absolute MVPA values of between-group differences for ActiGraph MVPA in our study (i.e., 12 minutes per week) were also slightly lower than the 40 minutes reported by Grimmett et al. (2019). However, results of Grimmett et al. (2019) were predominantly based on self-report PA and between-group differences in self-report MVPA in our study were substatially higher with 132 minutes per week. In addition, Grimmett et al. (2019) also acknowledge the problem of increased PA in control groups and thus also examined pre-post differences for intervention and control groups seperately. Again, effectsizes for OncoActive and the control group were slightly lower and absolute values in the review were higher than the ActiGraph MVPA values in our study but lower than the self-report MVPA values in our study. Yet, it should also be noted that this review also considered interventions including a supervised component. It is known that supervised interventions may result in larger effects (Grimmett et al., 2019; Turner et al., 2018), but also brings about higher costs. Other reviews regarding maintenance of outcomes in cancer populations often concern physical and psychosocial outcomes (Grimmett et al., 2019; Jankowski et al., 2014; Spark et al., 2013) which are often examined in supervised exercise trails (see **chapter 1**).

Absolute pre-post increases within OncoActive varied between 51 minutes MVPA per week at 6 months and 38 minutes MVPA per week at 12 months (ActiGraph measurement; **chapter 5 and 6**) may seem to be small. Yet, a meta-analysis showed that improvements of 35-100 minutes self-report MVPA per week are associated with reduced risks in overall and cancer specific mortality (Groen et al., 2018; Schmid & Leitzmann, 2014). From all of the discussed reviews and meta-analyses, it can be derived that up to now the majority of studies only used self-reported PA outcomes. Consequently, most evidence regarding the positive effects of PA and the corresponding guidelines is based on self-report PA. As already noted above and demonstrated in **chapter 2, 5 and 6**, self-reported PA is substantially higher than accelerometer-measured PA. This may imply that CPS may even benefit from smaller amounts of PA, although additional research is necessary to substantiate this (Smith et al., 2019; Vassbakk-Brovold et al., 2016; Warburton & Bredin, 2017).

Efficacy regarding health-related outcomes

The effects of OncoActive on fatigue, anxiety, depression, physical functioning and overall health-related quality of life (HRQoL) were examined as secondary outcomes. At 3 months, significant improvements in favor of OncoActive were already observed for fatigue and physical functioning. At 6 months, further improvements of fatigue and physical functioning were observed. Additionally, a significant improvement in depression was found (see **chapter 5**). Fatigue was still significantly lower in OncoActive participants at long-term follow-up as there was no change between 6- and 12-month follow-up in both groups. No difference between groups were found for physical functioning and depression at 12 months. Yet again, when looking at pre-post differences, significant improvements in physical functioning were observed in OncoActive participants, compared to small non-significant pre-post differences in the control group. Again, natural improvement of the control group as seen in other studies may have resulted in the lack of efficacy (Cabilan & Hines, 2017; Willems et al., 2017). No effects were found for anxiety and overall HRQoL.

Several systematic reviews have reported reduced fatigue, depression, physical functioning and HRQoL with exercise (Craft et al., 2012; Fong et al., 2012; Loughney et al., 2015; Mishra, Scherer, Geigle, et al., 2012; Mishra, Scherer, Snyder, et al., 2012; Schmitz et al., 2010; Speck et al., 2010; Szymlek-Gay et al., 2011). As mentioned in **chapter 1**, health-related outcomes are most often examined as outcomes of supervised exercise trials, which are primarily aimed at improving health instead of improving lifestyle (Courneya, 2010). Few studies primarily aimed at improving lifestyle have examined effects regarding health-related outcomes. In their meta-analysis of digital behavior change interventions, Roberts et al. (2017) reported a non-significant trend toward decreased fatigue, but no effects regarding HRQoL or mental health (i.e., anxiety and depression). A review on technology supported self-guided interventions showed promising findings on fatigue, but findings regarding HRQoL and subscales of HRQoL (e.g., physical functioning, role functioning, etc.), anxiety and depression were mixed (Kiss et al., 2019). More prominent effects were found for an intervention that consisted of modules on multiple topics including psychological problems (Yun et al., 2012). It is therefore promising, that a relatively low intensive intervention like OncoActive, which is only aimed at increasing PA is able to improve fatigue and physical functioning.

At 3-month follow-up, significant improvements in fatigue and physical functioning were observed for colorectal CPS but not for prostate CPS. At 6 months, also significant improvements in depression and physical functioning were found for colorectal CPS but not for prostate CPS (see **chapter 5**). These findings may implicate that up until 6 months, the OncoActive intervention was mainly effective in improving health outcomes for colorectal CPS. Colorectal CPS increased their PA more already early in the intervention (as shown in **chapter 5**), which may have resulted in immediate improvements in health outcomes. Prostate CPS increased their PA at a later time point (i.e., 6 months), therefore, effects regarding health-related outcomes may not have been present at the 6-month follow-up yet. Additionally, as expected from literature, it was noted that colorectal CPS experienced lower baseline values for health-related outcomes (Cabilan & Hines, 2017; LeMasters et al., 2013). On the one hand, these lower baseline values may have caused a larger need to improve their health and thus to improve PA, as mentioned previously. On the other hand, it may be more difficulty to improve high score on health-related outcomes even further, which may have been the case in prostate CPS. As a result, prostate CPS may not have experienced immediate health benefits. Moderation analyses at long-term follow-up indeed indicated that there were no longer differences in efficacy related to cancer type, indicating that the delayed improvement in PA in prostate CPS eventually may have resulted in improved health-outcomes. Yet, at 12-month follow-up, effects on fatigue were moderated by age, indicating decreasing improvements in fatigue, with increasing age. The latter finding was similar to an eHealth intervention providing multifaceted aftercare for cancer survivors (Willems et al., 2017) and can possibly explained by a higher perceived fatigue at baseline in younger participants (Husson et al., 2015).

STRENGTHS AND LIMITATIONS

The results presented in this thesis should be interpreted in light of their strengths and limitations. Although most issues were also addressed in the different chapters of this thesis, the current section provides an overview of strong and weak points with regard to the intervention, study population, study design and measurements.

Intervention

The tailored design and content of the OncoActive intervention can be considered a strength of the current study. As mentioned in **chapter 1**, there is a clear need for affordable and easily accessible PA programs for CPS. As argued by Hardcastle and Cohen (2017) home-based, unsupervised PA interventions tailored to cancer survivors' needs and preferences may be needed to achieve sustained behavior change. In addition, IJsbrandy et al. (2018) mentioned that interactive methods and individual tailoring are most successful in improving uptake of PA during and after cancer treatment. At the time of starting the OncoActive project, most interventions in the Netherlands included supervised programs (Kampshoff et al., 2010; Persoon et al., 2010; van Waart et al., 2010; Velthuis et al., 2010), therefore the studies in this thesis especially provided important new insights for the Dutch situation. The systematic development using the Intervention Mapping protocol and its base in behavioral change theories (see **chapter 3**) may have contributed to the efficacy of the intervention (Bartholomew et al., 2016; Bluethmann et al., 2017; Gourlan et al., 2016). In addition, both patients and healthcare providers were consulted several times during the development of the OncoActive intervention (see **chapter 3**). This may have resulted in the intervention suiting the needs of the population. Furthermore, the high use of the provided pedometer, which may have increased effects of the intervention can be regared a strength of the intervention (Bolman et al., 2019). The fact that OncoActive was provided through a combination of web-based and printed materials, may have increased the reach of our intervention (see **chapter 4**) and thereby its efficacy. Lastly, we contributed to developing more evidence-based interventions for cancer types other than breast cancer, for which currently the majority of evidence-based PA interventions were developed (Fong et al., 2012; Speck et al., 2010; Turner et al., 2018).

