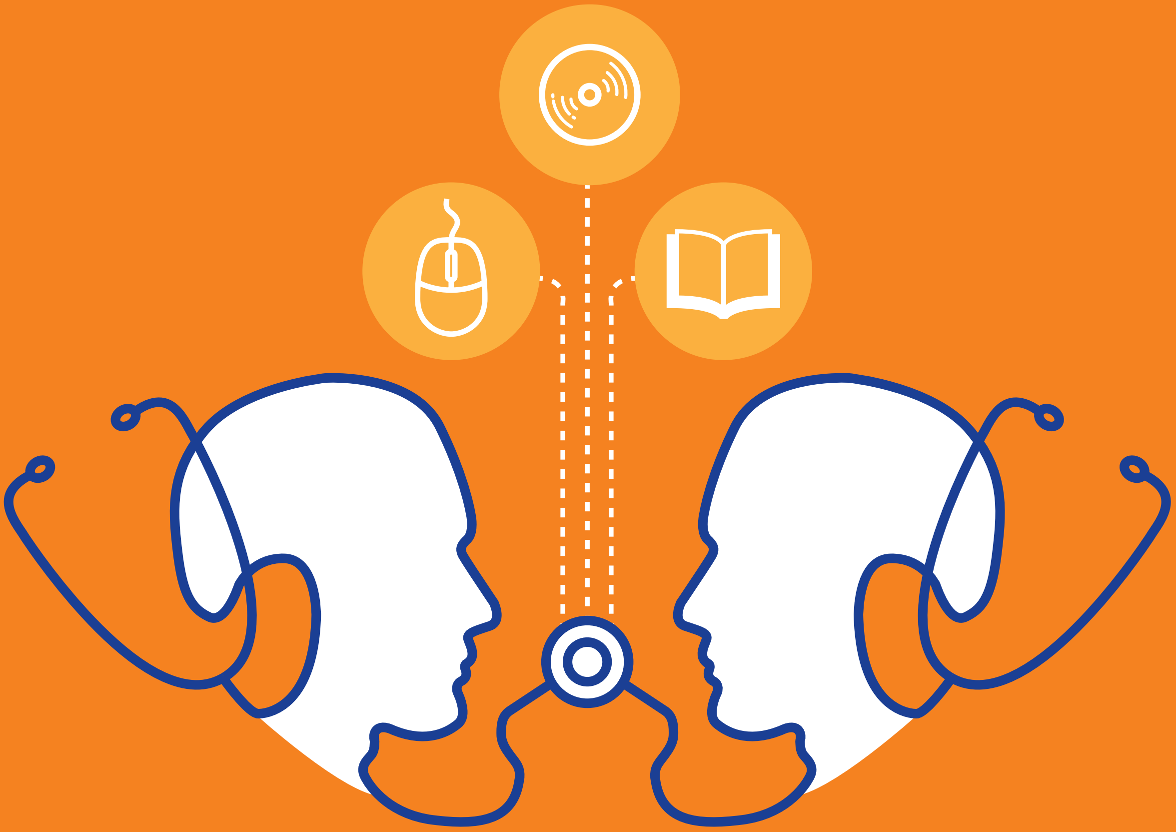
SELF-MANAGEMENT SUPPORTING REHABILITATION IN HEAD AND NECK CANCER PATIENTS



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VRIJE UNIVERSITEIT

SELF-MANAGEMENT SUPPORTING REHABILITATION IN HEAD AND NECK CANCER PATIENTS

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CONTENTS

1

GENERAL INTRODUCTION

Head and neck cancer (HNC) and its treatment often leads to acute and long-term consequences, affecting the patient's appearance and physical functions such as eating, speaking, and breathing [1]. These consequences can be monitored in an oncologic setting via patient reported outcome measures (PROMs) [2-11] and, if needed, patients can be referred to rehabilitation services including self-management interventions [12-14]. Patient engagement through self-management is widely recognized as crucial to improve health outcomes for people with a chronic condition [15-18]. Compared with the wealth of evidence for self-management interventions in other chronic diseases, this information in cancer patients is limited [19-25]. Self-management interventions in HNC patients are especially scarce [26]. We set out to investigate the usefulness of monitoring symptoms and quality of life in clinical practice, to evaluate the development, usability and feasibility of self-management interventions supporting rehabilitation in HNC patients, and to acquire insight into the factors influencing the usefulness of these interventions.

EPIDEMIOLOGY AND SYMPTOMS OF HEAD AND NECK CANCER

HNC is the sixth most common site of cancer for men and the eighth for women [27] with nearly 600,000 new cases and 300,000 deaths occurring globally each year [28,29]. In Europe, HNC accounts for an estimated 140,000 new cases [30]. In the Netherlands approximately 3000 patients with HNC are diagnosed each year [31,32]. HNC mainly originates in the oral cavity, oropharynx, hypopharynx, and the larynx. Approximately 85% of HNC tumors is of squamous cell histology. Five-year survival rates range from 30% among patients with a tumor originating in the hypopharynx, 50% in the oropharynx, 60% in the oral cavity [33], and to 69–88% in the larynx [34-36].

HNC is etiologically linked by common exposure to tobacco products and excessive alcohol consumption. Human papillomavirus (HPV) infections play an increasing role in the etiology of HNC, particularly of the oropharynx [37]. The incidence of HNC increases with age, with most patients presenting in their sixth through eighth decade of life, although patients with HPV-associated cancer tend to be younger [33,38,39].

Functionally, the head and neck region supports many fundamental physiologic processes including mastication, deglutition, respiration, and articulation. Tumors often significantly impact on these functions through their involvement of vital structures and treatment related sequelae [40].

TREATMENT

A major challenge in treating cancer is obtaining a high cure rate while preserving vital structures and function. This is especially true for cancers in the anatomically complex region of the head and neck, where important structures and functions are affected by both the cancer and its treatment [41-47]. Early stages (I and II) are generally well treated with single modality (surgery or radiation therapy), whereas the more advanced stages (III and IV) require combined modality treatment, including surgery with postoperative (chemo)radiation ((C)RT) or chemoradiation

(CRT) with surgical salvage if needed [48,49]. With the improvement in HNC detection and intensive multimodality treatments, treatment-related acute and late consequences are an emerging problem [42,50]. These consequences affect critical human functions such as breathing, speech, and the ability to swallow, and psychosocial aspects of the patients' life [51,52].

Surgical treatment

Many patients diagnosed with HNC undergo surgery which may affect one or more functions, and compromises the ability to eat, speak, and swallow, depending on the site and stage of the tumor and the type of surgery required [53,54]. Surgical resection of cancers in the oral cavity can negatively impact speech, mastication, and swallowing [55]. Major surgical treatment for oral or oropharyngeal cancer and microvascular soft tissue reconstruction can result in impaired swallowing [56], and a worse overall speech quality [57]. Surgical resection of pharyngeal and laryngeal tumors can have a negative effect on speech and swallowing, and can compromise the airway [48]. A total laryngectomy results in voice loss, and loss of smell, which decreases the sense of taste. The patient will encounter numerous other issues such as potential oral and airway dryness, communication challenges, changes in activities of daily living (showering/bathing routines), and changes to social and outdoor recreational activities (e.g., swimming, boating) [48]. Removal of lymph nodes in the neck (neck dissection) is associated with significant adverse effects related to appearance and function. Speech and swallowing dysfunctions can occur when the vagus and/or hypoglossal nerves are sacrificed [48,58]. Cosmetic alterations in the contour of the neck, limited range of motions of the shoulder, acute and chronic (neck and/or shoulder) pain, shoulder droop, deteriorated lateral flexion of the neck, and atrophy of the trapezius muscle along with shoulder fixation can occur [48,59-61].

Radiation treatment

Radiotherapy (RT) may cause acute and late toxicities that affect various organs and functions. Common acute toxic effects associated with RT are odynophagia (painful swallowing), dysphagia, muscle weakness, increased secretions, loss of taste, and hoarseness caused by laryngeal edema [54,62-64]. Significant late radiation-induced toxicities include fibrosis (scar tissue), and dysphagia [65]. Fibrosis manifests clinically as a reduction in tissue elasticity and flexibility. Depending on the anatomical location, consequences of fibrosis include distortion of tissues, reduction in range of joint movement, and lymphedema [66,67]. The considerable reduction of saliva leads to persistent dryness of mouth, oral discomfort, sore throat, difficulty in speech, taste alteration, and impairment of chewing and swallowing functions which can lead to nutritional depletion and weight loss [68-70]. Intensity modulated radiotherapy (IMRT) enables to spare some of the salivary tissue (usually at least one parotid gland). Swallowing-sparing IMRT (SW-IMRT) enables to reduce the dose to structures related to swallowing, including the pharyngeal constrictor muscles and the larynx [71,72]. SW-IMRT has therefore the potential to reduce acute and late radiation-induced dysphagia [65,68].

Multimodality treatment

For patients with advanced staged disease, the current preference is often a combination of surgery, radiotherapy and/or chemotherapy [73]. CRT is commonly used as the primary treatment for locally advanced HNC or as adjuvant therapy for tumors with poor clinical features [1]. Although intensive treatment regimens, altered fractionation schedules, and CRT can improve tumor control and patients' survival, they also lead to toxicity (e.g., mucositis, tinnitus, neuropathy, or dysphagia) [63,74,75]. Previous studies showed an increased symptom burden if chemotherapy is added to the treatment [76,77].

HEALTH RELATED QUALITY OF LIFE

With the increased use of aggressive combined modality regimens as primary therapy, HNC patients suffer from a variety of short, and long-term consequences secondary to their initial therapy that impact health related quality of life (HRQOL) [1,42,70,78]. HRQOL is a broad multi-dimensional concept which encompasses the physical, psychological, and social dimensions of mental and functional well-being. In cancer patients, HRQOL can be compromised due to the effects of the initial tumor and the side effects of treatment [79,80]. Given the high rates of acute and late posttreatment side effects in HNC patients, a self-oriented HRQOL evaluation can be a useful aid helping to identify and prioritize preferred outcomes or treatment goals, which otherwise would rely exclusively on endpoint results such as survival and tumor relapse [79-83]. In addition to using conventional pen and paper methods, computer-assisted HRQOL data collection by touch screen technology (e.g., OncoQuest) can be used to self-monitor the consequences of HNC and its treatment, and may improve quality and completeness of data collection [10,11]. Some of the HRQOL domains that are specifically related to HNC are summarized briefly below.

Changes in eating and swallowing

Dysphagia can have a significant impact on HNC patients' everyday lives. A wide range of physical changes to swallowing as well as changes to their emotions, perceptions of food, and to their lifestyles are reported [84]. At the most fundamental level the alterations to oral function often interfere with the kind of food and fluids that can be swallowed. Patients with a restricted mouth opening (trismus) have persistent problems with chewing and eating, dry mouth and lack of taste, all of which result in impaired HRQOL [85]. Numerous patients report that eating requires additional time, which reduces the pleasure of eating. As eating is an essential social activity, eating disorders can result in isolation of the HNC patient and HRQOL impairment [86,87]. RT may induce long-term edema, and fibrosis of several swallowing-related structures causing dysphagia and aspiration, with a significant detrimental effect on HRQOL [70,88-90].

Changes in nutritional status

HNC patients have a high risk of malnutrition secondary to the cancer itself and/or the side effects of treatment. According to a systematic review on the effect of nutritional interventions on nutritional status, HRQOL and mortality in HNC patients of Langius et al [91], 3-52% of the patients are malnourished in the period before the start of (C)RT. During (C)RT this percentage of malnourished patients rises to 44-88% [92,93]. Acute symptoms such as distortion of taste and smell may limit oral intake and lead to weight loss and dehydration during and directly after CRT [94]. Malnutrition and nutritional deficits have a significant negative impact on mortality, morbidity, and HRQOL [95]. HNC patients are in need of nutritional support and tube feeding for a long time period during and after treatment due to insufficient energy intake [96]. The presence of a long-term gastrostomy feeding tube is a very strong predictor of poorer HRQOL [97].

Changes in taste and smell

When taste is altered by HNC treatment, HRQOL is compromised because both nutrition and emotional well-being are affected [98]. Laryngectomy patients are known to suffer from anosmia, as one would expect, given the absence of nasal airflow after the operation. Among HNC patients treated with RT a statistically significant worse taste function was reported post-treatment than among those who did not receive RT [98].

Changes in speech and voice

Changes in speech and voice are most commonly associated with surgical intervention to the oral cavity [57] or larynx [99]. After total laryngectomy HRQOL decreases initially, and some areas recover slowly over the course of the year after surgery, and some remain significantly worse. Areas that do not recover to baseline level are physical functioning, role functioning, social functioning, fatigue, dyspnea, appetite loss, financial difficulties, senses, social contact and speech [74]. Since speech is highly important for social interaction, reduced speech intelligibility in particular may affect patients' HRQOL to a great extent [100,101]. Higher radiation doses to structures in and adjacent to the larynx result in lower HRQOL scores in the speech domains [102].

Changes in shoulder function

Long-term decreased shoulder flexion and abduction is associated with reduced HRQOL in HNC patients. A study of Eickmeyer et al [103] demonstrated that 5-year survivors of HNC reported persistent impairments in shoulder range of motion (ROM), the ability to perform basic activities of daily living (ADLs), and HRQOL in related domains of shoulder disability, recreation, and employment. Reduced ROM and HRQOL were related to the type of neck dissection and not to RT. In other studies in HNC patients significantly worse HRQOL scores have been reported in patients who received neck dissection compared to those without [104,105].

REHABILITATION AND SUPPORTIVE CARE IN HEAD AND NECK CANCER CARE

Prospective studies suggest a need to develop a more comprehensive healthcare system to support HNC patients' needs [106]. Findings indicate that HNC patients need a plan for the future, need help in navigating the healthcare system, and a healthcare system that better overarches the gap between in and outpatient care [107-109]. To enhance cancer rehabilitation (care targeting physiologic and functional impairments caused by cancer and its treatment) [110,111] and supportive cancer care (care provided to minimize symptom burden, and to prevent, control or relieve complications and side-effects) [109,112], self-management interventions could help to promote successful transition care and follow-up care coordination. Self-management interventions may result in physical and psychological benefits, and in some cases reduce patients' dependence on service use [18]. Studies in patients with chronic conditions have shown that comprehensive interactive interventions that augment medical treatments with self-management lead to better health outcomes and improved HRQOL than care that is strictly medically focused [113,114].

Self-management

Self-management is now a common term in health education and is attached to many health promotion and patient education interventions. There is no 'gold standard' definition of self-management. According to the definition of Barlow [114] self-management refers to the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition. In an attempt to give meaning and substance to the term self-management, Lorig and Holman defined self-management support as a dynamic, interactive and daily process, aimed at helping patients to engage in a set of tasks: medical management of the condition (taking medication, or adhering to a special diet) and emotional management (dealing with the emotional consequences of having a chronic condition). There are six core self-management skills: (1) problem solving, (2) decision making, (3) resource utilization, (4) forming of a patient/health care provider partnership, (5) taking action, (6) self-tailoring [115]. Self-management support interventions with specific instructions for self-care may enable patients to maintain their desired level of independence throughout the HNC care journey. However, interventions and strategies used to support self-management targeting HNC patients are scarce, and relatively little information is known about its usefulness in this patient population [12-14,26,116].

eHealth

As Internet use grows, health interventions including self-management components are increasingly being delivered online [117]. eHealth is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies [118,119]. Possible advantages of eHealth include user-centered tailoring, greater ability to monitor patients' use of intervention components by using electronically delivered prompts [120,121], (travel) cost saving benefits for the patient [122], and provision of a platform for interactive information seeking and sharing [123]. Recent research suggests that various interactive web-based interventions for cancer patients and their caregivers can be used to deliver (supplemental) supportive care [120,123-128]. These interventions can be used to remotely monitor and manage cancer symptoms over time [129], to provide coaching, education and information [130], to offer health-related online community support [131], or to provide e-messages and advice for self-management support [132]. Providing eHealth services can lead to people living with chronic illnesses gaining control of their illness, can improve the survivors' health statuses and quality of life, can promote self-care [118,133,], and can reduce their need for supportive care [134]. However, there are few computerized or web-based self-management interventions to improve HRQOL in cancer survivors [22,24,135-137], and even less in HNC care [116,122,138]. Therefore, we developed (eHealth) self-management interventions to support the rehabilitation of HNC patients, guided by a participatory design approach [139-141].

AIM OF THIS THESIS

The main aim of this thesis is to investigate the usefulness in terms of usability, feasibility, uptake, usage, satisfaction of, and adherence to newly developed (eHealth) self-management interventions supporting the rehabilitation among HNC patients. Furthermore, factors are investigated that may influence the usefulness of these self-management interventions, guiding future research on developing (eHealth) self-management interventions aiming to improve HNC patients' HRQOL.

THESIS OUTLINE

The three main (eHealth) self-management interventions in this thesis are (1) 'OncoQuest' (OQ), an application to monitor HRQOL, (2) 'Head Matters' (HM), a multimodal guided self-care exercise intervention to prevent speech, swallowing and shoulder problems in HNC patients during and after radiotherapy alone or in combination with chemotherapy, and (3) 'In Tune without Cords' (ITwC), a self-care intervention to support the rehabilitation of patients after total laryngectomy.

In **chapter 2**, self-monitoring of speech and swallowing complaints in HNC patients is evaluated. The objective is to evaluate the feasibility of a computerized system OQ as a way to monitor speech and swallowing complaints in relation to HRQOL by HNC patients.

In **chapter 3** the feasibility of a multimodal guided self-care exercise intervention HM to prevent speech, swallowing and shoulder problems in HNC patients during and after treatment with (C)RT is investigated. Several barriers and facilitators to self-care exercise adherence are studied using qualitative research techniques. Six- and 12-week adherence, and performance levels are assessed. Factors related to HM exercise performance are studied in **chapter 4**.

In **chapter 5**, the development and usability of a web-based guided self-care intervention ITwC for patients after a total laryngectomy facilitating (early) rehabilitation is studied. The feasibility of ITwC is investigated in a multicenter study and is described in **chapter 6**.