Some limitations should also be noted. Alltough studies show that CPS have a preference for unsupervised PA programs (Wong et al., 2018), systematic reviews

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consistently show that a supervised component increases efficacy, especially for more vulnerable subgroups (i.e older participants or those with physical limitations) (Buffart et al., 2018; Grimmett et al., 2019; Turner et al., 2018). This is also acknowledged by our finding that vulnerable sub-groups may be more difficult to reach by a web-based intervention (see **chapter 4**). As OncoActive is a completely distance-based intervention, efficacy could be increased by including some form of supervision or face-to-face contact. A possibility would be to develop a blended version of the intervention, or to combine it with an already existing supervised program. In addition, in the literature it is suggested that a stepped-care approach may be needed (Grimmett et al., 2019; Morey et al., 2015), in which patients with the lowest baseline values and highest need, receive more intensive interventions. For those already motivated to improve PA, a lower intensity intervention may be sufficiently adequate. This argument is supported by the finding that light intensive interventions were less effective in vulnerable subgroups, whereas those with the worst baseline scores are the ones that experienced the largest improvements after a PA program (Buffart et al., 2018; Grimmett et al., 2019). In addition, a self-guided intervention may also be more difficult for lower-educated patients, who are known to have lower (e)Health literacy (Rademakers, 2014). A blended or supervised intervention may therefore also be more beneficial for them.

Study population

Sample characteristics

A strength of the studies included in this thesis is the large study sample that participated in this trial. In accordance with the power calculation, we aimed to include at least 428 participant (214 per study arm). In total, 510 prostate and colorectal CPS provided informed consent, although recruitment lasted longer than originally planned. Yet, a small sample of 22 CPS could not be included in our studies, as they either did not meet inclusion criteria or did not complete baseline measurement, eventually resulting in final baseline study population of 478 participants.

The ratio prostate versus colorectal CPS was approximately 60% versus 40%. A small overrepresentation of prostate CPS may have been caused by the organization of care for prostate and colorectal cancer and by our recruitment strategy. Currently, in the Netherlands, the primary treatments for prostate cancer include a prostatectomy (often with a robot) or brachytherapy (Kloosterboer & Siesling, 2014), which are centralized in specialized hospitals or radiotherapy centers. Since a couple of these centers participated in our trial we had access to large samples of prostate CPS, resulting in a small overrepresentation of prostate CPS. In addition, colorectal CPS were initially recruited through oncology departments, but the majority of stage I-III colorectal CPS only require surgery and thus not visit the oncology department (Miller et al., 2016; Siesling et al., 2014). Therefore we also contacted surgery departments for recruiting participants in our study. Nevertheless, there may have been some delay in reaching colorectal CPS, which may have resulted in a small underrepresentation.

Only 8% of participants were still undergoing active treatments, which may also be related to the treatment regimens. As already mentioned primary treatment for prostate cancer (i.e., prostatectomy or brachytherapy) most often concerns a single treatment, implicating that most prostate CPS could not be undergoing active treatments as defined in the current study. Only the few prostate CPS that were receiving external beam radiotherapy were considered currently undergoing treatments, as hormonal therapy was not defined as a primary treatment. The majority of colon cancer patients diagnosed at stage I to III predominantly undergo surgery without any adjuvant treatments. Radiotherapy (possibly in combination with chemotherapy) is more frequently applied in rectal cancer, but mostly as neo-adjuvant treatments (i.e., before surgical intervention) (Miller et al., 2016). Therefore, only a small portion of colorectal CPS was currently undergoing active treatments. In addition, it is likely that a number of the colorectal CPS included in our study, were diagnosed in an early disease stage, as a result of a nationwide screening program for early detection of colorectal cancer introduced in the Netherlands in 2014 (Elferink, van der Vlugt, Meijer, Lemmens, & Dekker, 2014). Consequently, diagnose at an early stage may have resulted in a smaller portion requiring adjuvant chemotherapy and thus experiencing fewer treatment-related side effects. In summary, it can be concluded that the CPS included in our study may have been relatively healthy and that findings may not be completely representative for patients that are undergoing more burdensome (adjuvant) treatments.

Dropout

Dropout from the randomized controlled trial described in this thesis was very low. Dropout rates of 4%, 7% and 11% were reported at 3-, 6- and 12-month follow-up respectively (**chapter 5 and 6**). In addition, advice was read by almost the complete study population (Bolman et al., 2019). Low dropout rates are exceptional for (partly) digital interventions and even in the same range of supervised exercise programs, which are normally considered to have lower dropout rates (Eysenbach, 2005; Jankowski et al., 2014; Steins Bisschop et al., 2015). A review study of exercise interventions in cancer populations showed dropout rates varying from 9 to 11% during the intervention period with a majority of studies having a supervised component (Steins Bisschop et al., 2015). Dropout rates for studies assessing maintenance (and thus including a longer follow-up period) ranged from 10-44% (Jankowski et al., 2014). Again, the majority of the included studies incorporated a supervised component. Low dropout can thus be regarded a strength of the studies discussed in this thesis.

The low dropout rates observed in the current trial are remarkable. A possible explanation could be the high commitment of CPS to participate in the intervention. As it was clearly stated that PA could improve cancer- and treatment-related side effects and provide long-term health benefits, CPS may have been more motivated to complete the intervention (Corbett et al., 2018). It is for example noteworthy that dropout rates in the Active Plus intervention (for older adults) in which the links with health effects may not have been as essential, are substantially higher (Peels, Bolman, et al., 2012). Additionally, as explained in **chapter 4**, the fact that participants could choose their own preferred delivery mode may also have limited dropout rates: they were able to use either web-based or printed intervention materials and questionnaires according to their convenience.

Although dropout was low, analyses showed that selective dropout occurred in our studies. At 3 months intervention group participants and those with a lower intention were more likely to dropout, at 6 months colorectal CPS were more likely to dropout, and at 12 months intervention group participants were again more likely to dropout. Selective dropout is not uncommon in web-based PA interventions (Crutzen, Viechtbauer, Spigt, & Kotz, 2015; Kanera, Bolman, Willems, et al., 2016; Peels, Bolman, et al., 2012; Reinwand et al., 2015). A systematic review of Steins Bisschop et al. (2015) also showed larger dropout rates in intervention groups compared to control groups. In our trial, at 3 months, participants from the intervention group and participants with a lower intention to be physically active were more likely to drop out. Dropout of intervention group participants early in the intervention can possibly be explained by the fact that the OncoActive intervention did not meet their expectations causing them to quit participation (Crutzen et al., 2015) or by experiencing early effects and thus not requiring further support (Corbett et al., 2018). As short-term results of OncoActive were especially found for colorectal CPS, this may also explain why they were more likely to dropout at 6 months follow-up. Selective dropout at 12 months may have been caused by the fact that for the intervention group the intervention already ended, whereas the control group would receive their computer-tailored advice after this final measurement. Subsequently, the intervention group had nothing to expect and anecdotal evidence from responses to reminders showed that intervention group participants did not recognize the importance of follow-up measurements. Those with a low intention to be physically active may not have been motivated enough to continue participation and may thus have dropped out. Being not able to retain those with a lower motivation may thus be a limitation of the current study. Although selective dropout may affect findings, with the minimal dropout rates observed in our study the probability of an impact on findings is expected to be marginal. In addition, analyses regarding intervention efficacy were corrected for selective dropout and intention-to-treat analyses showed similar results.

Study design

The studies in the current thesis were based on a RCT primarily conducted to assess the efficacy of the OncoActive intervention. A RCT is regarded a strong study design providing the ability to compare two (or more) groups (Courneya, 2010; Flay, 1986). Usually a double-blinded trial is assumed to provide the highest level of evidence, however, due to the nature of the study, it was not possible to blind participants or the researchers. Although not blinding the researchers may be a limitation, the measurement protocol during the study was completely automated and protocolled, thus researchers were not able to influence these measurements. Nevertheless, by randomizing participants to either the intervention group or the usual care waitlist control group, we were able to compare the intervention efficacy in two balanced groups, avoiding selection bias, reducing confounding factors and thus improving the internal validity of our results (Flay, 1986).

Randomization of participants took place at the patient level. Although normally this is regarded the best method of randomization, it also means that patients from the same hospital were randomized to both conditions. As a result, there was a small possibility that participants from different conditions could meet each other in the hospital and discuss the content of the intervention, eventually causing contamination. However this was not considered very likely, as most participants were not currently undergoing active treatments and PA advice was individually tailored. Yet, for future research additional checks for contamination are recommended. However, as the current study used a waitlist design for the control group contamination may have occurred with regard to increasing PA behavior (Courneya et al., 2002). As discussed previously, control group participants may have been highly motivated to increase their PA and as a result they may have searched themselves for information regarding PA or PA programs to participate in. Additional in-depth analyses showed that only 5% of control group participants used other programs or support from a physiotherapist to increase their PA, but we cannot rule out the possibility that control group participants searched for information themselves. The fact that the control group also increased their PA (although not significantly) may have resulted in an underestimation of the intervention efficacy, as already discussed previously.

The RCT included a longitudinal design, which is considered a major strength. Outcomes were assessed at three (i.e., during the intervention), six (i.e., 2 months after the end of active intervention period), and 12 months (i.e., 8 months after the intervention ended). Therefore, we were able to gain insights in improvement already during the intervention, shortly after ending the intervention and at long-term follow-up. Especially evidence regarding long-term follow-up of exercise studies in a cancer population is limited (Aaronson et al., 2014; Courneya, 2014; Stacey et al., 2017). A systematic review in breast cancer survivors showed that only 10% of the included studies examined effects at least 3 months after the intervention ended (Spark et al., 2013) and a review regarding prostate cancer showed that only 2 out of 6 studies specifically targeted at prostate cancer included longer term follow-up measurements (Finlay et al., 2018).

Statistical analyses conducted in **chapter 5 and 6** also respected the longitudinal nature of the study. Multilevel linear regressions that controlled for the baseline value of the outcome measure, potential covariates, baseline differences and predictors of dropout were conducted. According to a study of Twisk et al. (2018) longitudinal covariance analysis, taking the baseline value of the outcome into account as a potential covariate, is the most reliable option to assess intervention effects in longitudinal studies. They demonstrated that due to regression to the mean, using a repeated measures analysis including the baseline value as an outcome or the analysis of change scores may lead to biased outcomes (Twisk et al., 2018). In addition, multilevel analysis is considered to be adequately able to handle missing data and it is suggested that it provides more reliable estimates than applying imputation methods (Twisk, 2006). Nevertheless, we conducted intention-to-treat analyses applying multiple imputation as sensitivity analyses. As shown in **chapters 5 and 6**, results from both analyses were similar.

The RCT conducted in the current study was aimed at examining efficacy regarding a wide range of primary and secondary outcomes, which in itself may be a strength of the study. However, the questionnaires to assess these outcomes were quit extensive and with a process evaluation being conducted additionally, even more questions were added. Therefore, it may have been burdensome for participants to complete the questionnaires, which may have increased dropout (Edwards et al., 2009; Sahlqvist et al., 2011). In addition, using a wide range of outcomes, requires multiple analyses to be conducted and thus introduces an elevated chance of Type 1 error. For future studies it may therefore be important to critically consider which outcomes are most important to assess.

Measurements

Data collection for the studies described in this thesis was based on objective measures for PA and self-report for PA and all other outcomes. For PA measurement the SQUASH questionnaire was used to assess self-report PA and the ActiGraph accelerometer was used to assess objective PA. An extensive discussion of the validity, reliability, advantages and disadvantages, and applicability in our study population was already provided in **chapter 2**. From this chapter it was concluded that a combination of both measures may provide the most comprehensive insights in PA. Therefore, applying both measurement methods is regarded a major strength of the current study.

Health-related outcomes were also assessed using self-report questionnaires. Fatigue was assessed using the Checklist Individual Strength (CIS) (Bultmann et al., 2000; Vercoulen et al., 1994). Although this questionnaire was originally developed to measure fatigue in patients with chronic fatigue syndrome, it has also been used in cancer populations and reference values for cancer survivors have been developed (Worm-Smeitink et al., 2017). A good internal consistency was found in our study population (**chapter 5**). Distress, consisting of anxiety and depression was assessed using the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). A systematic review including cancer patients showed a high internal consistency for both subscales and moderate to strong correlations with other questionnaires assessing distress (Bjelland et al., 2002; Vodermaier, Linden, & Siu, 2009). We also found a good internal consistency in our study (**chapter 5**). Overall HRQoL and physical functioning were assessed using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC QLQ-C30) (Aaronson et al., 1993). This questionnaire is specifically developed to assess HRQoL in cancer populations and showed acceptable internal consistency and test-retest reliability (Arraras Urdaniz et al., 2008; Koukouli, Stamou, Alegakis, Georgoulias, & Samonis, 2009). The subscales used in the current study also showed acceptable internal consistency (**chapter 5**). It is therefore assumed that the CIS, HADS and EORTC QLQ-C30 provided reliable estimates of fatigue, anxiety, depression, physical functioning and HRQoL in our study. However, it should be noted that self-report health outcomes may be affected by 'response shift', internal standards of participants may change over time, resulting in the inability to detect changes (Brug et al., 2017; Gerlich et al., 2016).

Missing data that resulted from incomplete questionnaires was imputed according to the guidelines provided in the manuals of the corresponding questionnaire for PA (SQUASH) and HRQoL (EORTC QLQ-C30). For fatigue (CIS) and distress (HADS), no specific guidelines for handling missing values were available. However, Bell et al. (2016) recommended that for the HADS a maximum of one missing item per subscale could be imputed with the mean of the questionnaire's subscale. With the absence of any recommendation regarding the CIS, we decided to apply a similar approach for this questionnaire.

Self-report data was gathered through questionnaires that could be completed either online or on paper (see **chapter 3 and 4**). In the web-based version it was mandatory to answer all questions, resulting in data without any missing data, which is an important advantage. However, a part of the study population completed the questionnaires on paper, resulting in some missing data. Nevertheless, approximately two thirds of the participants completed the web-based questionnaires (see **chapter 4)**. It is regarded very promising that in a relatively older population, such a large proportion used web-based questionnaires. A similar response rate comparing web- or print-based questionnaires in colorectal cancer patients was found in another study (Horevoorts, Vissers, Mols, Thong, & van de Poll-Franse, 2015). The substantial completion of web-based questionnaires may have improved the quality of our data. Finally, self-report questionnaires are associated with several disadvantages. Self-report measures may be prone to social desirability and recall bias (Kimberlin & Winterstein, 2008). However, there are no reasons to expect that bias would differ between the study arms. As a result, bias may have occurred similarly in both the OncoActive group and the usual care group. Yet, recall bias may have been a problem in **chapter 4**, which did not incorporate the control group. This study assessed intervention use, appreciation and motivational value. Intervention components were evaluated up to 3 months after receiving them. Therefore results may be biased and more immediate assessment or objective usage data would have been preferred.