In **chapter 7** the results obtained in the above described studies are discussed and placed into broader perspective. Strengths and limitations of the studies are discussed, and the implications of the findings for clinical practice, and directions for future research are described.

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2

COMPUTERIZED MONITORING OF PATIENT-REPORTED SPEECH AND SWALLOWING PROBLEMS IN HEAD AND NECK CANCER PATIENTS IN CLINICAL PRACTICE

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ABSTRACT

Objective

The aim of this study was to evaluate computerized monitoring of speech and swallowing outcomes and its impact on quality of life (QoL) and emotional well-being in head and neck cancer patients in an outpatient clinic.

Methods

Sixty-seven patients, treated by single or multimodality treatment, completed the EORTC QLQ-C30 and QLQ-H&N35 questionnaires and the Hospital Anxiety and Depression Scale in an outpatient clinic, using a touch screen computer system (OncoQuest), at baseline (at time of diagnosis) and first follow-up (1 month after end of treatment).

Results

Tumor sites included oral cavity (*n*=12), oropharynx (*n*=18), hypopharynx (*n*=8), and larynx (*n*=29). Tumor stage included carcinoma in situ (*n*=3), stage I (*n*=21), stage II (*n*=7), stage III (*n*=15), and IV (*n*=21). No speech or swallowing problems at baseline or follow-up were noted in 23% (speech) and 41% (swallowing) of patients. Twenty-one percent (speech) and 19% (swallowing) had problems at baseline and returned to normal scores at follow-up, while 16% (speech) and 19% (swallowing) had normal scores at baseline and developed problems at follow-up. Forty percent (speech) and 21% (swallowing) had persistent problems from baseline to follow-up. At baseline, speech problems were significantly related to tumor site and emotional distress. At baseline and follow-up, swallowing problems were significantly related to QoL and emotional distress. At follow-up, speech problems were significantly related to QoL, emotional distress, and swallowing problems.

Conclusions

Monitoring speech and swallowing problems through OncoQuest in an outpatient clinic is feasible. Many patients report speech and swallowing problems, negatively affecting their QoL and emotional well-being.

INTRODUCTION

Head and neck cancer (HNC) patients often have to deal with speech and swallowing problems before or after treatment, negatively affecting health-related quality of life (HRQOL). HNC patients may experience discomfort and functional deficits as a result of the disease itself, such as tumor-induced pain, and/or problems with swallowing and speaking prior to treatment. It has been estimated that 34-75% of HNC patients have speech or swallowing problems after treatment [1-3]. In clinical practice, various subjective and objective measures to evaluate posttreatment speech and swallowing outcomes are used. Speech outcomes can be assessed by indicators of speech production (e.g., oral function and articulation tests and aerodynamic and acoustical analyses), perceptual speech evaluation (e.g., intelligibility, articulation, nasality, speech rate, and acceptability), and by subjective measures to evaluate self-reported speech problems in everyday life situations (e.g., questionnaires). Swallowing outcome measures include objective assessment methods such as the modified barium swallow procedure with videofluorography [4], videofluoroscopy combined with manometry (manofluoroscopy) [5], fiberoptic endoscopic examination of swallowing [6], or scintigraphy [7]. Other clinician-rated dysphagia assessments can be performed by clinical swallowing evaluation (e.g., gathering information on current swallowing problems, reviewing medical history, observing signs relevant to the patient's medical status, conducting an examination of speech and swallowing structures, observing the patient during trial swallows, and by recording acute and late toxicity after radiotherapy) [8].

Patient-reported speech and swallowing problems are usually identified through questionnaires. Implementation of patient-reported outcomes in clinical practice may be facilitated by information technology, allowing real-time quick and easy presentation of results to clinicians [9-11]. In our institute, a touch screen computer-assisted data collection system, OncoQuest, was developed and implemented in clinical practice enabling structured monitoring of quality of life and emotional distress [12,13].

The purpose of this explorative study is to evaluate structured computerized monitoring of prospective patient-reported speech and swallowing outcomes from baseline (pretreatment) to first follow-up 1 month after treatment in HNC patients using OncoQuest and to investigate the impact of speech and swallowing problems on quality of life and emotional well-being.

METHODS

Patients

From February 2009 to July 2010, 67 newly diagnosed HNC patients filled out the patient-reported outcomes through OncoQuest. The inclusion criteria were curative treatment for primary tumors in the larynx, hypopharynx, oral cavity, or oropharynx. Exclusion criteria were: diseases causing cognitive dysfunction and poor understanding of the Dutch language. Age, gender, tumor site and stage, and treatment modality were recorded. Informed consent was obtained from all patients. This study was approved by the VU University medical ethics committee.

Outcome measures

Patients completed the EORTC QLQ-C30 [14] and EORTC QLQ-H&N35 [15] and the Hospital Anxiety and Depression Scale (HADS) [16] at the time of diagnosis and on their first follow-up after the end of treatment. The questionnaires were presented through OncoQuest, a touch screen computer-based data collection system. An example of the touch screen user interface is shown in Figure 1. One of the outcome variables in OncoQuest is time to complete the questionnaire: at their first visit, it took patients on average 8.7 min to complete all 79 items, and 8.0 min at first follow-up visit, 1 month after treatment.

Hoe zou u "de kwaliteit van het leven" gedurende de afgelopen week beoordelen?

Figure 1. Example of the user interface of OncoQuest

The EORTC QLQ-C30 is a cancer-specific questionnaire and comprises a global HRQOL scale (two items) and five functional scales: physical functioning (five items), role functioning (two items), emotional functioning (four items), cognitive functioning (two items), and social functioning (two items). There are three symptom scales: fatigue (three items), nausea and vomiting (two items), and pain (two items) and six single items relating to dyspnea, insomnia, loss of appetite, constipation, diarrhea, and financial difficulties. The QLQ-C30 subscale Global QoL is used in the present study.

The EORTC QLQ-H&N35 module covers specific HNC issues and comprises seven subscales: pain (four items), swallowing (five items), senses (two items), speech (three items), social eating (four items), social contact (five items), and sexuality (two items). There are ten single items covering problems with teeth, dry mouth, sticky saliva, cough, opening the mouth wide, weight loss, weight gain, use of nutritional supplements, feeding tubes, and pain-killers. The speech and swallowing subscales were used in the present study.

The scores of the QLQ-C30 and of the QLQ-H&N35 are linearly transformed to a scale of 0 to 100, with a higher score indicating a higher (i.e., more positive) level of functioning or global HRQOL, or a higher (i.e., more negative) level of symptoms or (speech and swallowing) problems. Presence of speech or swallowing problems was defined as a score ≥10 on the EORTC QLQ-H&N35 speech or swallowing subscale. These cutoff scores are based on a cohort of 110 subjects from the general population of whom 95% scored below 10 on these two subscales (unpublished data).

The HADS is a 14-item scale with two subscales, anxiety and depression. The total HADS score ranges from 0 to 42; the subscales range from 0 to 21. In psycho-oncology, the total HADS score is proven to be an accurate instrument to identify cancer patients with depression [17,18] and anxiety and other psychological sequelae. In the present study, a total HADS score of >15 was used as indicator of a high level of distress [19,20].

Data analysis

Patients were categorized regarding presence of speech problems (yes/no) or swallowing problems (yes/no), gender, tumor site (larynx/hypopharynx/oropharynx/oral cavity), tumor stage (carcinoma in situ/I/II/III/IV), and treatment: surgery/radiotherapy/chemoradiation/surgery (other than laryngectomy) and radiotherapy/surgery (laryngectomy) and radiotherapy/surgery and chemoradiation. Chi-square tests were used to investigate the relation between the presence of speech or swallowing problems and gender, tumor site (larynx/hypopharynx vs oral/oropharynx), tumor stage (cis/I/II vs III/IV), and treatment modality: single modality (surgery or radiotherapy) vs combined modality (surgery and radiotherapy/chemoradiation). Pearson correlation coefficients were used to test associations between speech or swallowing problems and global QoL (global QoL scale EORTC QLQ-C30) and emotional distress (total HADS score). For all tests, a *P* value less than .05 was considered statistically significant.

RESULTS

Patients

The patient group consisted of 51 males (76%) and 16 females (24%). Mean age was 64 years (range 43-83). Tumor sites included oral cavity (*n*=12), oropharynx (*n*=18), hypopharynx (*n*=8), and larynx (*n*=29). Tumor stage included carcinoma in situ (*n*=3), stage I (*n*=21), stage II (*n*=7), stage III (*n*=15), and IV (*n*=21). Patients were treated by surgery (*n*=18), radiotherapy (*n*=23), chemoradiation (*n*=12), surgery (other than laryngectomy) and postoperative radiotherapy (*n*=7), laryngectomy and radiotherapy (*n*=6), and surgery and postoperative chemoradiation (*n*=1; Table 1). Regarding assessment at first follow-up visit (follow-up), median time since the end of treatment was 1 month (SD 1.2 months).

Table 1. Characteristics of 67 patients.

		n (%)
Gender		
	Male	51 (76%)
	Female	16 (24%)
Mean age in years		64 (9.6, 43-83) (SD, range)
Tumour site		
	Oral cavity	12 (18%)
	Oropharynx	18 (27%)
	Hypopharynx	8 (12%)
	Larynx	29 (43%)
T-classification (stage)		
	Carcinoma in situ	3 (5%)
	I	21 (31%)
	II	7 (11%)
	III	15 (22%)
	IV	21 (31%)
Treatment		
	Surgery	18 (27%)
	Radiotherapy	23 (34%)
	Chemoradiation	12 (18%)
	Surgery and radiotherapy (other than laryngectomy)	7 (10%)
	Surgery and radiotherapy (laryngectomy)	6 (9%)
	Surgery and chemoradiation (other than laryngectomy)	1 (2%)

Patient-reported speech outcome

Mean EORTC QLQ-H&N35 speech subscale score was 22.72 (SD 26.3; range 0-100) at time of diagnosis and 29.52 (SD 25.5; range 0-89) at follow-up (Table 2). No patient-reported speech problems at baseline or follow-up were noted in 23% of the patients, 21% had speech problems at baseline and returned to normal scores at follow-up, while 16% of the patients had normal scores at baseline and developed problems at follow-up. Forty percent of the patients had persistent problems from baseline to follow-up (Figure 2). Speech reported outcomes were not significantly related to gender, tumor stage, or treatment modality. At baseline, speech problems were significantly related to tumor site (x^2=10.28, *P*=.00; more speech problems in oral and oropharyngeal cancer compared to laryngeal/hypopharyngeal cancer). At time of diagnosis (baseline), patient-reported speech outcomes were significantly related to emotional distress (*r*=.25, *P*=.04). At follow-up, patient-reported speech outcomes were significantly related to quality of life (*r*=–.49, *P*=.00), emotional distress (*r*=.53, *P*=.00), and swallowing outcomes (*r*=.40, *P*=.00).

Table 2. Overview of mean scores and standard deviation (SD) on the EORTC QLQ-C30 (global QoL), EORTC QLQ-H&N35 (speech problems), EORTC QLQ-H&N35 (swallowing problems) and HADS (distress) at baseline (at time of diagnosis) and first follow up (1 month after end of treatment).

	Time of diagnosis		First follow up visit	
	Mean	SD	Mean	SD
EORTC QLQ-C30 (global QoL)	68.03	22.12	69.40	19.54
EORTC QLQ H&N35 (speech problems)	22.72	26.27	29.52	25.54
EORTC QLQ H&N35 (swallowing problems)	19.03	25.16	26.87	29.19
HADS (distress)	9.82	8.26	8.97	6.98

A higher mean score indicates a higher (i.e., more positive) level of functioning or global QoL.
A higher mean score indicates a higher (i.e., more negative) level of speech, swallowing problems or distress symptoms.

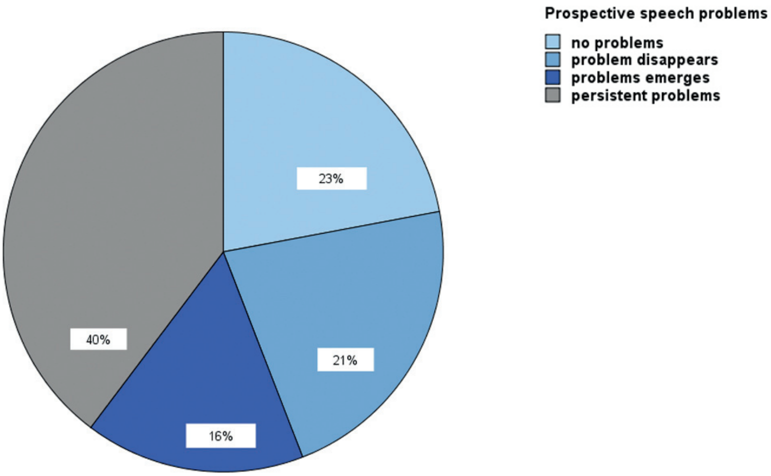

Figure 2. Prospective speech problems (*n*=67)

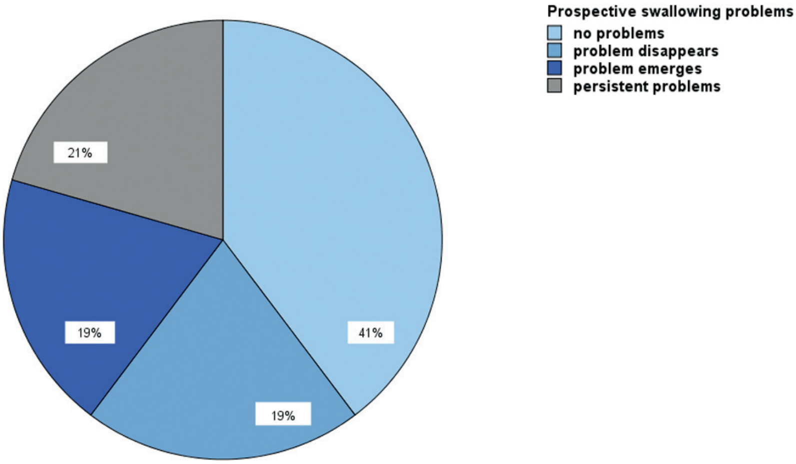

Figure 3. Prospective swallowing problems (n=67)

Patient-reported swallowing outcome

At time of diagnosis, mean EORTC QLQ-H&N35 swallowing subscale score was 19.03 (SD 25.2; range 0-83) and at follow-up 26.87 (SD 29.2; range 0-92; Table 2). No swallowing problems at baseline or follow-up were noted in 41% of the patients. Nineteen percent had swallowing problems at baseline and returned to normal scores at follow-up, while 19% had normal scores at baseline and developed swallowing problems at follow-up; 21% had persistent problems from baseline to follow-up (Figure 3). Patient-reported swallowing outcomes were significantly related to QoL at the time of diagnosis ($r=-.51$, $P=.00$) and at follow-up ($r=-.54$, $P=.00$), to emotional distress at time of diagnosis ($r=.52$, $P=.00$) and at follow-up ($r=.46$, $P=.00$), and to speech outcomes at follow-up ($r=.40$, $P=.00$). Swallowing reported outcomes were not significantly related to gender, tumor site and stage, or treatment modality.

DISCUSSION

This explorative study evaluated computerized monitoring of prospective patient-reported speech and swallowing outcomes in an outpatient clinic through OncoQuest, a touch screen computer system. A minority of the patients reported speech (21%) or swallowing problems (19%) at time of diagnosis, which is consistent with earlier studies [21,22]. In the present study, the majority either developed speech or swallowing problems after treatment (16 and 19%, respectively) or had persistent speech or swallowing problems from baseline to follow-up (40 and 21%, respectively). In total, 56% of the HNC patients had speech problems and 40% had swallowing problems at first follow-up.

Previous studies of objective and subjective speech and swallowing problems yielded similar results regarding speech problems (ranging from 46 to 64%) [23,24], and swallowing problems (ranging from 30 to 75%) [23,25]. Although prevalence rates vary significantly due to methodological issues as inclusion criteria and assessment methods, it is clear that a substantial part of HNC patients report speech or swallowing problems before and/or after treatment with a clear impact on QoL and emotional functioning. Also in earlier studies, speech and swallowing problems in HNC patients appeared to be significantly related to QoL and emotional well-being [26-31], as shown in the present study. Structured monitoring of speech and swallowing problems and QoL in clinical practice appears to be feasible, enhances patient-provider communication [32], and may facilitate physicians to focus quickly on issues that require further attention [10-12, 33] and to refer patients (if indicated) to speech and swallowing rehabilitation or other supportive care options in order to minimize acute and late effects of HNC and its treatment and to optimize QoL.

In this study, two time points were chosen (before treatment and shortly after end of treatment) to obtain insight in acute side effects of treatment and possible needs for supportive care at an early stage. All patients completed the questionnaires at those time points. Longer follow-up will provide more information on the course of speech and swallowing problems. However, in clinical practice, it is clear that the willingness to complete the questionnaires drops over time.

More long-term follow-up research is needed to assess efficacy of structured monitoring of speech and swallowing using a touch screen computer in clinical practice and to investigate moderating factors that may influence participation rate, such as age, gender, treatment modality, and burden of symptoms.

Speech and swallowing function can be improved in three ways. First, in planning surgery and (chemo-) radiation, head and neck oncologists may take into account the effects of their interventions on swallowing and speech production by using intensity-modulated radiotherapy to constrain the dose to be received by the swallowing muscles [34] and to minimize the impact on surrounding healthy tissues [35]. Second, a number of rehabilitative procedures are available to reduce or eliminate speech and swallowing problems after HNC surgery or (chemo-) radiation [36-38] by performing range of motion exercises, resistance exercises, swallow maneuvers, and compensation techniques. And third, speech and swallowing may be evaluated before treatment to determine the speech and swallowing status at start and to prepare the patient regarding possible speech and swallowing impairments.

It remains unclear whether patients might benefit from speech or swallowing rehabilitation (one of the main reasons to monitor patient-reported speech and swallowing outcome in the first place): efficacy studies of (pretreatment) speech and swallowing therapy are scarce [39-42]. A pilot study in our clinic revealed that mobility and flexibility exercises during a burdensome period of radiotherapy treatment are feasible. Exercises were easily learned and carried out according to plan. The protocol is extended with a DVD and a website (www.halszaken-vumc.nl) as helpful eHealth tools with information, film clips with examples of the exercises, and e-coaching. A prospective study is ongoing to investigate the effectiveness of this exercise protocol during radiotherapy. Next to effectiveness, this study will also provide insight into determinants and barriers regarding participation and compliance.