IMPLICATIONS FOR FUTURE RESEARCH

Directions for future research already emerged in the different chapters included in this thesis. These are discussed in more detail below. In addition, we also discuss some suggestions for future research based on a framework that conceptualizes the links between PA and cancer developed by Courneya (2014) that is shown in Figure 1. According to this framework, cancer variables can be determinants of PA, moderators of determinants, moderators of outcomes and cancer variables can be outcomes themselves.

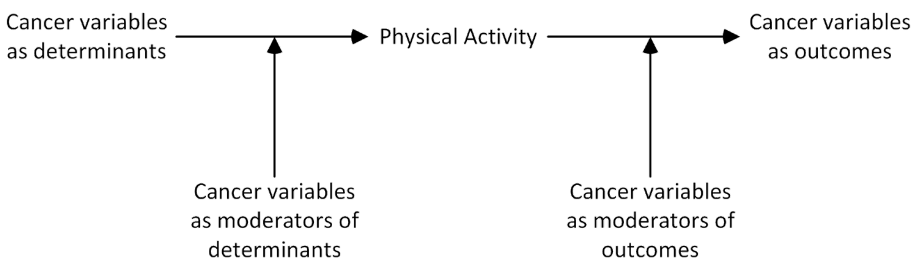

Figure 1 A framework for PA and cancer survivorship research (Courneya, 2014)

Cancer variables such as cancer type, type of treatment, stage of disease and disease outcomes may be determinants of PA. For example, type of cancer may influence the ability or motivation to be physically active. Psychosocial variables are assumed to mediate the effect of cancer variables on PA, but currently little is known about these processes (Courneya, 2014). Cancer variables may also moderate the relationship between PA determinants like attitude, confidence, social support, benefits and barriers and PA (see **chapter 1)**. It is therefore suggested that interventions promoting PA take cancer variables into account (Courneya, 2014), as we also did while developing OncoActive. Therefore, further analysis of the data on cancer variables and psychosocial determinants of PA collected in the current study could provide additional insights in the role of cancer variables as determinants of PA. Additional research regarding the moderating effect of cancer variables on PA determinants may aid further development of the OncoActive intervention. For future research it would be possible to extend the intervention to other cancer types or other disease stages and examine its efficacy. For example several health care providers from participating hospitals suggested that the OncoActive intervention could potentially be beneficial for non-curative prostate cancer patients on hormonal treatments.

Additional mediation analyses regarding OncoActive could provide further insights into how psychosocial determinants of PA are influenced by the intervention and whether this in turn influenced PA behavior. Additional research into which theoretical methods and practical strategies did or did not contribute to intervention efficacy could be useful to further optimize PA intervention for CPS.

In accordance with Courneya's framework, we found that intervention effects were moderated by cancer type but not by time since treatment (see **chapter 5**). Yet, we were not able to assess the moderating effect of active treatments versus having finished treatment as sample sizes of subgroups were too small. Under-powering is common in studies assessing the moderating effects of cancer variables. Therefore, additional research with a larger sample of participants undergoing active treatment would be necessary. In addition, more insight into the moderating role of other cancer variables can further aid targeting interventions to specific subgroups (Courneya, 2014).

As also mentioned in **chapter 1**, the most important link to establish is the effect of PA on cancer outcomes (e.g., increased survival) or intermediate outcomes (e.g., recurrence rates, therapy completion rates). Such evidence will likely motivate patients to become physically active, healthcare providers to recommend PA programs and insurance companies to reimburse such programs (Courneya, 2014). Unfortunately, cancer outcomes were not addressed in the current study as follow-up was only one year and only a small portion was actively treated. Although it would be interesting to examine cancer outcomes by conducting an additional follow-up measurement several years after the end of the intervention, additional large scale studies with long-term follow-up are needed to provide evidence regarding cancer outcomes. Currently, the CHALLENGE trail is conducted to investigate the effects of exercise on cancer recurrence and overall survival in colorectal CPS (Courneya et al., 2008). Although effects on cancer outcomes were not assessed, OncoActive was effective in increasing several health-related outcomes, such as fatigue, physical functioning and depression (**chapter 5 and 6**). In according with the literature, such improvements may have resulted from improvements in PA but additional mediation analyses are necessary to confirm this.

The OncoActive intervention is assumed to be a relatively low-cost intervention, as it is low in demand for personnel costs and does not require a physical location as is the case in structured exercise programs. Therefore, it would be highly relevant to assess the cost-effectiveness of the intervention. As reimbursed cancer rehabilitation in the

Netherlands currently is facility-based, information regarding cost-effectiveness is also relevant for further nationwide implementation and adoption. As discussed previously (see strengths and limitations), a stepped-care or blended approach is also a possibility for further implementation of the OncoActive intervention. Accordingly, additional research is necessary to identify what type of interventions (e.g., web-based, supervised, blended, etc.) works best for whom (Buffart et al., 2014; Buffart et al., 2018) and which healthcare professionals are most suitable to refer CPS to the intervention and eventually guide them.

Besides future directions for research regarding PA and cancer, this thesis also provided some suggestions for additional research regarding intervention use, delivery mode and PA measurement. As already mention previously, measurement of intervention use by self-reports is a limitation of the studies described in **chapter 4**. In order to gain more insights in actual use of web-based materials, the use of objective log data is recommended in future studies.

With advances in technology and the increasing familiarity of older adults with internet it is likely that eHealth intervention will be increasingly used in the future to keep healthcare affordable (Krijgsman et al., 2016). As vulnerable sub-groups (see **chapter 4**) may have lower eHealth literacy (Choi & Dinitto, 2013; Latulippe et al., 2017; Neter & Brainin, 2012) and thus be excluded when using only web-based materials, additional research is necessary to improve eHealth literacy of these subgroups. As print-based materials were used extensively among all participants, additional research should also provide insights into why there are preferences for print-based materials and examine cost-effectiveness of interventions in relation to delivery mode.

As discussed in **chapter 2**, to the best of our knowledge research regarding responsiveness of self-report questionnaires is limited and correlation and agreement between the SQUASH and ActiGraph to assess change in PA were only moderate. Therefore, additional research regarding responsiveness is warranted. As self-report PA was substantially higher than accelerometer-measured PA and currently PA guidelines and recommendations are established from evidence predominantly based on self-reports, additional large scale studies are necessary to examine if even small amounts of additional PA may improve health in cancer populations (Smith et al., 2019; Vassbakk-Brovold et al., 2016; Warburton & Bredin, 2017).

IMPLICATIONS FOR INTERVENTION ADAPTATION

In light of the promising outcomes of the OncoActive intervention, we provide some implications for adapting the intervention. Moderation analyses showed that the intervention was not effective in some subgroups. At short-term follow-up the intervention was predominantly effective in colorectal CPS, therefore it is recommendable to explore opportunities to further improve the short-term effects for prostate CPS. In addition, intervention efficacy was also moderated by educational level, sex and age (**chapter 5 and 6**). Therefore, it may be important to examine how intervention efficacy can be improved for subgroups that did reported limited of no effects. A possibility could be to critically review the textual information of the intervention again and make it easier to read. Especially since studies have shown that recall of information is best with easy texts and that written materials designed for those with a low health literacy may also be useful for a general audience (Meppelink, Smit, Buurman, & van Weert, 2015; Oliffe et al., 2019). Another option could be to enhance textual information with pictograms, illustrations, or interactive media like animations, video or audio. Several studies have shown that such features may improve information recall, satisfaction and health outcomes in older adults with and without cancer, and in people with low health literacy or a low socioeconomic status (Bol et al., 2015; Kim & Xie, 2017; Meppelink, van Weert, Haven, & Smit, 2015; Oliffe et al., 2019). Besides improving the intervention for the general population, from a 'design for all' perspective, applying such methods may also increase the accessibility of OncoActive for people with disabilities (e.g., poor visibility, intellectual disability, etc.) (Oogvereniging, Ieder(in), PGOsupport, MIND Landelijk platformf psychische gezondheid, & Patiëntenfederatie Nederland, 2019). Finally, as smartphones and tablets are important tools for people with a low socio-economic status, apps are increasingly used to access internet services. Optimizing OncoActive for mobile devices or developing an app may be important (Kim & Xie, 2017).

The content of OncoActive is based on the Dutch Cancer Rehabilitation guideline, which states that it is recommended that CPS are as physically active as possible and preferably adhere to PA guidelines for the general population (Comprehensive Cancer Center of the Netherlands (IKNL), 2011). Yet, recently, Dutch PA guidelines were adapted to be more in line with international guidelines. Major differences with the old guidelines include the fact that it is no longer required to be physically active on at least five days, the addition of bone and muscle strengthening exercises and the recommendation to avoid sedentary behavior (Weggemans et al., 2018). As a result, small adaptations may be required to update the OncoActive intervention for future implementation, although statements regarding strengthening exercise and sedentary behavior were already included (to some extent) in the current version of the intervention (see **chapter 3**).

Additional analyses revealed that especially the pedometer and exercises were highly used (Bolman et al., 2019). Both are very practical applications for increasing PA and thus it may be important to provide such options to bridge the intention-behavior gap. Several studies have also shown that pedometers (if used in addition with PA goals) are very useful to improve PA (Knols et al., 2010; Vallance et al., 2008). With advances in technology, pedometers could possibly be replaced by wearables like activity trackers and smartphone apps. Kenfield et al. (2019) showed that using a Fitbit activity tracker in an intervention for prostate CPS was feasible. A qualitative study among breast, prostate and colorectal cancer survivors showed that they were receptive to use publicly available PA apps, but recommended them to be integrated in cancer care, as they valued recommendations from healthcare professionals (Roberts, Potts, Koutoukidis, Smith, & Fisher, 2019). However, additional research should point out whether wearables and apps are effective substitutes for the pedometer within the OncoActive intervention.

Finally, as already addressed before, the OncoActive intervention could also be extended to include cancer types other than prostate and colorectal cancer. As OncoActive has shown to be beneficial for prostate and colorectal CPS, it may possible also provide benefits for other cancer types. Yet, additional research should proof this.

IMPLICATIONS FOR FUTURE IMPLEMENTATION

Since OncoActive was able to improve PA and health-related outcomes, some suggestions for future implementation in practice are provided. Currently, increasing PA and exercise is part of supervised oncological rehabilitation (Comprehensive Cancer Center of the Netherlands (IKNL), 2011). Although such intensive interventions are likely to be more effective in improving health-related outcomes than lower-intensity home-based programs (van Waart et al., 2015), they often do not result in improvement of PA after the end of the program (Kampshoff et al., 2015; van Waart et al., 2015) and not every patient is able and willing to participate in such demanding programs. International studies also showed that there is a substantial decline in PA after ending supervised oncology rehabilitation (Cheifetz, Dorsay, & MacDermid, 2015; Haas, Kimmel, Hermanns, & Deal, 2012). Technology-based interventions could improve maintenance after ending a supervised program (Gell, Grover, Humble, Sexton, & Dittus, 2017). Additionally, research showed that PA adoption after a supervised program in CPS is associated with higher processes of behavioral change and self-efficacy (Loprinzi, Cardinal, Si, Bennett, & Winters-Stone, 2012) Thus, as OncoActive is aimed at behavior change and addresses self-efficacy, the intervention could be very useful to improve PA after a supervised program. In addition, it is noteworthy that during this project we were contacted by some rehabilitation departments that would like to add an intervention like OncoActive to their supervised program, in order to obtain lifestyle changes. Staff from these departments acknowledged that although a supervised exercise program definitely has positive health effects, often time is too short to establish sustained health behavior changes. Although OncoActive can be offered to prostate and colorectal CPS on a stand-alone base or integrated into a stepped-care approach, it is also possible to combine OncoActive with an existing supervised PA program to improve PA maintenance.

In addition to the studies discussed in this thesis, we conducted a small scale survey study among physiotherapists and oncology nurses (n=57) regarding conditions for implementation of the OncoActive intervention (Van der Molen, Bolman, & Golsteijn, 2018). Intentions to recommend the OncoActive intervention to patients was high: 3.89 (on a scale of 1 to 5) and oncology nurses were of the opinion that OncoActive can be offered to patients without guidance of healthcare professionals. Physiotherapists acknowledge the relevance of the program, but preferred the additional involvement of a healthcare professional such as a physiotherapist (Van der Molen et al., 2018), which may be related to the fact that offering rehabilitation is their primary business. As mentioned above, both options are possible and may have their pros and cons and are relevant for further exploration.

Increasingly it has been argued that PA promotion should be part of routine cancer care (Cormie et al., 2018) and patients prefer oncologist to be involved as they perceive them as an authority (Hardcastle & Cohen, 2017; Wong et al., 2018). However, oncologists do not have in-depth knowledge of PA and exercise, have limited time to discuss topics with patients and do not now all pathways to guide patients in the right direction (Haussmann, Gabrian, et al., 2018; Haussmann, Ungar, et al., 2018; Nadler et al., 2017; Newton, Taaffe, Chambers, Spry, & Galvao, 2018). As a result, only few clinicians provide their patients with advice to promote PA (Nyrop et al., 2016).

Therefore, the OncoActive intervention provides a promising opportunity to increase PA referral by oncologists. The intervention can easily be referred to by healthcare providers. The intervention content then provides participants with the in-depth information regarding PA, that care providers may be lacking. As we demonstrated the efficacy of the intervention, OncoActive can thus be an easy-accessible option to improve cancer recovery and sustain behavior change in prostate and colorectal CPS that meets patients' preferences. In the future, the intervention can possibly extended to other cancer types.

GENERAL CONCLUSION

The studies described in this thesis showed that the OncoActive intervention was able to significantly improve PA and health-related outcomes in prostate and colorectal CPS. Using a systematic method to develop OncoActive was useful to provide a solid theoretical base for the intervention and may have contributed to its efficacy. By providing OncoActive through web-based and print materials, participation in the intervention was also possible for subgroups such as older aged or lower educated CPS, or CPS who are more fatigued or who are longer after their treatment. Although the largest effects were observed shortly after the intervention, long-term follow-up showed that intervention group participants were able to maintain their initial improvement in PA. With substantial differences being observed between self-report and objective PA, it is recommended for future studies to include both measures to gain more insights in PA and its associated benefits. Moreover, OncoActive was able to significantly decrease fatigue, a commonly reported side-effect of cancer, up until 12 months after the start of the intervention. Shortly after the end of the intervention, significant improvements were also found for depression and physical functioning, indicating that OncoActive may give prostate and colorectal CPS an earlier start to recovery. It is promising that such positive effects can be obtained with a relatively low-intensity intervention. As OncoActive is easily accessible it has the potential to reach a large population. Therefore, possibilities for large scale implementation should be explored, in order to make OncoActive publicly available and thus expand the population possibly experiencing the beneficial effect.