In the present study, the speech and swallowing subscales of the EORTC QLQ-H&N35 module were used to assess patient-reported speech and swallowing problems because they comprise only three speech and five swallowing items, and are thus quick and easy to use in a busy outpatient clinic. We used a cutoff score of 10 based on a cohort of 110 subjects from the general population of whom 95% scored below 10 on these two subscales (unpublished data). However, these short scales may not cover all speech- and swallowing-related issues. The Speech Handicap Index (SHI) and the Swallowing Questionnaire on Quality of Life (SWAL-QoL) may provide more specific information on self-reported speech and swallowing problems. The SHI was developed in a cohort of patients with oral or oropharyngeal cancer [43] and consists of 30 items on speech problems in daily life. The SHI was validated and a cutoff score of 6 (or higher) was defined on the total SHI scale to identify patients with speech problems in daily life after treatment for oral or oropharyngeal cancer, which was confirmed in a recent study on laryngeal cancer patients (unpublished data). In an earlier study, we translated and validated the 44-item swallowing-specific quality of life questionnaire SWAL-QoL and defined a cutoff score of 14 points (or higher) regarding the total SWAL-QoL score to identify patients with swallowing problems after treatment for oral or oropharyngeal cancer and [44]; this cutoff score was confirmed in a recent study on laryngeal cancer patients (unpublished data). Recently, based on the positive results of the present study regarding the feasibility to monitor speech and swallowing (as assessed by the short EORTC QLQ-H&N35 scales) in clinical practice, the SWAL-QoL and SHI have been built in OncoQuest. An ongoing research focuses on whether these longer questionnaires are also feasible in clinical practice.

CONCLUSION

Computerized monitoring of patient-reported speech and swallowing outcome in a busy outpatient clinic using a touch screen computer system (OncoQuest) is feasible. Many HNC patients report speech and swallowing problems before and after treatment, negatively affecting QoL and emotional well-being.

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3

MULTIMODAL GUIDED SELF-HELP EXERCISE PROGRAM TO PREVENT SPEECH, SWALLOWING, AND SHOULDER PROBLEMS AMONG HEAD AND NECK CANCER PATIENTS: A FEASIBILITY STUDY

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ABSTRACT

Objective

During a 6-week course of (chemo)radiation many head and neck cancer patients have to endure radiotherapy-induced toxicity, negatively affecting patients' quality of life. Pretreatment counseling combined with self-help exercises could be provided to inform patients and possibly prevent them from having speech, swallowing, and shoulder problems during and after treatment. The aim of this study was to investigate the feasibility of a multimodal guided self-help exercise program entitled Head Matters during (chemo)radiation in head and neck cancer patients.

Methods

Head and neck cancer patients treated with primary (chemo)radiation or after surgery were asked to perform Head Matters at home. This prophylactic exercise program, offered in three different formats, aims to reduce the risk of developing speech, swallowing, shoulder problems, and a stiff neck. Weekly coaching was provided by a speech and swallowing therapist. Patients filled out a diary to keep track of their exercise activity. To gain insight into possible barriers and facilitators to exercise adherence, reports of weekly coaching sessions were analyzed by 2 coders independently.

Results

Of 41 eligible patients, 34 patients were willing to participate (83% uptake). Of participating patients, 21 patients completed the program (64% adherence rate). The majority of participants (58%) had a moderate to high level of exercise performance. Exercise performance level was not significantly associated with age (P=.50), gender (P=.42), tumor subsite (P=1.00) or tumor stage (P=.20), treatment modality (P=.72), or Head Matters format (web-based or paper) (P=1.00). Based on patients' diaries and weekly coaching sessions, patients' perceived barriers to exercise were a decreased physical condition, treatment-related barriers, emotional problems, lack of motivation, social barriers, and technical problems. Patients' perceived facilitators included an increased physical condition, feeling motivated, and social and technical facilitators.

Conclusions

Head Matters, a multimodal guided self-help exercise program is feasible for head and neck cancer patients undergoing (chemo)radiation. Several barriers (decreased physical condition, treatment-related barriers) and facilitators (increased physical condition, feeling motivated) are identified providing directions for future studies. The next step is conducting a study investigating the (cost-)effectiveness of Head Matters on speech, swallowing, shoulder function, and quality of life.

INTRODUCTION

Head and neck cancers (HNC) in the oral cavity, nasopharynx, oropharynx, hypopharynx, and the larynx represent 5% of all cancers. About 2800 new cases are reported in the Netherlands each year. Treatment intensification using multimodality approaches, such as accelerated radiotherapy (RT), concomitant chemotherapy, and surgery with adjuvant RT with or without chemotherapy result in a significant improvement in loco-regional control and overall survival [1-3]. During a 6-week course of RT, many patients have to endure radiotherapy-induced toxicity such as oral mucositis, pain, salivary changes, dry mouth, skin toxicity, hoarseness, swallowing problems, trismus, fibrosis in the orofacial region, throat, neck and shoulders, and stiffness and pain in the neck and shoulders [4-15]. These acute side effects of radiation result in a significant symptom burden and interfere with normal physiologic functions and daily activities, such as chewing, swallowing and speech, and related social withdrawal and psychological distress, negatively affecting patients' quality of life [16,17]. Swallowing problems are among the most cited functional impairments after chemoradiotherapy [18-20] with an estimated prevalence of 43% to 64% [21,22]. These results emphasize the importance of prevention, monitoring, and management of swallowing dysfunction as an integral part of treatment protocols [23].

It is expected that fewer speech and swallowing problems persist when these acute side effects of radiation are prevented and/or managed in an early stage [24,25]. Pretreatment counseling by a speech and swallowing therapist (ST) could be provided to inform the patient and family on possible speech and swallowing problems that may occur during and after treatment [26]. Patients should, for example, be informed about the importance of continuing to swallow throughout their courses of (chemo)radiation ([C]RT), because inactivity of the swallowing muscles may lead to disuse atrophy, and then lead to future, temporary inability to consume food orally and long-term feeding tube dependency [19,27,28]. In order to possibly prevent atrophy of the head and neck muscles, to maintain speech and swallowing function, and to improve functional swallowing outcome and swallowing-specific quality of life following (C)RT, counseling combined with exercise prescription should be provided prior to (C)RT [29-34].

Research is, however, still in an early stage and much is unknown [35,36]. As a result, not all patients with HNC undergoing (C)RT are prescribed a standardized exercise program as a preventive measure [37]. Given the burdensome period of (C)RT for HNC patients, there is an urgent need for an easily accessible prophylactic education and exercise program, countering the radiation fibrosis, and safeguarding patients against additional consults with health care professionals during (C)RT. A multimodal self-help program is expected to enhance reach by overcoming logistical and financial barriers both on the part of health care providers and patients [38,39]. To our knowledge, there are no self-help programs offered with remote coaching, targeting prevention of deterioration of speech, swallowing, and shoulder function.

Therefore we developed Head Matters (HM), a multimodal guided self-help exercise program for HNC patients during (C)RT. The aims of the present feasibility study were (1) to explore uptake, adherence, and exercise performance (by exercise levels and exercise categories) of the guided self-help exercise program HM in HNC patients, (2) to explore predictors of exercise performance, and (3) to gain insight into barriers and facilitators to exercise adherence.

METHODS

Description of the self-help exercise program Head Matters (HM)

HM was developed by a team of health care professionals consisting of STs, otolaryngologists, head and neck surgeons, radiation oncologists, and a physiotherapist. HM comprises one face-to-face pretreatment counseling session on the first day of (C)RT to inform the patient of possible speech, swallowing, and shoulder problems during treatment, and to encourage patients to maintain speech, swallowing, and shoulder function during treatment.

HM consists of a 15-minute per day program with four categories of prophylactic exercises: (1) exercises to maintain mobility of the head, neck, and shoulders, (2) exercises to optimize and maintain swallowing function, (3) exercises to optimize and maintain vocal health and vocal function, and (4) exercises to optimize and maintain speech function and functional communication. Coaching is offered in weekly 10-minute coaching sessions by an experienced ST by phone or email.

Because the target group (HNC patients) does not have equal access to the Internet, HM is available in three different formats. Both the online format and booklet format offer general information about HNC and its treatment, with written descriptions of the exercises, and with photo and video examples of the exercises either offered online [40] or by means of a 15-minute instructional DVD. The third format consists of a 2-paged A4 leaflet that offers only a written description of the exercises. Multimedia Table 1 shows an overview of exercise categories and the three formats of HM. Examples of screenshots of the online format are shown in Figures 1 and 2.

Multimedia Table 1. Overview of Head Matters: exercise categories and formats

Exercise categories:

I) Exercises to maintain mobility of the head, neck and shoulders
  - moving shoulders up and down, circling shoulders forward and backward
  - bending head forward ('Chin tuck')
  - looking up ('Head back')
  - looking over left / right shoulder ('Head turn')
  - touching ear to shoulder ('Head tilt')

II) Exercises and strategies to optimize, and to maintain swallowing function
  - swallowing with strength ('Effortful swallow')
  - pulling back of the tongue to the back of the mouth and hold ('Tongue retraction')
  - swallowing two or three times per bite or sip
  - taking sips of water regularly
  - sit up straight during mealtimes, and minimize distractions during meals

III) Exercises to optimize vocal health, and to maintain vocal function
  - humming with gradually increased volume, and with exagerated jaw movement
  - slide up the pitch scale as high as possible; hold the high note for several seconds ('Falsetto exercise')

IV) Exercises to optimize speech function, and functional communication
  - articulate each syllable
  - stretching the tongue out straight
  - pushing tongue against left / right cheek
  - licking lips with the tip of the tongue
  - maintaining eye contact during conversation

Formats:

(a) online [40] with general information about HNC,
with written instructions, and photo and video demonstrations

(b) a 28-paged booklet with DVD, with general information about HNC,
with written instructions, and pictorial and video demonstrations

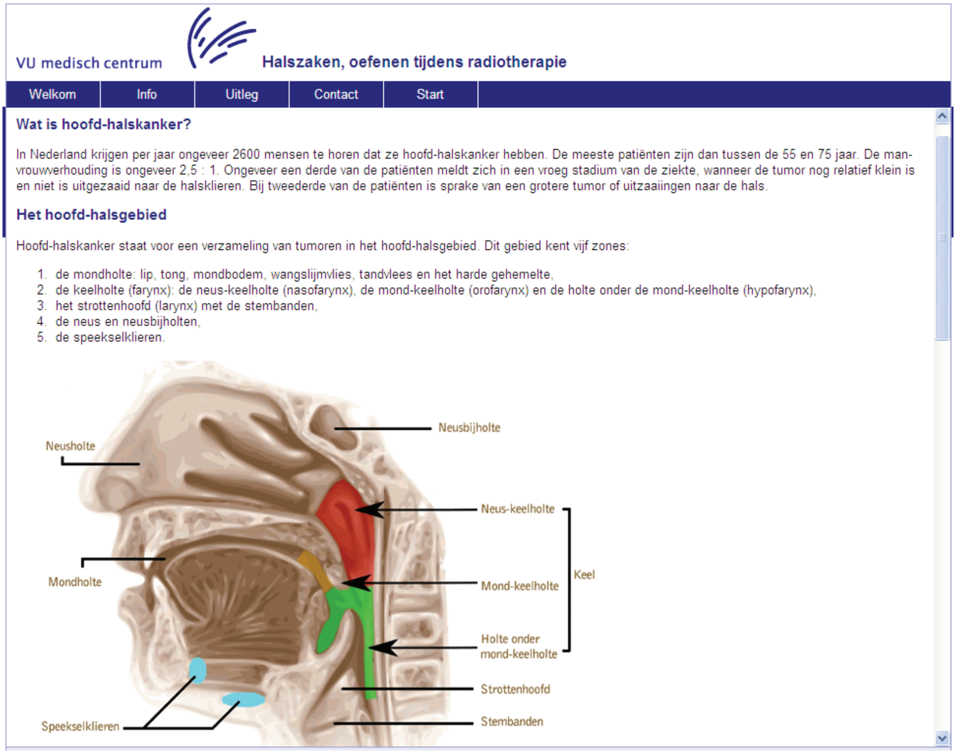
(c) a two-paged A4 leaflet with written instructions

Study sample and procedure

HNC patients treated at the VU University Medical Center Amsterdam, the Netherlands, had to fulfil the following criteria to be included in this feasibility study: (1) age ≥18 years, (2) HNC originating in the oral cavity, oropharynx, hypopharynx, or larynx, (3) stage I-IV cancer, according to the Union for International Cancer Control (UICC) TNM-classification system, (4) no distant metastases, (5) radiation, (C)RT or postoperative (C)RT, and (6) absence of any psychological, familial, sociological, or geographical condition potentially hampering compliance with the study protocol. Three radiation oncologists introduced the study to eligible patients who met the inclusion criteria based on medical chart reviews, and based on the conversation with the patient during a regular consultation. If a patient expressed interest in participation, he or she was approached by the researcher for further details about the study. The patient's written informed consent form was obtained.

Patients were invited to perform HM at home, at least once a day. If a patient was willing to perform the exercises, a 15-minute face-to-face instruction session by a ST was planned on the first day of (C)RT. Safety was ensured by demonstrating each exercise appropriately, by giving the participants adequate instructions on each exercise, and by providing an instruction leaflet, an instruction booklet (with DVD), or a log-in code to activate an account for the website [40]. Postoperative participants were offered the HM program on a leaflet. Patients with Internet access and treated with (C)RT were offered the HM online format and the HM instruction booklet with general information about HNC, written instructions, and photo demonstration. Patients without Internet access and treated with (C)RT were offered the HM instruction booklet with general information about HNC, written instructions, and photo and video demonstration (on DVD).

Patients were asked to fill out a diary on paper or online for 6 weeks. In their diaries, patients noted which exercises they performed (of the four categories), and the frequency of exercising (1, 2, or 3 times per day).



Wat is hoofd-halskanker?

In Nederland krijgen per jaar ongeveer 2600 mensen te horen dat ze hoofd-halskanker hebben. De meeste patiënten zijn dan tussen de 55 en 75 jaar. De man-vrouwverhouding is ongeveer 2,5 : 1. Ongeveer een derde van de patiënten meldt zich in een vroeg stadium van de ziekte, wanneer de tumor nog relatief klein is en niet is uitgezaaid naar de halsklieren. Bij tweederde van de patiënten is sprake van een grotere tumor of uitzaaiingen naar de hals.

Het hoofd-halsgebied

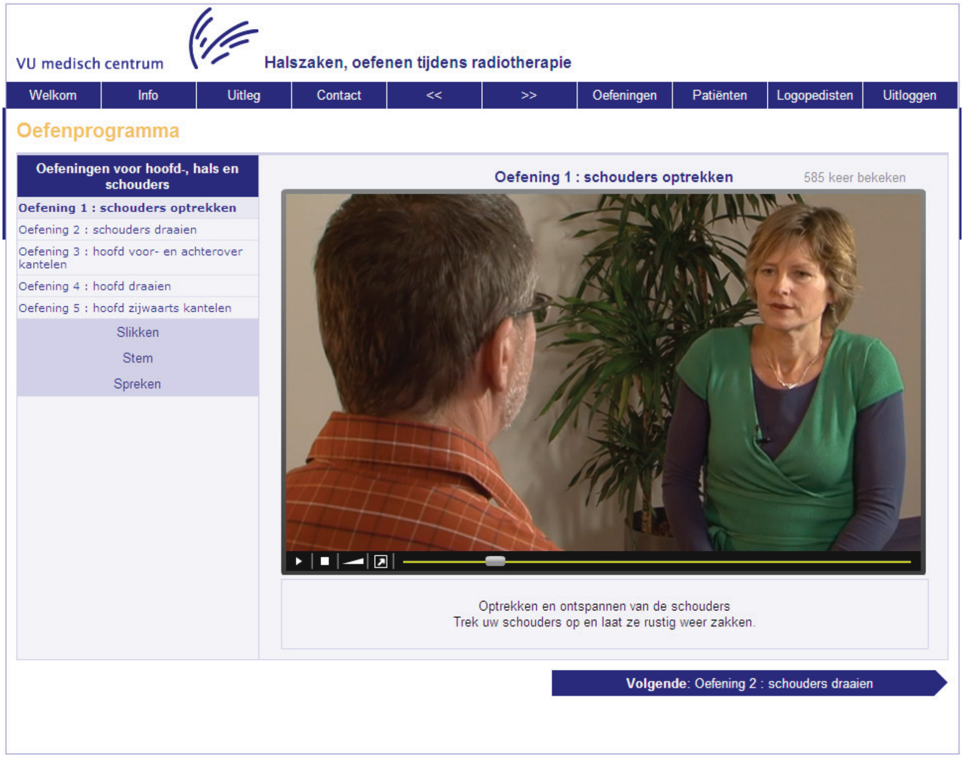
Hoofd-halskanker staat voor een verzameling van tumoren in het hoofd-halsgebied. Dit gebied kent vijf zones:

1. de mondholte: lip, tong, mondbodem, wangslijmvlies, tandvlees en het harde gehemelte,
2. de keelholte (farynx): de neus-keelholte (nasofarynx), de mond-keelholte (orofarynx) en de holte onder de mond-keelholte (hypofarynx),
3. het strottenhoofd (larynx) met de stembanden,
4. de neus en neusbijholten,
5. de speekselklieren.

Figure 1. Screenshot of Head Matters: general information about head and neck cancer

During 6 weeks of exercising, subjects participated in weekly 10-minute coaching sessions by a ST by phone or email to maintain motivation and to help them to achieve adherence to the HM protocol. During these coaching sessions, open-ended questions about general well-being were asked ("How are you?") and questions about exercise performance ("Could you tell me something about your exercise frequency this week?", and "Could you name any reasons (not) to exercise?"). The ST took a supportive role, while actively asking the participants for further explanations of their answers when necessary. During these weekly coaching sessions, notes were taken.