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SUMMARY

Cancer is a major health problem and burden to society in developed countries and incidence is expected to increase due to aging and a growing population. Prostate cancer is the most commonly diagnosed cancer in males in the Netherlands in 2018. Colorectal cancer ranks third both for males and females. Fortunately, mortality decreases as a result of advances in early detection and treatment. Increasing incidence and declining mortality results in a growing population of cancer survivors. The increasing population living after cancer imposes a significant burden on society, as cancer and cancer treatment are associated with both acute and chronic physical, psychological and psychosocial problems. Physical activity (PA) is suggested to positively influence the problems associated with cancer and cancer treatment and thereby to improve health and health-related quality of life (HRQoL) of prostate and colorectal cancer patients and survivors (CPS). Yet, the majority of CPS does not adhere to PA guidelines. Improving PA in this population is therefore of major importance. As a cancer diagnosis is regarded as a 'teachable moment' for behavior change this period provides an important opportunity to promote a healthy lifestyle including improving PA. In light of the rapidly growing population living with or after cancer there is a clear need for affordable PA programs that are easily accessible. In addition, a tailored approach is suggested to provide the highest effects. Using the internet to provide a computer-tailored program may therefore be useful to improve PA.

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The aim of this thesis was to develop and evaluate a computer-tailored PA program to increase PA in prostate and colorectal CPS, called OncoActive. This intervention was systematically developed and adapted from an existing similar intervention targeting older adults. The intervention was provided to participants through web-based and print-based materials and included a pedometer for goal-setting and monitoring purposes. The current thesis describes the systematic development of OncoActive and evaluates characteristics of use and efficacy regarding PA and health-related outcomes. In addition, PA measurement in prostate and colorectal CPS is examined.

Chapter 1 provides the background and rationale for promoting PA in prostate and colorectal CPS through a computer-tailored intervention. The beneficial effects of PA on cancer and treatment-related side effects and guideline adherence are considered. As PA is complex behavior, issues regarding measurement of PA are discussed. Determinants of PA and methods and possibilities to improve PA in the target population through computer-tailoring are examined. The evidence-based Active Plus intervention for older adults provided a useful starting point for the development of an intervention for prostate and colorectal CPS.

Chapter 2 is aimed at comparing PA according to a self-report questionnaire to assess PA to accelerometer-measured PA, both for cross-sectional measurements as for the ability to detect change over time. The results show that both measures show reasonable correlations and agreement, but that absolute amounts of PA are substantially higher for self-report compared to objective measures. Correlation and agreement are slightly higher for the number of days with at least 30 minutes PA per week compared to moderate-to-vigorous PA (MVPA). At the individual level agreement between both measures for classification of PA change was limited, but at group level correlation and agreement for PA change were reasonable, particularly when pre and post measurements concern the exact same week. The results indicated that it would be relevant to combine accelerometry and self-report measures.

Chapter 3 describes the systematic development of OncoActive by using the Intervention Mapping protocol to translate an evidence-based intervention for older adults to a new target population (i.e., prostate and colorectal CPS). OncoActive is a computer-tailored intervention aimed at increasing awareness, initiation, and maintenance of PA. Participants in the intervention group receive computer-tailored PA advice at three time points (at baseline, after 2 months and after 3 months) both online on a secured website and on paper (by mail). The content of the advice is structured in line with several behavior change theories and tailored to demographic, cancer-related, psychosocial and motivational factors, as well as the current PA behavior. The intervention targets pre-motivational constructs (e.g., awareness, knowledge), motivational constructs (e.g., self-efficacy, attitude, intrinsic motivation), and post-motivational constructs (e.g., goal setting, action and coping planning, self-regulation). In addition to the tailored advice, every participant receives a pedometer and access to interactive content on the website (e.g., role model videos, home exercise instruction videos, a module for goal setting using a pedometer, the option to consult a physical therapist and additional information). This chapter also describes the outline of the randomized controlled trial (RCT) conducted to evaluate the OncoActive intervention.

Chapter 4 aims to identify factors that are associated with using web-based and printed intervention materials. It is investigated whether demographic, cancer-related, PA-related or health-related factors are related to the initial choice for the intervention (i.e., web or print) and during the remainder of the intervention (i.e., only using print materials or using a combination of web- and print-based materials). A higher age, longer time since treatment completion and higher fatigue are associated with a lower likelihood of web-based participation, whereas a higher education and having completed treatments were associated with a higher likelihood of web-based participation. Those who initially chose to start the intervention web-based, used a combination of web- and print materials, whereas initial print-based participants predominantly used print materials, indicating that the use of printed intervention materials was substantial. Therefore, it seems important to offer Web- and print-based materials alongside each other. Providing Web-based materials only may exclude vulnerable groups that could benefit from PA interventions.

Chapter 5 presents the short-term efficacy of the OncoActive intervention. Efficacy regarding several PA and health-related outcomes are assessed, during and shortly after the end of the intervention are examined and compared to the control group. Three months after baseline OncoActive participants significantly increased their self-reported PA, physical functioning and fatigue. Six months after baseline, self-reported and ActiGraph PA increased significantly. Furthermore, OncoActive participants reported significantly improvements in physical functioning, fatigue, and depression. No significant differences were found for anxiety and overall HRQoL. Subgroup analyses showed higher increases in PA for colorectal cancer participants at 3 months (self-report MVPA), and for medium and highly educated participants' PA at 6 months (ActiGraph MVPA). Health outcomes at 6 months were more prominent in colorectal CPS and in women. It is concluded that the intervention provides opportunities to accelerate cancer recovery, but long-term follow-up should examine whether effects are sustained.

Sustainability of effects is thus examined in **chapter 6**. The results show that differences between both groups remained for self-report days with at least 30 minutes PA, but not for other PA outcomes. Nevertheless, short-term effects regarding PA in the OncoActive group did not decrease significantly between 6- and 12-month follow-up, indicating that efficacy was maintained. In addition, within the OncoActive condition, PA increased significantly from baseline to 12-month follow-up. Not finding significant differences compared to the control group may have been due to the control group slightly increasing their PA non-significantly. Furthermore, at 12 months, fatigue was still significantly lower in OncoActive, but no significant differences were found for depression and physical functioning.

Chapter 7 provides a discussion and overview of the main findings from this thesis. In addition, strengths and limitations and implications for future research, intervention adaptation and implementation are discussed. Important strengths and limitations regarding the intervention, study design, study population and measures are discussed. For future research it is recommended to further explore the role of cancer variables on PA and the role of PA on cancer outcomes. Additional analysis of collected data or future long-term follow-up data could provide important additional new insights. In addition, it is recommended to further explore the working mechanisms of the intervention and cost-effectiveness. For adaptation of the intervention it is suggested that opportunities to increase efficacy (especially for certain subgroups) and the use of apps or wearables should be further explored. In addition, new PA guidelines should be implemented and adaptations can be made to make the intervention available to other cancer types. There are several opportunities to implement OncoActive in practice that should be further explored.

In conclusion, this thesis showed that the systematically developed OncoActive intervention was able to improve PA and health-related outcomes such as fatigue in prostate and colorectal CPS. OncoActive may give prostate and colorectal CPS an earlier start to recovery and also improves their PA behavior. As OncoActive is an easy-accessible and low-demanding intervention, possibilities for large scale implementation are explored. The findings from this thesis support the relevance of OncoActive and thereby provides arguments to make OncoActive publicly available and thus expand the population possibly experiencing the beneficial effects.