The study was conducted according to regular procedures of the local ethical committee of the VU University Medical Center, Amsterdam.



Optrekken en ontspannen van de schouders
Trek uw schouders op en laat ze rustig weer zakken.

Figure 2. Screenshot of Head Matters. Exercise 1: Move your shoulders up and down

Measures

Demographic (i.e., gender, age) and clinical (i.e., tumor subsite and stage, treatment modality) information of participating patients was extracted from the hospital information system.

Uptake

Uptake of HM addressed how many patients were willing to start HM during (C)RT (uptake percentage).

Adherence

Adherence concerned the degree to which HNC patients followed HM at least once a day during 6 weeks of (C)RT and was assessed in two ways: (1) patient-completed diaries, and (2) percentage of patients who started and kept up exercising for 6 weeks.

Exercise performance level

Patient-completed diaries were used to identify exercise performance levels. A low level of exercise performance consisted of an exercise performance of all exercise categories during 6 weeks at most once a day on average (range 0-168). A moderate level consisted of an exercise performance of all categories during 6 weeks between once and twice a day on average (range 169-336). A high level of exercise performance was defined as an exercise performance of all exercise categories during 6 weeks at least twice a day on average (range 337-504).

To gain insight into which exercises were performed most often, the diaries were analyzed in more detail regarding the frequency of exercising (1-3 times) and type of exercise (four categories). Exercise performance by exercise format was defined as how well the prescribed exercise regimen was followed by patients, following a specific format (online exercising or exercising by leaflet or booklet).

Feasibility

HM is defined to be feasible in case of an uptake percentage >50%, adherence rate >50%, and when >50% of the patients perform at least the minimum number of exercises (168) during 6 weeks (moderate or high performance level). This definition of feasibility is based on adherence rates reported in previous research [32,37]. In a retrospective study, adherence to unsupervised, home-based swallowing exercises is quite low, ranging from 13% for full adherence to 32% for partial adherence [37]. Van der Molen [32] retrospectively assessed adherence via two self-report items estimating duration of adherence in days and familiarity with exercises 10 weeks after treatment. They found that 14% of the total sample reported doing exercises every day during the entire radiation treatment and follow-up period and that 57% stopped their exercises after an average of 3.5 weeks.

Barriers and facilitators to exercise

Reports of the coaching sessions were used to identify patients' perceived barriers and facilitators to perform HM during (C)RT.

Data analysis

Quantitative data were analyzed using IBM SPSS Statistics for Windows, version 20. Descriptive statistics were used to summarize the sociodemographic and clinical characteristics of the study participants and the data on uptake, adherence, and performance level of HM.

Patients were categorized regarding exercise performance level (low, moderate, high), and age (≤60 years vs ≥61 years, based on median split), tumor subsite (oral cavity, oropharynx, hypopharynx, larynx, other), tumor stage (I, II, III, IV), treatment (RT, chemoradiation [CRT], surgery, and [C]RT), and format of HM (leaflet, booklet, online). Fisher's Exact tests were used to determine differences in exercise performance level (performance level low vs moderate/high) regarding age, gender, tumor subsite (oral cavity/oropharynx vs hypopharynx/larynx), tumor stage (stage I/II vs III/IV), treatment modality ([C]RT vs postoperative [C]RT), and format of HM (online vs leaflet vs booklet). For all analyses, $P \leq .05$ was considered statistically significant.

Reports of the weekly coaching sessions were analyzed by 2 independent observers (IC and CvU). Both coders separately read all reports of the weekly coaching sessions several times to familiarize themselves with the data. Barriers and facilitators for exercising were selected and coded independently into categories. Subsequently, the coders met to discuss their findings and resolve differences with the aim of reaching consensus, after which categories were refined, and subcategories were identified. The coders met regularly with a third coder (IV) to resolve disagreements in coding.

RESULTS

Uptake and participants' characteristics

In total, 41 eligible patients were referred to the study. Due to shortage of time, 7 of the 41 patients refused to participate; 34 patients agreed to participate and were enrolled in the study (83% uptake). One patient agreed to participate but died 1 week after giving written informed consent. Eleven postoperative patients (33%) received HM on a 2-paged leaflet, 11 patients (33%) chose to receive HM in a 28-page booklet format with photos and video examples on a DVD, and another group of 11 patients (33%) chose to receive HM online.

The mean age of the participants was 60 years (range 21-77). Of the 33 patients (76% male, and 24% female), one third of the patients was treated with RT (33%), one third of the patients was treated with CRT (33%), and one third with surgery (33%). After surgery, 7 patients received postoperative RT, and 4 patients received postoperative CRT (Multimedia Table 2).

In the planned face-to-face instruction session, 26 of the 33 patients (79%) received exercise instructions on day one of (C)RT. The other 7 patients (21%) received their exercise instructions 3-11 days earlier and started exercising before (C)RT started. In total, 33 patients filled out a diary.

Multimedia Table 2. Patient characteristics

	n (%)
Gender	
Male	25 (76)
Female	8 (24)
Mean age in years	60 (10.62, 21-77) (SD, range)
Tumour site	
Oral cavity	8 (24)
Oropharynx	15 (46)
Hypopharynx	3 (9)
Larynx	7 (21)
Tumour classification (stage)	
I	5 (15)
II	2 (6)
III	8 (24)
IV	18 (55)
Treatment	
Radiotherapy	11 (33)
Chemoradiation	11 (33)
Postoperative (chemo-)radiation	11 (33)

Adherence and exercise performance level

Of the 33 patients who were interested in performing exercises, 21 patients started and kept up exercising for 6 weeks (64% adherence rate). Of the 33 patients, 14 patients (42%) were performing the exercises at a low level (exercise frequency range of 4-167 during 6 weeks), 10 patients (30%) were exercising at a moderate level (exercise frequency range of 196-332), and 9 patients (27%) were exercising at a high level (exercise frequency range of 372-495) (Multimedia Table 3).

Multimedia Table 3. Exercise performance levels

Performance level	Patient number [a]	Week number [b]						Total number of exercises performed
		1	2	3	4	5	6	
Low (4-167)	PT 10 ONLINE	0	0	0	4	0	0	4
	PT 4 ONLINE	0	0	8	0	0	0	8
	PT 17 BOOKLET	0	12	0	0	0	0	12
	PT 8 ONLINE	0	8	4	12	8	0	32
	PT 18 BOOKLET	0	0	11	11	9	5	36
	PT 7 ONLINE	0	0	0	27	21	3	51
	PT 33 LEAFLET	34	16	8	8	0	0	66
	PT 15 BOOKLET	34	7	10	8	7	7	73
	PT 12 BOOKLET	12	22	24	16	0	0	74
	PT 24 LEAFLET	20	28	28	0	0	0	76
	PT 32 LEAFLET	9	16	31	29	24	27	136
	PT 22 BOOKLET	16	27	29	25	26	30	153
	PT 29 LEAFLET	12	36	36	36	36	0	156
	PT 5 ONLINE	20	12	32	50	28	25	167
Moderate (196-332)	PT 20 BOOKLET	29	39	36	32	28	32	196
	PT 16 BOOKLET	48	70	28	28	28	12	214
	PT 13 BOOKLET	40	47	28	48	36	28	227
	PT 30 LEAFLET	48	48	51	40	34	10	231
	PT 26 LEAFLET	76	60	36	36	36	12	256
	PT 23 LEAFLET	36	84	80	25	21	35	281
	PT 11 ONLINE	0	28	36	84	84	81	313
	PT 9 ONLINE	0	24	50	76	80	84	314
	PT 6 ONLINE	39	55	65	56	59	46	320
	PT 19 BOOKLET	48	84	84	36	24	56	332
High (372-495)	PT 14 BOOKLET	48	84	42	42	84	72	372
	PT 28 LEAFLET	40	71	74	76	76	56	393
	PT 31 LEAFLET	12	84	84	84	84	48	396
	PT 27 LEAFLET	18	84	84	84	84	48	402
	PT 3 ONLINE	60	69	69	78	76	52	404
	PT 25 LEAFLET	48	84	84	80	69	47	412
	PT 1 ONLINE	49	80	84	84	66	60	423
	PT 2 ONLINE	72	84	84	84	84	84	492
	PT 21 BOOKLET	84	84	84	84	84	75	495

[a] HM via leaflet (n=11), booklet (n=11), or online (n=11)

[b] 0 = non-active (no exercises per week)
84 = highly active (maximum number of exercises per week)

Exercise performance by exercise category

Figure 3 presents an overview of all 33 patients regarding the course of exercise through the 6 weeks of (C)RT. Patients most often performed the exercises to maintain mobility of the head, neck, and shoulders. The exercises least performed by patients were to optimize vocal health and maintain vocal function. During the first 2 weeks, exercise performance of all 33 patients increased from 224 to 366 exercises, on average. After the second week, a decline in exercise performance of all participants in all exercise categories was observed. During the sixth week of (C)RT, patients were still performing HM exercises, with an average of 259 times.

Based on these results, HM appears to be feasible in general, with an uptake percentage >50% (in the present study 83%), with an adherence rate >50% (in the present study 64%), and with a moderate to high performance level >50% of the patients performing exercises in all categories at least once a day on average (in the present study, 58% of the participants).

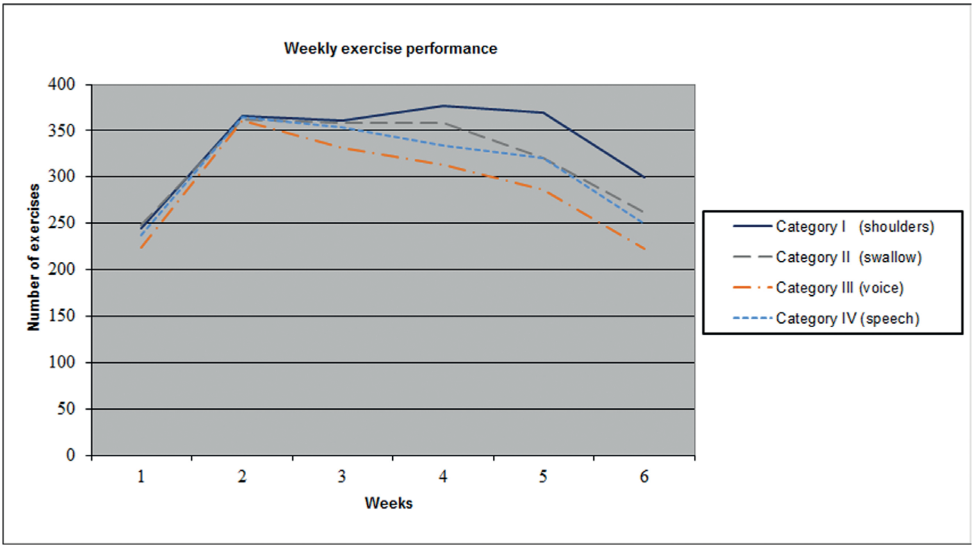


Figure 3. Weekly exercise performance by exercise category

Predictors of exercise performance

Exercise performance level was not significantly related to age (*P*=.50), gender (*P*=.42), tumor subsite (*P*=1.00), tumor stage (*P*=.20), or treatment modality (*P*=.72). Exercise performance level was also not significantly different regarding HM format (*P*=1.00).

Barriers to exercise

Overview

From the analysis of reports of weekly coaching sessions, several barriers to perform HM emerged: a decreased physical condition, treatment-related barriers, emotional problems, lack of motivation, social barriers, and technical problems (Multimedia Table 4).

Decreased physical condition

During coaching sessions, participants commented that they did not perform the exercises because of oral complications and throat problems (e.g., swallowing, speech and voice problems, limited mouth opening, skin and oral wounds, oral infections, saliva problems, swelling, taste problems, having a poor appetite, and dental extractions), as well as stiffness in the neck and shoulders. In addition, participants mentioned more general physical symptoms resulting from cancer or cancer treatment, such as pain, nausea, weight loss, and fatigue, which prevented them from performing the exercises.

Treatment-related barriers

Some participants indicated that daily travelling to the outpatient clinic for (C)RT or just the (C)RT itself was too time-consuming to perform exercises. Others mentioned feeling embarrassed having to perform (voice) exercises in a hospital ward during hospitalization for chemotherapy.

Emotional problems

Some participants noted that they found it difficult to focus on and pay attention to HM due to emotional problems (e.g., anxiety, worrying, having panic attacks, feeling scared).

Lack of motivation

Some participants indicated that they did not feel motivated to exercise because of not experiencing any complaints. Others mentioned that they were not convinced that the exercises would help. Some did not feel motivated to perform the exercises at home and preferred face-to-face contact with a ST. Others commented that the exercise program would distract them from their daily routine or reported a lack of motivation because of a “perceived information overload” during treatment.

Social barriers

Some participants reported problems combining HM at home and work situations. Especially informal caregivers and participants with job responsibilities could not find the time to exercise and felt not able to concentrate on the exercise program.

Technical problems

With regard to technical issues, patients reported installation problems and were not able to see the demonstration videos on the computer. One participant indicated that the exercise repetitions on DVD took too much time, leading to boredom. Four participants mentioned that they lost their log-in password or forgot the website address and therefore could not see the exercise demonstrations on video.

Facilitators to exercise

Overview

Besides barriers, facilitators to perform HM during (C)RT emerged: an increased physical condition, a general sense of psychological well-being, feeling motivated, and social and technical facilitators (Multimedia Table 4).

Increased physical condition

Some participants mentioned that a regained vocal function, an improved appetite, and a decreased size of their tumor enabled them to perform HM. Others mentioned that an increased general physical condition (e.g., regained energy) facilitated exercise performance.

General sense of psychological well-being

Some participants stated that a general sense of psychological well-being, expressed as feeling good and being good-humored, encouraged them to perform the exercises.

Feeling motivated

Participants reported enhanced motivation to perform the exercises because the exercises were simple and easy to follow. A motivational facilitator for some of the participants was that they knew the exercises by heart and could therefore perform the exercises while taking a shower or while on their way to the hospital (in a taxi). Some reported that they enjoyed the exercises because they experienced them as relaxing. They indicated liking the swallowing strategies at breakfast, lunch, or dinner. Others stated feeling motivated because, by adhering to the exercise program, they felt able to contribute to their own recovery process. Some stated that they adapted the exercises to their own ability and decided to perform the exercises more carefully and slower than demonstrated, and in shorter sessions throughout the day.

Participants stated that they enjoyed the design of HM. They especially mentioned the face-to-face introduction of the exercises and weekly coaching sessions as motivational.

Social facilitators

Participants indicated social support in the home situation to be an important facilitator. Some felt encouraged to exercise because they performed the exercises together with their partner and/or family. Others felt motivated because their partner and/or family reported improvement due to exercising, such as a better speech function. One participant reported performing (more of) the exercises while being off duty, while another performed (more of) the exercises during working hours.

Technical facilitators
Online or DVD exercise demonstrations were indicated by participants as an enabler to perform the exercises (in the right way and at the same place) as instructed.

Multimedia Table 4. Patients' perceived barriers and facilitators to perform Head Matters

	BARRIERS	FACILITATORS
Physical condition	Decreased condition of the head and neck - oral complications - throat discomfort - stiffness in neck and shoulders Decreased general condition - pain - nausea - weight loss - fatigue	Increased condition of the head and neck - increased appetite - better vocal function - decrease of tumour (size) Increased general condition - having regained energy
Treatment related factors	Treatment related barriers - hospitalization - time consuming treatment protocols - great time loss travelling to hospital	
Psychological functioning	Emotional problems - anxiety - worrying - panic attacks - finding it difficult to focus	General sense of psychological well being - feeling good - being good-humoured
Motivational issues	Lack of motivation - experiencing (no) complaints - lack of confidence that exercising will help - no preference for a self-help program - distraction of daily routine - perceived information overload	Motivational facilitators - simple and easy-to follow exercises - experiencing (direct) benefits of exercising - adapt exercises to one's own ability - enjoying the exercise program with weekly coaching sessions and a face-to-face introduction
Social issues	Social barriers at home - time constraints and inability to focus because of being a caregiver	Social facilitators at home - partner and patient are performing exercises together - partner encourages patient to perform the exercises - partner and family motivate by reporting improved speech function
	Social barriers at work - time constraints and inability to focus because of high workload	Social facilitators at work - performing exercises while being at work - off duty: time to perform the exercises
Technical issues	Technical problems - not able to see the videos on the computer - exercises on DVD take too much time - failure to remember login password or website address	Technical benefits - online or DVD exercise demonstrations make it easy to perform the exercises as instructed

DISCUSSION

Results from this feasibility study indicated that the guided self-help exercise program HM is feasible among HNC patients undergoing primary or postoperative (C)RT with high uptake and reasonable adherence rates. The majority of the included patients performed at least the minimum number of exercises during 6 weeks (moderate or high performance level).

The majority of HNC patients in our study (34/41, 83%) responded positively to the offer of pretreatment counseling on exercises to maintain speech, swallowing, and shoulder function while undergoing (C)RT. While the efficacy of our guided self-help exercise program is yet to be demonstrated, the high uptake of HM suggests that this program may have addressed specific needs among the target population.

To understand the true benefits of an exercise program, the adherence rates of patients involved in such programs is one of the key issues [31]. In the present study, adherence rate to the home-based HM program was 64%. Adherence to similar prophylactic exercise programs targeting HNC patients varied between 14% (a home-based program) [32] and 68% (twice a week supervised hospital-based exercises, combined with home-based exercises) [32-34]. Results are, however, not fully comparable because HM, unlike the other interventions, is a self-help program. Self-help programs, especially those administered online, often suffer from non-adherence [41,42]. The adequate adherence rate found in our study suggests that an exercise program such as HM can be offered in a home-based self-help format, with the use of self-regulating strategies, including diary keeping, possibly enhancing motivation, and adherence.

We explored predictors of exercise performance in HNC patients willing to use a guided self-help exercise program during (C)RT with minimal therapist guidance, offered in three exercise formats. Initially, we developed a leaflet format, followed in a later stage by an online and booklet format of HM, including photo and video demonstration of the exercises. Although we expected the later formats would possibly lead to a higher exercise performance level, in the present study no relation between exercise performance level and exercise format (exercising online or exercising by leaflet or booklet) were found. The small sample size of this feasibility study, lack of randomization, and lack of statistical power limited the comparability of findings and may explain why exercise performance levels and exercise format were not related significantly. Furthermore, exercise performance levels were based on patient-completed diaries and may not truly reflect the user's experience and dose. In the upcoming study on (cost-)effectiveness of HM, we will maintain the online and booklet formats. The use of web-based diaries enables health care providers to send reminders to participants and may provide interactive Internet feedback tailored to each patient, improving adherence. Despite the high prevalence of Internet access in the Netherlands and advantages of eHealth interventions, including multimedia presentation, easy updating of the information provided and tailoring, we think a booklet format is still required [43]. Within a specific part of the population of HNC patients (with higher age and lower socioeconomic status) the percentage of patients for whom an online intervention is not eligible is deemed high, because of low eHealth literacy skills, concerns about Internet privacy, and/or preferences for using a booklet [44,45]. Furthermore, online exercise videos and exercise demonstrations on DVD help HNC patients to safely and properly perform the exercises. Although the adherence rate in the present study was adequate (64%), efforts to increase adherence rate are needed. Low or non-adherence has been proposed as a risk and a reason for a possible limited impact of self-help programs [46].

To understand and possibly intervene in the process of non-adherence, our third objective was to study patients' perceived barriers and facilitators to adhere to HM. Barriers to adhere to HM are comparable to results of other studies on prophylactic education and exercise programs, either home-based and/or institution-based, targeting patients who are about to undergo (C)RT for HNC [32,34]. Physical barriers to perform self-help exercises as identified in our study are in accordance with the findings of Kotz [34], who reported that 69% of HNC patients were unable to perform the swallowing exercises throughout the entire course of (C)RT because of oral pain, throat discomfort, and overall fatigue. Van der Molen [32] reported that 37% of HNC patients stopped training because of pain in the mouth, nausea, and fatigue. Additionally, LaGorio and Carnaby [47] reported that adherence of the preventative swallowing exercises was significantly associated with presence of depression and fatigue. Overall, it is important to realize that HNC patients often struggle to cope with the challenges of treatment while attempting to manage the other aspects of their lives such as work responsibilities, family issues, and social relationships [48]. HNC patients in our study reported time constraints, time consuming treatment protocols, being a caregiver, and distraction of daily routine as barriers to adhere to the HM exercises. These reports are consistent with previous qualitative studies [49,50]. During coaching sessions, exercise acceptance and adherence may be improved by paying attention to psychosocial factors [42,47], for example by providing e-counseling [51-53]. These counseling interventions deserve attention and may be uniquely beneficial as they spare patients the cost and burden of traveling to a hospital for psychosocial care [54]. However, the effects of such (psychosocial) interventions are yet unclear [55]. Future research is needed to assess the impact of (combined) coaching strategies (face-to-face, email, and/or telephone contact).

In the present study, several adherence facilitators related to the multimodal design of HM were identified, such as simple and easy-to-follow exercises, online or DVD demonstrations, the face-to-face introduction of HM, and the weekly coaching sessions. Efforts to enhance exercise adherence in HNC patients should focus on optimizing enjoyment while managing symptoms, providing education in overcoming treatment-related barriers, helpful types of support, self-monitoring, reminders, and telephone follow-up [56-58]. Other researchers suggest the use of a hook (a message or program design to build curiosity) to engage participants who are starting the intervention [49].

Results of earlier studies demonstrated the importance of the introduction session of a self-help program, to be able to achieve a successful dissemination. For health-related interventions, it is deemed crucial that the introduction is provided by a care professional who is a credible source for patients and who is committed to the program [59]. HM has the advantage that health care professionals have been involved in the development of the intervention, which increases commitment to the intervention and hereby the chance of optimal dissemination [60].

The outcome of our feasibility study provided support that a guided self-help exercise program during (C)RT is feasible. However, some limitations should be mentioned. The results were based on a relatively small sample size from a single center setting, which may have hampered the generalizability. Furthermore, no information was obtained from patients who refused to participate. Information from a non-participating group of patients would give a more balanced view of the perceived barriers to the HM program and to the feasibility of the program.

Another limitation was that exercise adherence and performance levels were reported on the basis of patients' self-reported data (diaries). Use of paper diaries to capture patient experiences are favored due to familiarity, ease of use, low cost, and allowing locus-of-control by the patient. However, intentionally or not, many individuals may have difficulty keeping faithful records.

Furthermore, the data may have been influenced by social desirability effects [61,62] and may not truly reflect the user's experience and dose. Ideally, self-reports should be supplemented using alternative objective sources of data, such as usage statistics (number of log-ins, frequency, duration, activities completed, time spent online, pages opened), combined with qualitative measures, such as semi structured telephone interviews [63,64].

Though strengths of the present study include high uptake, the position of both the researcher and participant need to be considered. As typical of evaluative research, the interaction between an evaluator and participant may have produced an understanding that portrayed the feasibility in an excessively positive light. Hence, future research will focus on consistency of the barriers and facilitators perceived by participants with findings from quantitative analysis of adherence and the impact of different HM formats [65].

Finally, we explored barriers and facilitators to adherence. The qualitative nature of these data in this study did not enable us to identify the barriers and facilitators that would make the largest contribution to the adherence with and compliance to the self-help program. Further quantitative research is therefore needed.

CONCLUSIONS

This feasibility study demonstrated that a multimodal guided self-help exercise program HM is feasible for HNC patients undergoing (C)RT. Feasibility of the exercise program in HNC patients is supported by high uptake (83%) and a reasonable adherence (64%). Several barriers (decreased physical condition, treatment-related barriers) and facilitators (increased physical condition, feeling motivated) were identified providing directions for future studies. Because HM is feasible, a study will be carried out investigating the (cost-)effectiveness of self-help exercises among HNC patients to prevent speech, swallowing, and shoulder problems after treatment.

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4

PROPHYLACTIC EXERCISES AMONG HEAD AND NECK CANCER PATIENTS DURING AND AFTER SWALLOWING SPARING INTENSITY MODULATED RADIATION: ADHERENCE AND EXERCISE PERFORMANCE LEVELS OF A 12-WEEK GUIDED HOME-BASED PROGRAM

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Submitted

ABSTRACT

Objective

The aim of this study was to investigate adherence, exercise performance levels and its associated factors in head and neck cancer (HNC) patients following a guided home-based prophylactic exercise program 'Head Matters'(HM) during and after treatment with swallowing sparing intensity modulated radiation therapy (combined with chemotherapy) ((C)SW-IMRT).

Methods

Fifty patients followed HM to prevent swallowing, speech, and shoulder problems. Adherence (percentage of patients who kept up exercising) and exercise performance level (categorized as low: ≤1, moderate: 1-2, and high: ≥2 time(s) per day, on average) were assessed using patient-completed diaries. Associations between 6- and12-week exercise performance levels (low vs moderate/high), and age, gender, tumor site and stage, treatment, format, amount of coaching sessions and baseline HNC specific symptoms (EORTC QLQ-H&N35) were investigated. Changes in exercise performance levels in relation to each of these symptoms (at weeks 1 to 6, and at 12 weeks) were analyzed.

Results

Six- and 12-week adherence rates were 70% and 38% respectively. Exercise performance levels were most frequent low (during 6 weeks: 40%; during 12 weeks: 54%), and decreased over time (during 6 weeks: 34% moderate and 26% high; during 12 weeks: 28% moderate and 18% high). The addition of chemotherapy to SW-IMRT (CSW-IMRT) was the only factor significantly associated with low exercise performance level during 6 weeks (*P*=.015) and 12 weeks (*P*<.001).

Conclusions

Adherence to a guided home-based prophylactic exercise program is high during (C)SW-IMRT but drops afterwards. Exercise performance levels vary and are especially low in patients treated with chemotherapy in combination with SW-IMRT.

INTRODUCTION

The number of head and neck cancer (HNC) patients treated with organ preservation protocols, aiming to improve loco-regional tumor control and overall survival [1-3] is increasing. However, radiotherapy (RT) has a significant toxicity profile, particularly when combined with chemotherapy (CRT) [4]. Treatment-related side-effects, such as xerostomia, taste changes, oesophageal strictures, mucositis, fatigue, fibrosis and swelling of laryngeal and pharyngeal soft tissues, trismus, and pain may have a severe impact on patients [5]. These side-effects affect swallowing, speech, and shoulder function, interfere with patient's activities, and have a deteriorating effect on health related quality of life (HRQOL) [6-10]. The introduction of intensity modulated radiation therapy (IMRT) allows for more conformal dose distribution, aiming to minimize the dose to the surrounding healthy tissues, especially to the parotid glands [11], leading to improved HRQOL [12]. In later stages, attempts were made to also spare other organs at risk (OARs), such as the submandibular glands [13], and the swallowing structures [14]. Van der Laan et al [1,14] demonstrated that, compared to standard IMRT, reduction of the dose to the swallowing OARs (SWOARs) has the potential to reduce the risk on swallowing problems through swallowing sparing IMRT (SW-IMRT). It is hypothesized that patients should be encouraged to maintain oral intake and to perform exercises to promote ongoing use of the muscles in the head and neck area, and of the swallowing and speech mechanisms during and after treatment ('Eat and exercise') [15,16]. Therefore, we developed a guided home-based prophylactic exercise program 'Head Matters' (HM) [17], to enhance the potential benefits of SW-IMRT and to prevent swallowing, speech and shoulder problems.

Traditionally, strategies for swallowing, speech and shoulder rehabilitation following treatment are provided after problems have occurred [18]. However, it has been suggested to start prophylactic exercise programs before and during active treatment [15,16,19-27]. Offering HNC patients a prophylactic exercise program to perform exercises for swallowing, speech, and shoulder muscles may delay the decline of lean muscle mass [28] in the head and neck area, and may limit the extent of post-treatment impairment [15,19,29], eventually leading to improved HRQOL [15,16,21-27,30].

The current literature on the feasibility of prophylactic exercises in HNC patients is, however, heterogeneous, and patients' adherence to prophylactic exercises during active treatment seems to be a challenge, given the various adherence rates of 13-71% [17,21,25,31-33]. Treatment-related and patient-related factors may limit patients' ability to adhere to (prophylactic) exercises. In our earlier report on the feasibility of a guided home-based prophylactic exercise program during 6 weeks of (adjuvant) (C)RT, HNC patients mentioned several barriers to exercise, such as a decreased general physical condition, a decreased condition of the head and neck, motivational issues, and treatment-related barriers [17]. A limitation of that study was the qualitative nature of the data, which made it difficult to identify associating factors with exercise performance levels. Also, patients in that study were not treated with SW-IMRT.

Since little is known about the factors associated with exercise performance levels in HNC patients undergoing SW-IMRT, the purpose of the present study was (1) to investigate adherence to a

12-week home-based exercise program during SW-IMRT, (2) to investigate exercise performance levels, (3) to investigate whether demographic or clinical factors and HNC specific HRQOL at baseline are associated with exercise performance levels, and (4) to investigate whether exercise performance levels are associated with the course of HNC specific HRQOL during the entire 12-week exercise program.

MATERIAL AND METHODS

Design

A prospective clinical cohort study.

Patients

The study population was composed of HNC patients planned for SW-IMRT between 2011 and 2013 in the VU University Medical Center (VUmc), Amsterdam, The Netherlands. Patients had to fulfil the following criteria: (1) age ≥ 18 years, (2) cancer originating in the oral cavity, oropharynx, hypopharynx, or larynx, (3) SW-IMRT alone or in combination with chemotherapy ((C)SW-IMRT), (4) performance status 0-2 on the World Health Organization Scale [34], (5) absence of severe cognitive impairment, and (6) sufficient mastery of the Dutch language. Patients who previously underwent surgery, RT or CRT, who had prior malignancies, and/or distant metastases were excluded. Patients with RTOG grade 2-4 swallowing dysfunction (according to the RTOG/EORTC Radiation Morbidity Scoring Criteria for dysphagia with grades ranging from 0 to 5 [35] at baseline were also excluded to ensure that the observed swallowing dysfunction was induced by RT and not by tumor extension.

Patients were treated with curative intent using (C)SW-IMRT. In all patients, parotid glands and swallowing structures were spared when possible, without compromising the dose to the target volumes. A simultaneous integrated boost technique was used with bilateral elective irradiation of the neck nodes to a total dose of 57.75 Gy, using a dose per fraction of 1.65 Gy. The primary tumor and pathological lymph nodes were treated to a total dose of 70 Gy, in fractions of 2 Gy. Chemotherapy was given concurrently with radiotherapy and consisted generally of cisplatin 100 mg/m2 intravenously on days 1, 22 and 43.

The study was approved by the ethical committee of the VU University Medical Center Amsterdam. Written informed consent was obtained from all participating patients.

Intervention

The guided home-based exercise program Head Matters (HM) targeting prevention of swallowing, speech, and shoulder problems was developed by a team of health care professionals consisting of speech and swallowing therapists, head and neck surgeons, radiation oncologists, and physiotherapists. HM consists of a 15-minute per day program with four categories of prophylactic exercises: (1) exercises to maintain mobility of the head, neck, and shoulders (e.g., 'Moving shoulders up and down', 'Circling shoulders forward and backward') ('Shoulder'), (2) exercises to optimize and maintain swallowing function (e.g., 'Swallowing with strength: effortful swallow', 'Taking sips of water regularly' ('Swallow'), (3) exercises to optimize and maintain vocal health and vocal function (e.g., 'Humming with gradually increased volume, and with exaggerated jaw movement', 'Slide up the pitch scale as high as possible' (Falsetto exercise) ('Voice'), and (4) exercises to optimize and maintain speech function and functional communication (e.g., 'Articulate each syllable', 'Stretching the tongue out straight') ('Speech'). HM informs the patient on possible swallowing, speech and shoulder problems during treatment, aims to prevent these problems to occur, and encourages patients to perform exercises in order to maintain function [17]. HM is available in two different formats: (a) online [36] with general information about HNC, with a written description of the exercises, and with photo and video examples of the exercises, (b) a 28-paged booklet, with the same information as the online version, with photo examples of the exercises, and a 15-minute instructional DVD with video examples of the exercises.

Before patients start HM at home, a 15-minute face-to-face instruction session by a speech and swallowing therapist is planned on the first day of (C)SW-IMRT. Each exercise is demonstrated appropriately, by giving the participants adequate instructions on each exercise, and by providing an instruction booklet (with DVD), or a log-in code to activate an account for the website. Also, remote coaching is offered in weekly 10-minute coaching sessions by an experienced speech therapist by phone. Patients are asked to fill out a diary on paper or online for 12 weeks. In their diaries, patients note which exercises (of the four exercise categories) they performed, and the frequency of exercising (1, 2, or 3 times per day).

Measures

A study specific survey was composed comprising items on sociodemographic data (age, gender, HM format, amount of coaching sessions) and on HNC specific HRQOL (EORTC-QLQ-H&N35). The EORTC-QLQ-H&N35 module covers specific HNC issues and comprises 7 subscales: pain (4 items), swallowing (5 items), senses (2 items), speech (3 items), social eating (4 items), social contact (5 items) and sexuality (2 items). According to the EORTC guidelines, the scores of the EORTC-QLQ-H&N35 are linearly transformed to a scale of 0-100, with a higher score indicating a higher (i.e., more positive) level of functioning, or a higher (i.e., more negative) level of symptoms or problems [37].

This survey was assessed at baseline (T0), every week from the 1st till the 6th week of treatment with (C)SW-IMRT (T1-T6), and 6 weeks after treatment (T7). Clinical data (tumor site, tumor stage, treatment modality) were abstracted from the hospital information system.

Adherence

Adherence concerned the percentage of patients who started and kept up with the HM exercise program at least once a day across a 6 and 12-week period during and after treatment with (C)SW-IMRT. Adherence was assessed using patient-completed diaries.

Exercise performance levels

To gain insight into the course of exercise performed per patient, exercise performance levels per week as well as over 6 and over 12 weeks were analyzed.

Exercise performance was categorized in three groups: low, indicating an average exercise performance of all exercise categories at most once a day, moderate, with an average between once and twice a day, and high, with an average of at least twice a day for all exercise categories.

To gain insight into which exercise category was performed most often, the diaries were analyzed in detail regarding frequency of exercising (1-3 times) and type of exercise (‘Shoulder’, ‘Swallow’, ‘Voice’, ‘Speech’).

Factors associated with exercise performance level

Data were collected on gender, age, tumor site (oral cavity, oropharynx, hypopharynx, larynx), tumor stage (I, II, III, IV), treatment modality (SW-IMRT or CSW-IMRT), format (online or booklet), coaching (amount of sessions), and on HNC specific HRQOL (EORTC-QLQ-H&N35).

Data analysis

Descriptive statistics were used to summarize adherence, exercise performance levels, amount of coaching sessions, demographic and clinical characteristics, and HNC specific HRQOL (EORTC-QLQ-H&N35).

A chi-square test was used to examine differences in exercise performance level at 6 and 12 weeks (low vs moderate/high), regarding gender (male vs female), tumor site (oral cavity/oropharynx vs hypopharynx/larynx), tumor stage (stage I/II vs stage III/IV), treatment modality (RT vs CRT), and format (booklet vs online). Fisher’s Exact tests were used when the assumption of the expected value of each cell of 5 or higher was not met. Independent samples *t*-tests were used to investigate differences in exercise performance level at 6 and 12 weeks (low vs moderate/high) regarding age, and Mann Whitney *U* tests regarding the amount of coaching sessions (at 6 or 12 weeks), and HNC specific HRQOL at baseline (EORTC-QLQ-H&N35).

Generalized estimating equations (GEEs) with a logit link function and autoregressive correlation matrix of the first order (AR(1)) were used to analyze the longitudinal changes in exercise performance level (low vs moderate/high) per week in relation to each of the symptom subscales of the EORTC-QLQ-H&N35. The model included both the current value of the symptom subscales as well as the lagged value (i.e. the value of the symptom subscale at the previous assessment) of the symptom subscale. Confounding factors were added as fixed effects in the model.