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SAMENVATTING

Kanker is een belangrijk gezondheidsprobleem en heeft een grote impact op de samenleving. Naar verwachting neemt het aantal nieuwe gevallen de komende jaren toe door vergrijzing en een groeiende bevolking. Prostaatkanker was de meest voorkomende vorm van kanker onder Nederlandse mannen in 2018 en colorectale kankers zijn voor zowel vrouwen als mannen de derde meest voorkomende vorm van kanker. Kankersterfte neemt gelukkig steeds verder af door ontwikkelingen op het gebied van vroege opsporing en behandeling. Door de toenemende incidentie en de afnemende sterfte wordt de populatie die leeft met de gevolgen van kanker steeds groter. Omdat kanker en de bijbehorende behandelingen vaak gepaard gaan met acute en chronische gezondheidsproblemen op fysiek, psychologisch en psychosociaal gebied, neemt de impact op de samenleving toe. Fysieke activiteit heeft een positief effect op deze gezondheidsproblemen en kan daarmee de gezondheidsgerelateerde kwaliteit van leven van prostaat- en darmkankerpatiënten verbeteren. Desondanks beweegt de meerderheid van de prostaat- en darmkanker patiënten onvoldoende. Het is daarom van groot belang dat deze groep gestimuleerd wordt meer te gaan bewegen. Een kankerdiagnose wordt vaak gezien als een 'teachable moment' en biedt daarom mogelijkheden een gezonde en actieve leefstijl te bevorderen. Mede gezien de groeiende populatie is het van belang dat beweeginterventies betaalbaar en voor de doelgroep eenvoudig toegankelijk zijn. Daarnaast lijkt een 'op-maat' aanpak het meest effectief en kansrijk. Een 'computer-tailored' programma dat via het internet wordt aangeboden heeft daarom een goede potentie om fysieke activiteit te bevorderen.

Het ontwikkelen en evalueren van een 'computer-tailored' programma om fysieke activiteit bij prostaat- en darmkankerpatiënten te bevorderen was het belangrijkste doel van dit proefschrift. Deze OncoActief interventie werd systematisch ontwikkeld door een effectieve interventie voor 50-plussers aan te passen voor de nieuwe doelgroep. De interventiematerialen waren beschikbaar in een papieren vorm en op een website. OncoActief deelnemers ontvingen bovendien een stappenteller om doelen te kunnen stellen en hun eigen fysieke activiteit te monitoren. Dit proefschrift beschrijft de systematische ontwikkeling van OncoActief en evalueert karakteristieken van gebruikers en effecten op het gebied van fysieke activiteit en gezondheidsgerelateerde uitkomsten. Daarnaast is ook onderzocht hoe fysieke activiteit in prostaat- en darmkankerpatiënten het beste gemeten kan worden.

Hoofdstuk 1 beschrijft de achtergrond en de reden voor het bevorderen van fysieke activiteit in prostaat- en darmkankerpatiënten door middel van een 'computer-tailored' interventie. Het hoofdstuk beschrijft de positieve effecten van fysieke activiteit op gezondheidsproblemen ten gevolge van kanker en de bijbehorende behandeling. Ook is beschreven in hoeverre kankerpatiënten aan de beweegrichtlijnen voldoen en wat problemen zijn rond het meten van een complex gedrag als fysieke activiteit. Verder geeft het hoofdstuk een overzicht van determinanten van fysieke activiteit in prostaat- en darmkankerpatiënten en de mogelijkheden om fysieke activiteit te bevorderen door 'computer-tailoring'. De evidence-based Actief Plus interventie voor 50-plussers bleek een goed uitgangspunt te zijn voor de ontwikkeling van een interventie voor prostaat- en darmkankerpatiënten.

Hoofdstuk 2 vergelijkt fysieke activiteit gemeten door een zelf-rapportage vragenlijst en fysieke activiteit gemeten met een beweegmeter. Zowel cross-sectionele metingen als veranderingen in beweeggedrag over de tijd zijn vergeleken. De resultaten lieten redelijke correlaties en overeenstemming tussen beide meetmethoden zien. Het absolute aantal zelf-gerapporteerde minuten matig-tot-intensieve fysieke activiteit (moderate-to-vigorous PA; MVPA) was echter veel hoger in vergelijking met het aantal minuten objectief gemeten beweeggedrag. Correlatie en overeenstemming waren iets sterker voor het aantal dagen waarop men ten minste 30 minuten matig intensief bewoog in vergelijking met minuten MVPA. Overeenstemming tussen beide maten was beperkt wanneer op individueel niveau gekeken werd naar deelnemers die geclassificeerd werden als personen die meer gingen bewegen en personen die niet meer gingen bewegen. Op groepsniveau werden wel redelijke correlatie en overeenstemming gevonden voor veranderingen in beweeggedrag. Dit was met name het geval wanneer zelfrapportage en objectieve metingen voor zowel de voor- als de nameting exact dezelfde week betroffen. De resultaten tonen aan dat het belangrijk is om zelf-rapportage instrumenten te combineren met objectieve metingen.

Hoofdstuk 3 beschrijft de systematische ontwikkeling van OncoActief, waarbij een evidence-based interventie voor 50-plussers is aangepast aan de nieuwe doelgroep (prostaat- en darmkanker-patiënten) met behulp van het Intervention Mapping protocol. OncoActief is een 'computer-tailored' interventie met als doel deelnemers bewust te maken van het eigen beweeggedrag, te stimuleren meer te gaan bewegen en dit bewegen vol te blijven houden. Deelnemers ontvangen drie keer een advies-op-maat: bij de start, 2 maanden na de start en 3 maanden na de start. Adviezen zijn beschikbaar op papier (per post) en online via een beveiligde website. De inhoud van deze adviezen is gebaseerd op diverse gedragsveranderingstheorieën en sluit aan bij het huidig beweeggedrag en demografische, kanker-gerelateerde, psychosociale en motivationele kenmerken van de deelnemer. De interventie richt zich op pre-motivationele concepten (bijv. bewustzijn, kennis), motivationele concepten (bijv. eigeneffectiviteit, attitude, intrinsieke motivatie) en post-motivationele concepten (bijv. doelen stellen, actie- en coping plannen, zelfregulatie). Naast het advies-op-maat krijgt elke deelnemer ook een stappenteller en toegang tot interactieve informatie op de website (bijv. video's met rolmodellen, video's met thuis-oefeningen, een module om stappen-doelen te stellen, de optie om een vraag te stellen aan een fysiotherapeut en extra informatie). Dit hoofdstuk beschrijft ook de opzet van het gerandomiseerde onderzoek dat werd uitgevoerd om de OncoActief interventie te evalueren.

Hoofdstuk 4 beschrijft factoren die geassocieerd zijn met het gebruik van schriftelijke en online interventie materialen uit OncoActief. De relatie van demografische, kanker-gerelateerde, fysieke activiteit gerelateerde en gezondheidsgerelateerde variabelen met de initiële keuze voor online of schriftelijk deelname aan de interventie is onderzocht. Daarnaast is ook gekeken naar de relatie van deze karakteristieken met het verdere gebruik van de interventie (i.e., worden alleen schriftelijke materialen gebruikt of een combinatie van schriftelijke en online materialen?). Een hoge leeftijd, langere tijd na afronding van de behandeling en meer vermoeidheid waren geassocieerd met een lagere waarschijnlijkheid voor initiële online deelname, terwijl een hoog opleidingsniveau en het afgerond hebben van de behandeling juist geassocieerd waren met een hogere waarschijnlijkheid om online deel te nemen. Deelnemers die in eerste instantie online participeerden, gebruikten tijdens het verdere verloop van de interventie veelal een combinatie van schriftelijke en online materialen. Degenen die in eerste instantie schriftelijk participeerden bleven ook tijdens het verdere verloop voornamelijk de schriftelijke materialen gebruiken. Dit impliceert dat schriftelijke materialen substantieel gebruikt worden en dat het belangrijk kan zijn online en schriftelijke interventiematerialen naast elkaar aan te bieden. Alleen online aanbieden van materialen kan leiden tot uitsluiting van kwetsbare groepen die juist baat kunnen hebben bij een beweeginterventie.

Hoofdstuk 5 beschrijft de effecten van OncoActief op de korte termijn. De effecten met betrekking tot diverse fysieke activiteit- en gezondheidsuitkomsten zijn onderzocht en vergeleken met de controlegroep, gedurende en kort na afloop van de interventie. Drie maanden na de start van OncoActief verbeterden de zelf gerapporteerde fysieke activiteit, het fysiek functioneren en vermoeidheid van deelnemers aan de interventie. Zes maanden na de start verbeterden zowel zelf gerapporteerde als objectief gemeten fysieke activiteit, fysiek functioneren, vermoeidheid en depressie. Voor angst en gezondheidsgerelateerde kwaliteit van

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leven werden geen significante verschillen gevonden tussen de interventiegroep en de controlegroep. Analyses in subgroepen lieten grotere toenames in fysieke activiteit zien voor darmkankerpatiënten na 3 maanden (zelfrapportage MVPA) en voor midden- en hoogopgeleide deelnemers op 6 maanden (ActiGraph MVPA). Gezondheidsgerelateerde effecten werden voornamelijk gevonden voor darmkankerpatiënten en vrouwen. OncoActief biedt mogelijkheden om het herstel na kanker te bevorderen, maar onderzoek met een langere follow-up moet aantonen of de effecten worden behouden.

Behoud van effecten is onderzocht in **hoofdstuk 6**. De resultaten lieten zien dat verschillen in het voordeel van de interventiegroep ten opzichte van de controlegroep bleven bestaan voor het aantal zelf gerapporteerde dagen per week met minimaal 30 minuten matig intensieve fysieke activiteit, maar niet voor de andere beweegmaten (i.e., zelf gerapporteerde MVPA, ActiGraph MPVA en dagen met fysieke activiteit gemeten met de ActiGraph). Toch toonden de analyses ook aan dat de toename van fysieke activiteit op de korte termijn niet significant afnam tussen 6 en 12 maanden follow-up en dat de interventiegroep dus in staat was om het veranderde gedrag vol te houden. Bovendien was binnen de interventiegroep het beweeggedrag na 12 maanden significant hoger dan bij de start. Mogelijk werden er geen significante verschillen met de controlegroep gevonden omdat de controle groep ook iets meer ging bewegen (echter niet significant) gedurende het onderzoek. Met betrekking tot de gezondheidsgerelateerde effecten werd na 12 maanden wel een significant lagere vermoeidheid gevonden voor de OncoActief groep in vergelijking met de controlegroep. Er werden geen significante verschillen gevonden in depressieve klachten en fysiek functioneren.

Hoofstuk 7 geeft een overzicht en discussie van de belangrijkste bevindingen van dit proefschrift en de sterke en zwakke punten van het onderzoek. Daarnaast beschrijft dit hoofdstuk implicaties voor verder onderzoek, interventieaanpassing en implementatie. Sterke punten en beperkingen van de interventie zelf, de onderzoeksopzet, de studiepopulatie en de meetinstrumenten worden besproken. Voor vervolgonderzoek kunnen aanvullende analyses van de verzamelde data of toekomstige metingen met een langere follow-up nieuwe inzichten geven in de rol van kanker-gerelateerde variabelen op fysieke activiteit en de rol van fysieke activiteit op kanker uitkomsten. Verdere aanbevelingen betreffende onderzoek naar de werkingsmechanismen van de OncoActief interventie. Ook een studie naar de kosteneffectiviteit wordt aanbevolen. Aanbevelingen voor de verdere ontwikkeling van de interventie omvatten de verkenning van mogelijkheden om de effectiviteit in bepaalde subgroepen te verbeteren en hoe apps of wearables gebruikt kunnen worden in de interventie. Daarnaast dient de interventie aangepast te worden naar de nieuwe beweegrichtlijnen en eventueel zou de interventie aangepast kunnen worden naar andere vormen van kanker. Er zijn verschillende mogelijkheden om OncoActief te implementeren in de praktijk die verder verkend moeten worden.

Concluderend laat dit proefschrift zien dat de systematisch ontwikkelde OncoActief interventie in staat is om fysieke activiteit te bevorderen en gezondheidsgerelateerde effecten, zoals een vermindering van vermoeidheid, te bewerkstelligen bij prostaat- en darmkankerpatiënten. OncoActief kan deze groep dus een sneller herstel bieden en het beweeggedrag stimuleren. Omdat OncoActief een gemakkelijk toegankelijke en laagdrempelige interventie is, worden de mogelijkheden voor grootschalige implementatie onderzocht. De resultaten onderbouwen de relevantie van OncoActief en geven voldoende redenen om OncoActief publiek toegankelijk te maken, zodat de doelgroep kan profiteren van de positieve effecten.

D

DANKWOORD

"Nobody said it was easy" *The Scientist – Coldplay*

En makkelijk was het ook niet altijd, daarom wil ik iedereen hartelijk bedanken voor de bijdrage en/of support die ervoor gezorgd hebben dat ik nu het laatste hoofdstuk van dit proefschrift kan schrijven. Een aantal mensen wil ik in het bijzonder bedanken.

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ABOUT THE AUTHOR

Rianne Golsteijn was born on February 26th, 1986 in Geleen, The Netherlands. She graduated from secondary school (VWO) in 2004 at the Bisschoppelijk College in Echt and subsequently obtained a Bachelor's degree in General Health Sciences in 2007. In 2008, she completed her Master's degree in Physical Activity and Health with an internship at the Netherlands organization for applied scientific research (TNO). In the same year she started with a second Master's degree in Public Health with a specialization in Health Economics, Policy and Management, from which she graduated in 2010. In addition to this degree, she followed courses on Trial-based Economic Evaluations and Intervention Mapping.

With the ability to combine her interest in physical activity and economic evaluations, Rianne started working as a research assistant at the Open University from January 2010. First on the Active Plus project (a computer-tailored physical activity intervention for adults aged over fifty) and later on also for a short period on the Cancer Aftercare Guide (an online computer-tailored intervention for cancer survivors). In June 2013, Rianne started her own PhD research at the Open University under the supervision of Prof. Dr. Lilian Lechner, Prof. Dr. Catherine Bolman and Prof. Dr. Hein de Vries. During this project she systematically developed and evaluated a computer-tailored physical activity intervention for prostate and colorectal cancer patients and survivors. The studies that resulted from the project were published in various international journals and presented at national and international conferences. During one year of her PhD, Rianne also worked part-time as a teacher for the department of methodology and statistics at the faculty of Psychology and Educational Sciences of the Open University.

From 2017 to 2018, Rianne worked as a researcher at the center of expertise for Innovation in Healthcare at PXL University of Applied Sciences and Arts in Hasselt, Belgium. Currently, Rianne works as an assistant professor for the departments of health psychology and methodology and statistics at the Open University.

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