Data were analyzed using IBM SPSS Statistics for Windows, version 22. For all analyses, $P<.05$ was considered statistically significant.

RESULTS

Participants

One hundred and two patients were eligible during the study period. Thirty-seven patients did not participate (36%). Of these 37 patients, 19 were not willing to exercise, 12 refused to fill out any questionnaires, and 6 declared to be unfit to exercise. Five patients were excluded. Of these 5 patients, one patient was excluded because of treatment with postoperative (C)SW-IMRT, and 4 patients did not receive SW-IMRT. Of 60 patients who performed the exercises, 10 diaries were not available, leaving a study sample of 50 patients. Table 1 shows the demographic, tumor and treatment characteristics of the study population, and the HM format that participants chose (online or booklet). Of 50 patients 78% was male, and 22% was female. The mean age of participants was 61 years (range 40-77). Tumor sites included oropharynx (60%), larynx (30%), and hypopharynx (10%). Of all participants, 46% was treated with SW-IMRT, and 54% with CSW-IMRT.

Table 1. Demographic and clinical characteristics (*n*=50)

Age	
Mean age, years (range)	61 (40-77)
	n (%)
Gender	
Male	39 (78)
Female	11 (22)
Tumor site	
Oropharynx	30 (60)
Larynx	15 (30)
Hypopharynx	5 (10)
Tumor stage	
I	4 (8)
II	3 (6)
III	17 (34)
IV	26 (52)
Treatment	
SW-IMRT	23 (46)
CSW-IMRT	27 (54)
HM format	
Online	26 (52)
Booklet	24 (48)
12-week coaching sessions	
Median (range)	9 (4-12)

Adherence

Of 50 patients, 35 patients started and kept up exercising across the first 6 weeks (6-week adherence rate of 70%) and 19 patients kept up exercising up to 12 weeks (12-week adherence rate of 38%).

Exercise performance level

Table 2 presents the 12-week exercise performance levels, and exercise performance levels per week of all 50 individual patients (the total number of exercises performed per week ranged from 0 to 84 (4 exercise categories 3 times per day for 7 days)).

Of all patients (*n*=50), 20 patients (40%) had a low 6-week exercise performance level (the total number of performed exercises over 6 weeks ranged from 1 to 168 exercises in total), 17 (34%) had a moderate (ranging from 169 to 336 exercises), and 13 (26%) had a high exercise performance level (ranging from 337 to 504).

Of all 50 patients, 27 patients (54%) had a low 12-week exercise performance level (ranging from 1 to 336 exercises), 14 (28%) had a moderate (ranging from 337 to 672 exercises), and 9 (18%) had a high exercise performance level (ranging from 673 to 1,008 exercises).

Figure 1 presents the weekly exercise performance by exercise category. Patients most often performed the exercises to maintain mobility of the head, neck and shoulders (category 1 'Shoulder') and the exercises and strategies to optimize, and to maintain swallowing function (category 2 'Swallow').

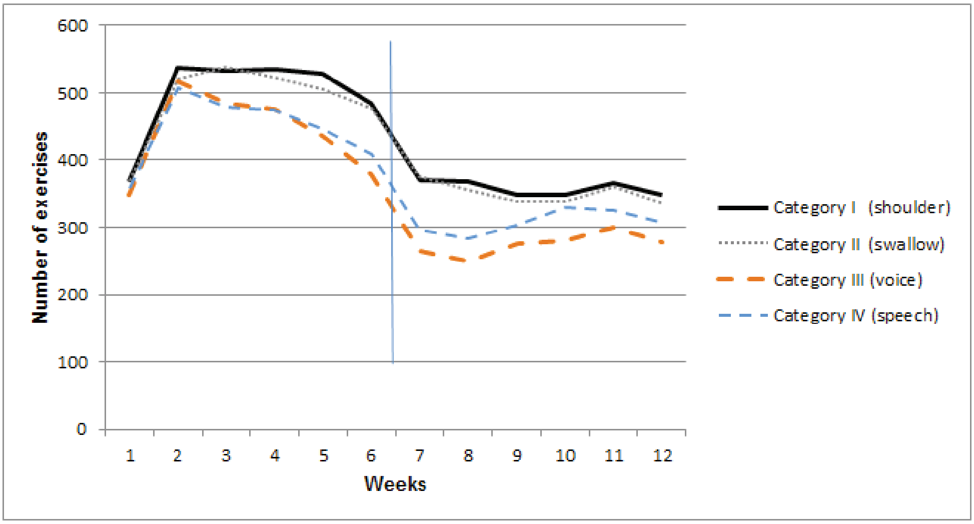

Figure 1. Total number of weekly performed exercises by exercise category (*n*=50)

Factors related to exercise performance levels

Table 3 shows the 6- and 12-week exercise performance levels in relation to demographic and clinical factors, HM format and to the median number of coaching sessions. Significantly more patients treated with chemotherapy (CSW-IMRT) had a low exercise performance level over the first 6 weeks compared to patients who were treated with SW-IMRT alone (56% vs 22%, *P*=.015) as well as over the entire 12 weeks (78% vs 26%, *P*<.001). Exercise performance levels during 6 and 12 weeks were not significantly associated with age, gender, tumor site, tumor stage, HM format or amount of coaching sessions.

HNC specific HRQOL at baseline was not associated with exercise performance level during or after treatment (Table 4).

Changes in exercise performance levels per week in relation to the value of the EORTC QLQ-H&N35 subscales in the previous week were analyzed. Exercise performance level was significantly related to the symptom item 'Problems with mouth opening': experiencing more problems with mouth opening in the previous week yielded lower odds for a moderate to high exercise performance level in the next week (OR (95% CI) = 0.91 (0.84-0.99), *P*=.037 (Table 5)). This means that the more problems a patient experiences with opening his mouth in the previous week, the more likely it is he will have a lower exercise performance level the next week. However, after correcting for treatment modality (SW-IMRT vs CSW-IMRT), this significant effect of problems with mouth opening disappeared (*P*=.16).

Table 2. Participant's weekly and 12-week exercise performance levels (*n*=50)

Patient number	Format	Week number												Total number of exercises performed	12-week exercise performance level
		1	2	3	4	5	6	7	8	9	10	11	12		
73	ONLINE	0	0	0	4	0	0	0	0	0	0	0	0	4	Low (1-336)
9	ONLINE	0	0	8	0	0	0	0	0	0	0	0	0	8	
74	ONLINE	0	0	0	0	12	0	0	0	0	0	0	0	12	
106	BOOK	0	12	0	0	0	0	0	0	0	0	0	0	12	
76	BOOK	15	0	0	0	0	0	0	0	0	0	0	0	15	
132	ONLINE	0	0	8	4	4	0	0	0	0	0	0	0	16	
44	BOOK	0	0	11	11	9	5	7	6	5	6	7	6	73	
69	BOOK	12	23	24	16	0	0	0	0	0	0	0	0	75	
154	ONLINE	16	14	25	21	6	7	0	0	0	0	0	0	89	
150	ONLINE	0	8	4	12	8	0	16	16	12	16	4	0	96	
40	ONLINE	0	0	0	29	21	3	15	17	15	12	0	0	112	
183	BOOK	34	7	10	8	7	7	7	7	7	7	7	7	115	
155	BOOK	12	12	6	11	12	12	13	11	12	11	11	9	132	
109	ONLINE	44	12	0	0	0	0	0	0	0	0	40	56	152	
96	BOOK	3	8	9	1	32	31	4	17	20	15	18	19	177	
151	BOOK	8	28	16	17	14	14	14	15	18	18	18	14	194	
80	BOOK	28	36	40	12	4	8	4	16	24	12	20	16	220	
38	ONLINE	24	40	48	44	48	40	0	0	0	0	24	0	268	
149	BOOK	40	47	28	48	36	28	0	0	28	0	12	4	271	
137	BOOK	16	28	29	25	26	30	17	34	30	28	23	0	286	
95	BOOK	18	24	26	18	28	19	24	24	28	24	25	28	286	
78	BOOK	29	39	36	32	28	32	25	1	4	10	28	28	292	
55	ONLINE	12	63	48	51	20	20	12	8	4	16	28	28	310	
130	ONLINE	34	34	49	41	34	15	30	49	15	0	12	0	313	
45	BOOK	48	56	56	56	56	24	20	0	0	0	0	0	316	
37	BOOK	36	84	84	36	24	56	0	0	0	0	0	0	320	
110	ONLINE	24	28	28	16	28	28	28	28	28	28	28	28	320	
107	ONLINE	32	12	32	50	28	25	33	43	25	27	23	20	350	Moderate (337-672)
71	ONLINE	21	72	61	64	47	50	44	27	0	0	0	0	386	
97	ONLINE	48	56	52	40	36	36	32	8	0	36	32	28	404	
75	BOOK	36	84	56	56	56	56	0	0	12	28	28	28	440	
57	ONLINE	28	56	52	58	52	40	28	28	36	20	28	24	450	
170	BOOK	72	84	84	72	72	69	0	0	0	0	0	0	453	
134	BOOK	57	63	67	60	60	66	47	44	0	0	0	0	464	
39	BOOK	0	0	48	48	48	48	40	56	48	48	48	48	480	
94	ONLINE	44	68	54	46	28	32	36	30	36	56	56	56	542	
118	ONLINE	64	84	84	84	84	69	63	16	0	0	0	0	548	
22	BOOK	48	70	28	28	28	12	0	0	84	84	84	84	550	
14	ONLINE	39	55	66	56	59	46	17	25	42	50	53	49	557	
186	ONLINE	63	66	60	48	60	54	55	53	46	46	9	0	560	
187	BOOK	72	84	84	84	84	76	67	52	8	0	0	0	611	
93	ONLINE	0	64	80	84	80	68	53	28	36	36	64	80	673	High (673-1,008)
168	ONLINE	0	28	36	84	84	81	63	63	63	63	63	63	691	
129	ONLINE	0	24	50	76	80	84	43	38	84	80	84	84	727	
20	BOOK	48	84	42	42	84	72	84	84	84	84	84	84	876	
182	ONLINE	52	80	84	84	66	60	64	75	79	80	76	84	884	
133	ONLINE	64	84	80	80	72	84	60	84	84	84	64	44	884	
72	BOOK	72	84	84	84	84	75	75	84	84	84	84	84	978	
167	BOOK	60	84	84	84	84	84	84	84	84	84	84	84	984	
70	ONLINE	72	84	84	84	84	84	84	84	80	84	84	84	992	

0 = non-active (does not perform any exercises)
84 = high performance (i.e. 4 exercise categories 3 times per day for 7 days)

Table 3. Six- and 12-week exercise performance levels (low vs moderate/high) in relation to demographic and clinical factors

	Low level after 6 weeks N (%)	Moderate to high level after 6 weeks N (%)	*P* value	Low level after 12 weeks N (%)	Moderate to high level after 12 weeks N (%)	*P* value
	20 (40)	30 (60)		27 (54)	23(46)	
Age			.48			.12
Mean age, years (range)	60 (46-76)	62 (40-77)		59 (40-76)	63 (50-77)	
Gender			.74			.97
Male	15 (38)	24 (62)		21 (54)	18 (46)	
Female	5 (45)	6 (55)		6 (54)	5 (46)	
Tumor site			.56			.64
Oropharynx	13 (43)	17 (57)		17 (57)	13 (43)	
Larynx / Hypopharynx	7 (35)	13 (65)		10 (50)	10 (50)	
Tumor stage			1.00			.69
I / II	3 (43)	4 (57)		3 (43)	4 (57)	
III / IV	17 (40)	26 (60)		24 (56)	19 (44)	
Treatment			.015			<.001
SW-IMRT	5 (22)	18 (78)		6 (26)	17 (74)	
CSW-IMRT	15 (56)	12 (44)		21 (78)	6 (22)	
HM format			.42			.25
Online	9 (35)	17 (65)		12 (46)	14 (54)	
Booklet	11 (46)	13 (54)		15 (63)	9 (37)	
Weekly coaching sessions			.18			.63
Median (range)	5 (3-6)	4 (2-6)		9 (4-12)	9 (4-12)	

Table 4. Six- and 12-week exercise performance levels (low vs moderate/high) in relation to HNC specific HRQOL at baseline

EORTC-QLQ-H&N35	Low level after 6 weeks	Moderate to high level after 6 weeks	*P* value	Low level after 12 weeks	Moderate to high level after 12 weeks	*P* value
	N=20 (40%)	N=30 (60%)		N=27 (54%)	N=23 (46%)	
	Mean (SD)			Mean (SD)		
Oral pain	26.2 (22.0)	30.3 (28.5)	.83	27.5 (26.2)	30.1 (26.1)	.61
Swallowing problems	17.5 (22.1)	20.8 (24.2)	.52	19.4 (24.8)	19.6 (21.8)	.70
Sense problems	7.5 (16.6)	3.9 (12.9)	.18	7.4 (16.8)	2.9 (10.8)	.20
Speech problems	16.7 (23.8)	22.6 (26.8)	.31	16.9 (22.7)	24.1 (28.5)	.27
Problems with social eating	10.0 (12.8)	14.2 (21.6)	.83	13.9 (21.2)	10.9 (15.2)	.75
Problems with social contact	7.3 (10.8)	9.8 (17.6)	.95	8.4 (14.1)	9.3 (16.5)	.81
Teeth problems	11.7 (22.4)	22.2 (35.4)	.38	16.0 (28.3)	20.3 (34.4)	.81
Problems with mouth opening	5.0 (12.2)	14.4 (31.2)	.51	9.9 (24.1)	11.6 (27.7)	.99
Dry mouth	10.0 (15.7)	11.1 (22.0)	.86	11.1 (22.6)	10.1 (15.7)	.79
Sticky saliva	20.0 (25.1)	12.2 (23.9)	.18	21.0 (29.4)	8.7 (15.0)	.16
Coughing	20.0 (19.9)	18.9 (20.9)	.80	19.7 (19.1)	18.8 (22.1)	.75
Feeling ill	11.7 (16.3)	16.7 (24.4)	.61	13.6 (19.1)	15.9 (24.3)	.86

Table 5. Course of HNC specific HRQOL in relation to weekly exercise performance level (low vs moderate/high) during 12 weeks

EORTC-QLQ-H&N35	Current value			Lagged value		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Oral pain	1.03	0.94 - 1.12	0.57	0.93	0.81 - 1.06	0.26
Swallowing problems	1.07	0.97 - 1.19	0.19	0.90	0.80 - 1.01	0.063
Sense problems	1.04	0.92 - 1.18	0.56	0.94	0.83 - 1.06	0.31
Speech problems	0.95	0.85 - 1.07	0.41	0.94	0.84 - 1.04	0.22
Problems with social eating	1.09	0.95 - 1.24	0.22	0.85	0.71- 1.01	0.058
Problems with social contact	0.81	0.65 - 1.02	0.068	1.04	0.89 - 1.21	0.65
Teeth problems	1.04	0.92 - 1.17	0.55	0.95	0.86 - 1.06	0.39
Problems with mouth opening	0.95	0.82 - 1.09	0.43	0.91	0.84 - 0.99	**0.037***
After correcting for treatment	0.96	0.81 - 1.13	0.59	0.93	0.84 - 1.03	0.16
Dry mouth	0.97	0.85 - 1.11	0.70	0.93	0.83 - 1.03	0.16
Sticky saliva	0.96	0.87 - 1.07	0.46	0.92	0.81 - 1.04	0.16
Coughing	1.04	0.95 - 1.13	0.43	0.91	0.81 - 1.0	0.080
Feeling ill	0.97	0.87 - 1.07	0.54	1.00	0.91 - 1.11	0.99

OR = odds ratio for moderate/high performance level per increase of 10 points on the subscale. *$P<0.05$

DISCUSSION

The key findings of this study are that in HNC patients treated with (C)SW-IMRT adherence to a guided home-based prophylactic exercise program was high in the first 6 weeks (70%), but dropped after completion of treatment. Exercise performance levels varied and were especially low in patients treated with chemotherapy in combination with SW-IMRT compared to those treated with SW-IMRT only. Results also showed that problems with mouth opening in the previous week were a risk factor for a lower exercise performance level the next week. However, after correcting for type of treatment, this significant effect disappeared, implying that changes in exercise performance levels are mainly due to type of treatment.

Few studies have investigated exercise adherence rates among HNC patients during treatment. These studies have yielded inconsistent findings with adherence rates ranging from 13% to 71% [17,21,25,31-33]. This variety of adherence percentages may be a matter of definition. In the present study we made use of a rather rigid definition of adherence. Adherence was viewed as a dichotomous outcome with a pre-specified threshold value. This means for instance that a patient who was adherent to the program for 6 weeks and took a break from exercise for a week but continued to exercise for the next 5 weeks, was defined as non-adherent. Adherence can also be viewed as a categorical or as a continuous outcome (the total amount of exercise performed or the percentage of exercises completed [38]. In our opinion, however, only percentage of actual exercise activity over an expected exercise activity, or the amount of exercise sessions completed at the prescribed level divided by the total number of exercise sessions prescribed, reflects the essence of adherence [39].

It is suggested that higher adherence rates are associated with weekly face-to-face follow-up, or weekly follow-up by telephone or e-mail [32]. To overcome the problem with low adherence, a more frequent supervision by a health care professional could therefore be an option [25]. However, our study showed no significant association between amount of coaching sessions and exercise performance levels (as a proxy measure of adherence). Further research is needed regarding how to optimize patient adherence, and patient engagement during treatment.

Besides insight into adherence to an intervention it is also interesting to have a closer look on how well patients perform. Therefore, exercise performance levels were analyzed. Our study showed that of 50 participating HNC patients, forty percent had a low 6-week prophylactic exercise performance, while more than half of participants had a low 12-week exercise performance. In only a few studies exercise performance levels during (C)RT were reported. In a study of Mortensen [32] evaluating the impact of home-based prophylactic swallowing exercises on swallowing-related outcomes in HNC patients treated with curative RT, more patients (53 percent) than in our study had low 5-week exercise performance levels. In a retrospective observational study of Hutcheson [15], evaluating the independent effect of maintaining oral intake during (C)RT among patients with pharyngeal cancer, 45 percent of adherent patients reported to have performed the prescribed prophylactic exercises more than 4 times per day. Fifty-five percent of adherent patients performed the exercises 4 or fewer times per day.

Our study showed that lower 6- and 12-week exercise performance levels were significantly associated with treatment modality (CSW-IMRT vs SW-IMRT). Additionally we found a progressively downward trend in prophylactic exercise performance, indicating that exercise performance levels were reduced as (C)SW-IMRT treatment advanced. Previous studies showed an increased symptom burden if chemotherapy was added to the treatment [5]. HNC patients undergoing CRT are experiencing several toxicities which may result in a reduction of the number of sets of prophylactic exercises completed [40].

In the present study we tested whether HNC specific HRQOL or symptoms were associated with exercise performance level. Study results showed that experiencing more complaints of a limited mouth opening during and after treatment with (C)SW-IMRT was a risk factor for lower exercise performance levels of home-based prophylactic exercises. A limited mouth opening is a well-known complication of HNC and its treatment [41]. Several studies have shown that a limited mouth opening (trismus), is negatively associated with HRQOL [42], significantly impacts activities of daily living, and is associated with speech problems, difficulty eating or drinking, malnutrition, and difficulty with oral hygiene [43]. This may influence motivation to exercise, resulting in low exercise performance levels. However, after correcting for type of treatment, this significant effect disappeared.

A limitation of this study was that the study sample consisted of motivated HNC patients who were committed to exercise and also to complete their exercise dairies. Study results may not be generalizable to a wider population of HNC patients who may feel less motivated. Another limitation of our study is that we included a relatively small number of participants (n=50) and therefore could not explore all factors that arose from our qualitative study, such as general physical condition, fatigue, and emotional problems as possible risk factors for lower exercise performance levels [17]. In the present study, we chose to focus on (deterioration of) HNC specific quality of life outcomes as possible barriers for exercise performance. To evaluate (other) factors possibly associated with exercise performance levels, larger studies should be conducted using objective functional measures (e.g. the degree of trismus) in addition to patient-reported outcomes [5,7]. Furthermore, daily exercise behaviour was self-reported by participants and therefore may be subject to bias. In an attempt to minimize bias, exercise logs were completed daily. It is not certain, however, that these instructions were followed.

The strengths of this study lies in the use of 6 and 12 week adherence data, and data on levels of exercise performance, extending the research on home-based prophylactic exercise interventions. There is growing evidence of the potential benefits of prophylactic exercises among HNC patients undergoing (C)RT [21,23-25,31]. Information on frequency and intensity of exercise performance (some of the fundamental metrics of exercise behaviour) [44], although easy to devise and report, are seldom included in published clinical trials, making collective conclusions about adherence rates and exercise performance difficult to draw [45]. Future trials should therefore include adherence and exercise performance level as possible mediating factors of (cost-) effectiveness.

CONCLUSION

Adherence of HNC patients to a guided home-based prophylactic exercise program during (C) SW-IMRT is high, but drops afterwards. Exercise performance levels vary and are especially low in patients who are treated with chemotherapy in combination with SW-IMRT.

Acknowledgment

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5

A PARTICIPATORY DESIGN APPROACH TO DEVELOP A WEB-BASED SELF-CARE PROGRAM SUPPORTING EARLY REHABILITATION AMONG PATIENTS AFTER TOTAL LARYNGECTOMY

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ABSTRACT

Objective

The aim of this study was to develop a web-based self-care program for patients after total laryngectomy according to a participatory design approach.

Methods

We conducted a needs assessment with laryngectomees (*n*=9) and their partners (*n*=3) by means of a focus group interview. In 4 focus group sessions, a requirement plan was formulated by a team of health care professionals (*n*=10) and translated into a prototype. An eHealth application was built including illustrated information on functional changes after total laryngectomy as well as video demonstrations of skills and exercises. Usability of the prototype was tested by end users (*n*=4) and expert users (*n*=10). Interviews were held to elicit the intention to use and the desired implementation strategy.

Results

Six main self-care topics were identified: (1) nutrition, (2) tracheostomy care, (3) voice prosthesis care, (4) speech rehabilitation, (5) smell rehabilitation, and (6) mobility of head, neck, and shoulder muscles. Expert users expressed concerns regarding tailored exercises, indicated a positive intent to implement the intervention in routine care, and expressed a need for guidance when implementing the intervention. End users and expert users appreciated the content completeness and multimedia-based information built into the application.

Conclusion

The participatory design is a valuable approach to develop a self-care program to help meet users’ needs.

INTRODUCTION

Following total laryngectomy, patients can encounter challenges while returning home [1,2]. Changes in altered airway, swallowing, taste, loss of voice and nasal function, difficulties in neck and shoulder movement, and social embarrassment have a profound effect on a patient's quality of life [3,4].

Self-management skill training is a critical element of rehabilitation, and is necessary in order to encourage patients to learn and apply new self-care skills [5]. The information and support needs of laryngectomees during the transition from hospital to home are extensive [6]. Meeting these needs is a complex task for health care professionals [7]. Providing eHealth (using information and communication technology, especially the Internet, to improve health care [8]) has the potential to be (cost-)effective, to improve quality of life, and to have beneficial effects on health literacy, decision-making, health care participation, psychological well-being, and physical activity levels [9,10]. Alongside usual care for laryngectomees, eHealth offers an innovative approach to promote self-care education [11] and has great potential to enhance recovery, improving hospital-to-home transition, accessibility of supportive care [12], and reintegration into the community [2]. However, to our knowledge there are no web-based self-care programs for patients after total laryngectomy.

The overall aim of this study was to develop and test the usability of a web-based self-care program for laryngectomees by means of a participatory design approach. To be effective in empowering patients' engagement, it is important to carefully match the program to their specific needs [13]. Expert and end user usability testing is essential to ensure that patients' needs are met and that patients are able to navigate the website appropriately and efficiently [14,15]. To anticipate potential adoption problems, it is important to include all stakeholders, such as health care professionals, during the entire developmental phase. In the present study, a 3-phase development life cycle method (Figure 1) was employed, incorporating end users' input with the expertise of health care professionals [16-19].

Recently, more attention has been paid to the development of eHealth technologies based on participatory development, co-design, and user-centered persuasive design techniques [13,17-19]. A participatory design approach to develop a web-based self-care program is rather new and has not often been put into practice in speech pathology and phoniatrics. There is thus a need for scientific studies reporting on the operationalization of these novel approaches in practice. The findings presented here may inform others designing or evaluating web-based self-care programs using a participatory design approach.

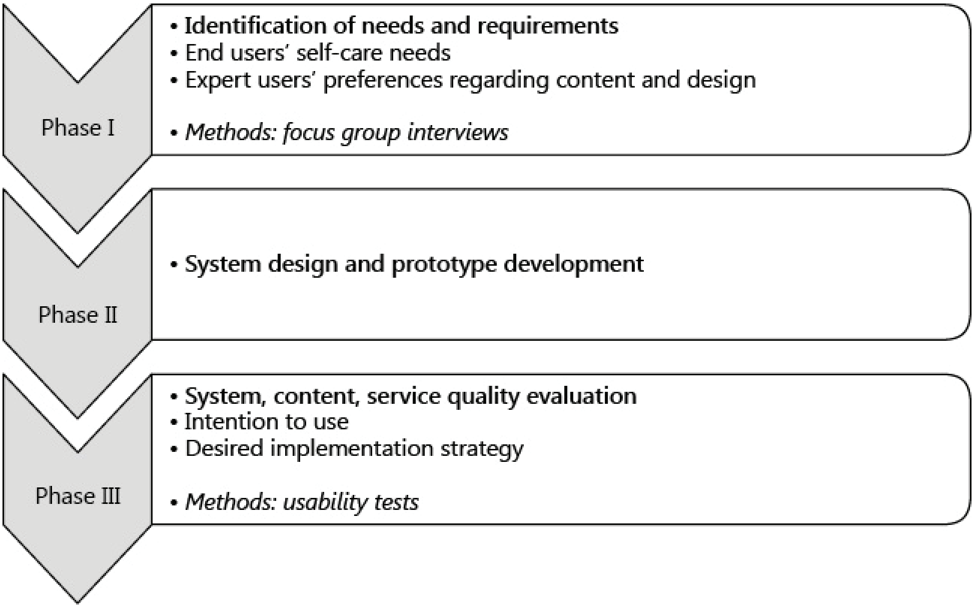

Figure 1. A 3-phase life-cycle method

PHASE I: IDENTIFICATION OF NEEDS AND REQUIREMENTS

METHODS

Patients' self-care needs after total laryngectomy

A focus group interview was held with patients (*n* =9, mean age 64.4 years, 6 male and 3 female) and their partners. Patients were recruited from the Dutch Patient Society for Laryngectomees [20]. The mean time elapsed since total laryngectomy was 11.6 years (SD 8.0, range 2-22). The interview lasted 120 min, was held at the VU University Medical Center (VUmc), Amsterdam, The Netherlands, and was conducted by 2 moderators following a topic guide (Table 1). In part 1 of the interview, needs regarding the management of illness and treatment side effects at home and perspectives regarding the future self-care program were identified. In part 2, the findings were presented to the participants in order to reflect on these and provide additional input [21].

Table 1. Interview topic guides

Focus group questions
(patients after total laryngectomy and partners)
1. 'What kind of self-care information and education was received after total laryngectomy?'
2. 'What was helpful and what was missing?'
3. 'What are the most important self-care information topics you need towards managing your illness and treatment side effects at home?'

Focus group questions
(health care professionals)
1. 'What do you find to be the biggest challenge in providing self-care information and education?'
2. 'Which problems do you currently encounter providing self-care support?'
3. 'What are the most important self-care topics concerning total laryngectomy you provide?'

Think-out-loud tasks during end user and expert user usability evaluation
Information search tasks
1. Search for information about the purpose of the web-based program, and how to use the program.
2. Search for information about 'Maintaining a healthy weight and maintaining physical fitness'.
3. Search for information about 'Esophageal speech'. Watch the demonstration video.

Cognitive tasks
4. Log into the private website (speech therapists). Navigate to your workbook, choose and perform exercise.
5. Indicate that you performed the exercise ('done'). Check your most recent update.
6. Watch the 'Jaw exercises' instruction video. Perform the 'Jaw exercises' (speech therapists).
7. Search for information about 'Voice prosthesis'.
   Watch the demonstration video 'How to clean your voice prosthesis' (speech therapists).
8. Log out (speech therapists).

Exit interview questions
(patients after total laryngectomy and speech therapists)
1. 'Do you consider yourself a potential user of the program?'
2. 'How and when should this self-care program be implemented within care as usual?'

Health care professionals' preferences regarding content and design

To gain better insight into health care professionals' requirements, we conducted 4 focus group interviews. Three male and 7 female health care professionals were recruited from a multidisciplinary expert team at the VUmc. The sample comprised 2 head and neck surgeons, 1 oncology nurse, 3 speech therapists, 1 physiotherapist, 1 dietician, 1 psychologist, and 1 medical social worker. The health care professionals on average had a working experience with total laryngectomy patients of 15 years (range 6-26). The interviews lasted 1 h, were held between April and August 2011, and were led by a moderator (I.C.C.) following a topic guide (Table 1).

Data Analysis

Field notes and meeting minutes of the focus group interviews with patients and their partners and with health care professionals were analyzed by 1 coder using thematic analysis.

RESULTS

Patients' self-care needs after total laryngectomy

Patients indicated that an online self-care program could be helpful and was expected to enable the delivery of trustworthy and up-to-date information about functional changes after total laryngectomy and of self-care strategies. Patients indicated that a self-care program should include video demonstrations of self-care skills and exercises for head, neck, and shoulder muscles, as well as exercises to reduce lymphedema. They emphasized that the program should send out a positive message. Patients and their partners identified 2 broad themes to be included in an online self-care program: (1) information on how to master treatment-related changes of physical function and (2) information on how to manage emotions. Six subthemes were identified under the physical function theme: (1) difficulty eating, (2) difficulty swallowing, (3) stiff neck and neck and shoulder pain, (4) lymphedema in the head and neck area, (5) difficulty speaking, and (6) tracheostomy and voice prosthesis care. One subtheme was identified under the theme managing emotions: psychosocial care (Table 2).

Table 2. Overview of end users' self-care needs

Information on how to master treatment-related changes of physical function		
1.	Difficulty eating	How to use tube feeding at home, on vacation What to do when having taste problems What to do when having chewing problems How to make nutritional, tasteful meals
2.	Difficulty swallowing	What to do when having swallowing problems during/after (chemo)radiation What to do when having a dry mouth What to do when having too much saliva
3.	Stiff neck, neck and shoulder pain	Get expert physiotherapist's instructions/feedback How to perform flexibility exercises
4.	Lymphedema in the head and neck area	Get expert lymphedema physiotherapist's instructions/feedback How to perform exercises for the head and neck area to reduce lymphedema
5.	Difficulty speaking	What to do when having speech difficulties during/after (chemo)radiation How to gain insight on speech rehabilitation options after total laryngectomy How to inform the partner about speech rehabilitation after total laryngectomy
6.	Tracheostomy and voice prosthesis care	How to choose and use the best adhesive stoma patches How to cope with thick mucus How to cough after total laryngectomy How to perform skin care around the tracheostomy [during (chemo)radiation] How to perform inner cannula care How to perform stoma care How to clean the voice prosthesis
Information on how to manage emotions		
7.	Psychosocial care	How to receive support from a health care professional, the partner, and/or family

Health care professionals' preferences regarding content and design

The health care professionals had strong ideas about concepts that should be incorporated into the self-care program. Despite thorough hospital discharge preparation, they indicated that patients still feel challenged in finding support and information on self-care at home. According to the health care professionals, the program should be developed as a support tool for problem-solving at home (troubleshooting) and to provide self-care information and education. The health care professionals suggested adding the subtheme 'smelling' to the theme 'physical functioning' to provide information about the possible relation of taste problems to smelling due to the absence of nasal airflow.

PHASE II: SYSTEM DESIGN AND PROTOTYPE DEVELOPMENT

METHODS

A prototype of 'In Tune without Cords' was created based on the needs assessment results. During prototype development, the team met regularly to provide feedback on several prototype versions.

RESULTS

Figure 2 provides details on the content of the 'In Tune without Cords' prototype.

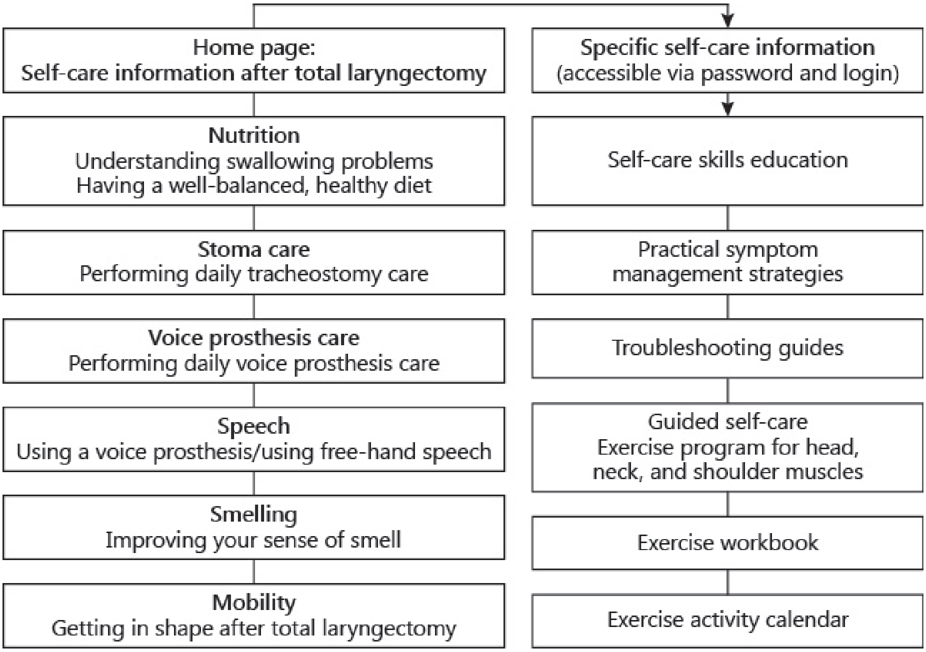

Figure 2. Overview of the website content

PHASE III: SYSTEM, CONTENT, AND SERVICE QUALITY EVALUATION

METHODS

End User Testing

Usability evaluations were conducted with end users (patients; *n*=4; 3 male and 1 female) recruited from the Dutch Patient Society for Laryngectomees [20] (*n*=3) and from the VUmc outpatient clinic (*n*=1). The patients had an average age of 63 years (SD 8.2, range 51-69). The mean time elapsed since total laryngectomy was 15.5 years (SD 10, range 1-24). The patients were asked to familiarize themselves with the 'In Tune without Cords' website and conducted a series of tasks while 'thinking out loud'. Task incompletion was monitored. To elicit the intention to use and the desired implementation strategy, interviews were held (Table 1). The usability evaluations were held at the VUmc, lasted between 36 and 80 min (mean 59.2, SD 20.7), and were recorded using Morae^{TM} software and transcribed verbatim.

Expert User Testing

Expert usability evaluations were conducted with a sample of 1 male and 9 female speech therapists recruited from 5 university medical centers. We asked speech therapists to participate as they play a vital role in pre- and postoperative care. The speech therapists on average had 16 years of working experience with laryngectomees (SD 7.9, range 1-26). They were asked to 'walk through' the application guided by scenarios and patients' user tasks. All expert-based usability evaluations were conducted in pairs. The interviews were held to elicit the intention to use and refer as well as the expert users' desired implementation strategy (Table 1). The expert usability evaluations were held at the speech therapists' workplace, lasted between 29 and 76 min (mean 62.8, SD 19.1), and were recorded using Morae software and transcribed verbatim.

Data Analysis

In analyzing the usability evaluations, we made use of transcripts supported by Morae recordings. The transcripts were coded by 2 coders who independently selected citations using a coding scheme concerning system quality (ease of use), content quality (usefulness and relevance), and service quality (the process of care provided) [22-25]. Next, the 2 coders met to discuss their findings and to resolve differences. They developed a framework in which (sub)themes were defined. After coding, the raw data were examined again to ensure that all data were reflected in the coding [26]. Quotes, which we included in this manuscript, were translated from Dutch into English and anonymized. Finally, statistics for task incompletion rates were computed.

RESULTS

System Quality

The laryngectomees and speech therapists appreciated the ease of access of 'In Tune without Cords' by its availability from home. The speech therapists emphasized that 'In Tune without Cords' would not be suitable for those without Internet access and those unmotivated (Table 3). Through clear navigation and presentation of information, the system was deemed easy to use even for inexperienced Internet users. The patients valued the efficient search functionality to find specific self-care information. The 'Read more' link to dose the information provided was appreciated. An unclear navigation aspect mentioned was a lack of orientation cues, not making the user's location on the site apparent. Video start buttons and instructions on how to fill out workbooks were reported to be missing. The speech therapists reported the theme 'Nutrition' to consist of too many subthemes. The patients and speech therapists both appreciated the use of engaging multimedia. The patients who acted in the demonstration videos were indicated to be seen as inspiring role models. The patients reported they valued the application as a helpful tool to learn how to cope with the functional changes: 'This would really be helpful. After surgery I had to figure it out all by myself.' According to the speech therapists, having to perform all exercises for a long period of time and to watch the same video repeatedly seemed excessive.

Content Quality

The patients and speech therapists indicated that 'In Tune without Cords' provides an accurate online source of relevant information and represents current views about self-care (Table 3). Inaccurate elements, such as usage of a photo of an old-fashioned stoma cover, were also mentioned. According to the speech therapists, some videos needed editing: 'You hear a voice telling you something about leakage and how you can monitor it. At the same time the ENT surgeon is doing completely different things.' According to the speech therapists, 'In Tune without Cords' could support the information provided by health care professionals: 'It may happen that health care professionals forget to provide all information to patients'. Texts were evaluated by patients as easy to read as well as complete: 'All you need to know about self-care after total laryngectomy'. The information provided was reported to be comprehensible. Negative comments of speech therapists were mainly on self-care information not reflecting their ideas. Furthermore, they reported that electrolaryngeal speech was demonstrated inadequately and that a 'voice prosthesis leakage animation' was missing.

Service Quality

The speech therapists indicated that offering head and neck exercises and informing on how to obtain good nutritional status could be beneficial (Table 3). Both patients and speech therapists reported that 'In Tune without Cords' would help patients to take ownership of care. The speech therapists indicated that the skills are being properly demonstrated utilizing videos: ‘It could help laryngectomees not to waste time doing the wrong things’. Negative comments of speech therapists were mainly on the unavailability of an implementation protocol and on an unclear job description: would they have to act as a guide or a coach, or would they be acting as a ‘Big Brother watching’? The speech therapists valued the provision of coaching by telephone or email. Online 24/7 support was valued by the patients. They expected that this could lead to increased confidence and reassurance as well as an increased ability to acquire self-care information at their own pace and to recognize minor symptoms early. Both patients and speech therapists stated that ‘In Tune without Cords’ could also be used to advise informal caregivers and health care professionals unfamiliar with total laryngectomy. Negative comments were reported by speech therapists having doubts regarding tailored exercises: ‘I wish I could compile an individualized list of exercises to recommend to my patients’ and regarding exercise performance quality. To enable monitoring of exercise performance quality, 1 patient suggested the introduction of Skype; to monitor quantity, the use of check marks was suggested by patients and speech therapists.

End Users’ Task Completion

Three users needed help with information search task 1 (Table 1). All patients were able to complete tasks 2 and 3 and the first cognitive task. One participant needed help navigating and filling out his workbook (task 4). None of the patients could complete cognitive task 5. The participants said they were hindered by unclear reference information.

Intention to Use and Refer

Overall, all intended to use and refer to ‘In Tune without Cords’ when available. According to some patients and speech therapists, ‘In Tune without Cords’ should be introduced at intake, i.e. *before* total laryngectomy. Others preferred to introduce it *after* total laryngectomy, i.e. before hospital discharge, serving as a starting point for follow-up care. The speech therapists considered themselves to be most suitable to introduce ‘In Tune without Cords’, because of their involvement in pre-rehabilitation.

Prototype Modification

Clear navigation instructions were added to the menu (e.g. ‘You are on the public website’). When clicked on, the color of the heading text changed, making the user’s location on the site apparent. Considering the theme ‘Nutrition’, the text amount on a webpage was re-sized, and meaningful subheadings were used. New animations and video demonstrations were implemented in the prototype. Due to financial and time restraints, we were unable to develop a ‘Frequently Asked Questions’ section and a ‘Voice prosthesis leakage animation’ and to edit the electrolaryngeal speech video.

Table 3. End user and expert user usability evaluation

Strengths	Weaknesses
System quality	
Ease of access	
Available	Unavailable
– at home (TLP*, ST#)	– for unmotivated TLP* and those without Internet (ST#)
Ease of use	
Clear navigation, presentation of information	Unclear navigation, presentation of information
– search functionality (TLP*) – ‘Read more’ link (TLP*, ST#) – eligible for inexperienced Internet user (TLP*) – right color palette (TLP*); good voice-overs (ST#) – online step-by-step self-care information (TLP*)	– lack of orientation cues: no video start button; low-contrast (un)selected headings (TLP*, ST#); where to begin on home page (ST#); how to fill out workbook (TLP*, ST#) – lack of overview (‘Speech methods’, ‘Nutrition’) (ST#)
Design persuasiveness	
Design related to user values, needs	Design not related to user values, needs
– engaging multimedia/inspiring role models (TLP*, ST#) – coping with functional changes after TL^ (TLP*)	– no need to watch same exercise video 3×/day (ST#) – no ‘Frequently Asked Questions’ section (TLP*) – unable to load exercise performance pie chart (ST#)
Content quality	
Accuracy	
Up-to-date, relevant information	Lack of up-to-date, relevant information
– represents current view about self-care (TLP*, ST#) – reference sources are provided (ST#)	– unavailable brochure (ST#) – old-fashioned stoma cover (TLP*, ST#) – voice prosthesis videos need editing (ST#)
Consensus based	
Standard-, theory-, or guideline-based information	Information not based on theory, standard, or guideline
– gathered by expert team (TLP*, ST#) – website with a professional look (ST#) – to support information provided by HCPs” (ST#)	– not all self-care advice reflects STs’ point of view (ST#), e.g., inadequate demonstration of electrolaryngeal speech (ST#)
Completeness	
Provision of sufficient information	Lack of sufficient information
– on 6 main self-care topics (TLP*, ST#)	– lack of ‘Voice prosthesis leakage’ animation (ST#)
Comprehensibility	
Information is clear, understandable	Lack of clear, comprehensible information
– readable/comprehensible texts (TLP*)	– dietician needs to clarify nutritional information (ST#)

Table 3. End user and expert user usability evaluation *(continued)*

Service quality	
Perceived usefulness	
Benefits	Drawbacks
– exercises/good nutritional status (ST#) are very important topics in 1st year after TL^ (TLP*) – to help TLP* take ownership of care (TLP*, ST#) – no waste of time doing the wrong things (ST#)	– unavailable implementation protocol (ST#) – website guidance needed: workload HCP” (ST#) – unknown role of HCP”: coach, coordinator? (ST#) – unpleasant role: ‘Big Brother is watching’ (ST#)
Operationalization	
Provision of prompt services; ability to give feedback or provide coaching	Lack of prompt services; not being able to give or get feedback or provide coaching
– by telephone or email (ST#); get (online) 24/7 guidance, support, reassurance, increased confidence when leaving hospital after TL^ (TLP*) – acquire self-care information at own pace (TLP*) – less need to have (hospital) meetings (TLP*, ST#) – early recognition of minor symptoms (TLP*) – on exercise performance *quantity* (ST#) – to remind TLP* to perform self-care (TLP*, ST#) – partnership between TLP* and HCP” (ST#) – to inform informal caregiver/care professional unfamiliar with TL^ (TLP*, ST#)	– by phone: TLP* may not use phone, because of speech problems (TLP*) – doubts on level of exercise tailoring (ST#) – some exercise programs target treatment phase (e.g. during radiation) and not specific symptoms – (ST#) on exercise performance *quality* (ST#): suggest – developing chat version or Skype with webcam (TLP*) on exercise performance *quantity*: suggest to use check marks (‘done’ = ✓) (TLP*, ST#)

TLP* = patient after total laryngectomy (end user); ST# = speech therapist (expert user);
TL^ = total laryngectomy; HCP” = health care professional.

DISCUSSION

The purpose of this study was to develop and test the usability of ‘In Tune without Cords’, aiming to support laryngectomees in their rehabilitation process. The participatory design approach used was fruitful. This approach resulted in more insight into patients’ self-care needs and in high levels of satisfaction among patients and speech therapists in the usability tests. While a couple of (web-based) interventions to promote self-management in head and neck cancer patients have been developed [27,28], ‘In Tune without Cords’ is the first web-based intervention to support laryngectomees, hereby fulfilling the reported need for a web-based self-care program [2]. Affecting motivation, skill building, and behavioral change demands instructional strategies that move beyond text on a screen. Multimedia can be particularly appropriate when an intervention includes motor skill building [29] and is expected to address patients’ self-care needs in a better way.

The needs and requirement assessments provided a good basis for informing the content and design of ‘In Tune without Cords’. In line with others [1,2], our study revealed that patients experience challenges in their rehabilitation process related to physical changes, in relation to psychological concerns [30], and with regard to integrating their new situation into their everyday life. Because of its low priority, ‘Information how to manage emotions’ was not included. Possibly, ‘In Tune without Cords’ could be linked to the website of the Dutch Patient Society for Laryngectomees [20], which provides a list of peer support groups or individuals willing to serve as contacts, as well as to an existing eHealth intervention available in the Netherlands targeting anxiety and depression in head and neck cancer patients [31].

Usability studies enable developers to discover problems with the web-based program, to explore end users’ experiences, and minimize the likelihood of end users having difficulties using the system [32]. The importance of usability tests for eliciting detailed information on user interaction has been demonstrated in several studies [33,16]. Usability studies typically involve 5-7 end users [34], since a sample of 5 end users reveals 85% of the problems [35]. Therefore, the sample of 14 users (4 laryngectomees and 10 speech therapists) in the present study was sufficient.

The study results did not show a clear position regarding by whom and when ‘In Tune without Cords’ should be introduced. According to some, it should be introduced *before* total laryngectomy, while others stated that it should be introduced *after*. A survey among head and neck cancer patients showed that patients were satisfied with pretreatment information, while a better preparation for the long-term effects on functioning and quality of life was suggested as an improvement [36]. Minimal evidence exists on how best to prepare patients for chronic treatment side effects, despite it being recommended as good clinical practice [37]. Further research is needed to identify the proper timing of implementation.

A limitation of this study is that only one multidisciplinary expert team was formed to gain insight into health care professionals’ perceived content requirements. Substantial differences between expert teams may exist, and care should be taken to consider different perceptions [38]. However, pairs of experts from 5 university medical centers performed the usability evaluations in order to tailor the content of the application. Strengths of this study are the stakeholders' engagement, co-creation with users [19], and focus on the next phase in the development process by inquiring factors that either impede or facilitate the implementation of this eHealth application in clinical practice.

The refined prototype of 'In Tune without Cords' will be used in a feasibility study. A feasibility study is needed to provide more insight into actual uptake before studying (cost-)effectiveness. When the program have been proven to be (cost-)effective, the next step will be its sustainable implementation in current clinical practice.

CONCLUSION

The participatory design is a valuable approach to develop a self-care program to help meet users' needs. The findings from this study were used to refine the prototype of 'In Tune without Cords'.

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6

AN ONLINE SELF-CARE EDUCATION PROGRAM TO SUPPORT PATIENTS AFTER TOTAL LARYNGECTOMY: FEASIBILITY AND SATISFACTION

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ABSTRACT

Objective

The aim of this study was to investigate the feasibility of an online self-care education program supporting early rehabilitation of patients after total laryngectomy (TLPs) and factors associated with satisfaction.

Methods

Health care professionals (HCPs) were invited to participate and to recruit TLPs. TLPs were informed on the self-care education program ‘In Tune without Cords’ (ITwC) after which they gained access. A study specific survey was used (at baseline T0 and post intervention T1) on TLPs’ uptake. Usage, satisfaction (general impression, willingness to use, user-friendliness, satisfaction with self-care advice and strategies, Net Promoter Score (NPS)), sociodemographic, and clinical factors were analyzed.

Results

HCPs of 6 out of 9 centers (67% uptake rate) agreed to participate and recruited TLPs. In total, 55 of 75 TLPs returned informed consent and the baseline T0 survey and were provided access to ITwC (73% uptake rate). Thirty-eight of these 55 TLPs used ITwC and completed the T1 survey (69% usage rate). Most (66%) TLPs were satisfied (i.e., score ≥7 (scale 1-10) on 4 survey items) with the self-care education program (mean score 7.2, SD 1.1). NPS was positive (+5). Satisfaction with the self-care education program was significantly associated with (higher) educational level and health literacy skills (*P*=.004, *P*=.038, respectively). No significant association was found with gender, age, marital status, employment status, Internet use, Internet literacy, treatment modality, time since total laryngectomy, and quality of life.

Conclusion

The online self-care education program ITwC supporting early rehabilitation is feasible in clinical practice. In general, TLPs are satisfied with the program.

INTRODUCTION

Laryngeal cancer is the second most common cancer of the upper aerodigestive tract [1]. Worldwide, it accounts for 130,000 new cases per year in men and 21,000 in women, with significant differences in incidence across countries [2]. In The Netherlands, ±700 persons are diagnosed with laryngeal carcinoma annually [3]. Each year, about 150 Dutch patients undergo total laryngectomy (TL) [4].

A TL is performed in patients with advanced laryngeal cancer or in patients with recurrent disease after treatment with (chemo)radiation. Patients who underwent TL (TLPs) face various physical and emotional challenges while returning home after surgery [5]. Changes in airway management, nasal function, swallowing and taste, loss of voice, neck and shoulder mobility problems, and impaired social functioning have a considerable impact on the quality of life of TLPs [6-9].

The provision of self-care education might be an effective strategy to adjust to these functional changes and to improve quality of life [10]. By providing access to clinician-generated self-care education via the Internet, patients can participate more effectively in their care and are supported in their information seeking [11-13]. The development and evaluation of tailored self-care education in a variety of forms, such as Internet and DVD, are urgently needed for patients who have undergone surgery for head and neck cancer (HNC) [14,15].

To bridge the transition from hospital to home and to support self-management during rehabilitation after TL, an online program 'In Tune without Cords' (ITwC) was developed, featuring a self-care education program and an exercise program. Both programs are provided with illustrated, tailored information and video demonstrations. To ensure that ITwC would adequately meet the needs of the end-users, a participatory design approach was followed, with stakeholders' involvement in the development process [16,17]. To guarantee the best utilization of the eHealth intervention, it is essential to be attentive to the usability, keeping in mind its intended users (e.g., clinicians, patients), task (e.g., medication management, self-management), and the environment (e.g., the outpatient clinic, at home) [18]. In a previous study on the usability of ITwC [19], TLPs and health care professionals (HCPs) evaluated content, completeness, and ease of use of a prototype of ITwC. Some technical revisions were made based on usability test results. However, usability of technology is determined not only by its user-computer interactions, but also by the degree to which it can be successfully integrated in the intended work environment [18]. Therefore, the aim of the present study was to investigate the feasibility of the self-care education program of ITwC in clinical practice by assessing uptake and usage rate and user satisfaction of ITwC supplementary to regular care. Secondary aim of this study was to investigate which sociodemographic and clinical factors are associated with user satisfaction.

METHODS

Study design

A single group cross-sectional study design was used, with a survey at baseline (sociodemographic and clinical information, Internet use, Internet literacy, health literacy, and quality of life) and a post intervention survey (usage, perceived satisfaction) 2 weeks after.

Patients and procedures

HCPs (a fellow head and neck surgery, specialized nurses or speech therapists) of 9 departments of Otolaryngology-Head and Neck Surgery involved in laryngectomy care (represented in the Dutch Head and Neck Oncology Cooperative Group) [20] were invited to participate and recruit eligible patients for this study which took place between December 2013 and December 2014. Patients eligible for study participation met the following inclusion criteria: (1) recently underwent TL for laryngeal cancer; (2) underwent TL between 3 months to 2 years prior; (3) 18 years of age or older; (4) able to read, write, speak, and understand Dutch; (5) some Internet experience; and (6) access to the Internet at home. After receiving informed consent, patients were asked to fill out a paper-and-pencil survey (T0) and to return the survey by mail. Subsequently, login codes were provided to the patients by mail in order to gain access to the ITwC application for 2 weeks. In case of technical problems, telephone assistance was available. After 2 weeks of access, participants were encouraged by mail to fill out the second survey (T1). The study was conducted according to regular procedures of the local ethical committee of VU University Medical Center, Amsterdam.

Intervention

The self-management application ITwC [21] consists of a self-care education program and an exercise program. The education program provides general information about the larynx, laryngeal cancer, and the functional changes after TL. Specific self-care information is arranged into the following six themes: (1) nutrition; (2) tracheostomy care; (3) voice prosthesis care; (4) speech rehabilitation; (5) smell rehabilitation; and (6) mobility of head, neck, and shoulder muscles. The web pages on specific self-care contain self-care skills education (e.g., “How to use adhesive tracheostomy patches”), practical symptom management strategies (e.g., “What to do when having taste problems”), and lists of troubleshooting guides targeting several symptoms (e.g., “Self-care strategies to overcome difficulty swallowing due to thick saliva”). Furthermore, ITwC consists of an exercise program with exercises for the head, neck, and shoulder muscles, aiming to prevent subsequent speech, swallowing, and shoulder problems after oncologic treatment. Self-care information, skills education, and exercises are illustrated with video animations, images, photos, and video demonstrations. Access to ITwC was restricted to study participants only via a login code. The present study focused on the online self-care education program. Therefore, participants had no access to the exercise program (see Figure 1).

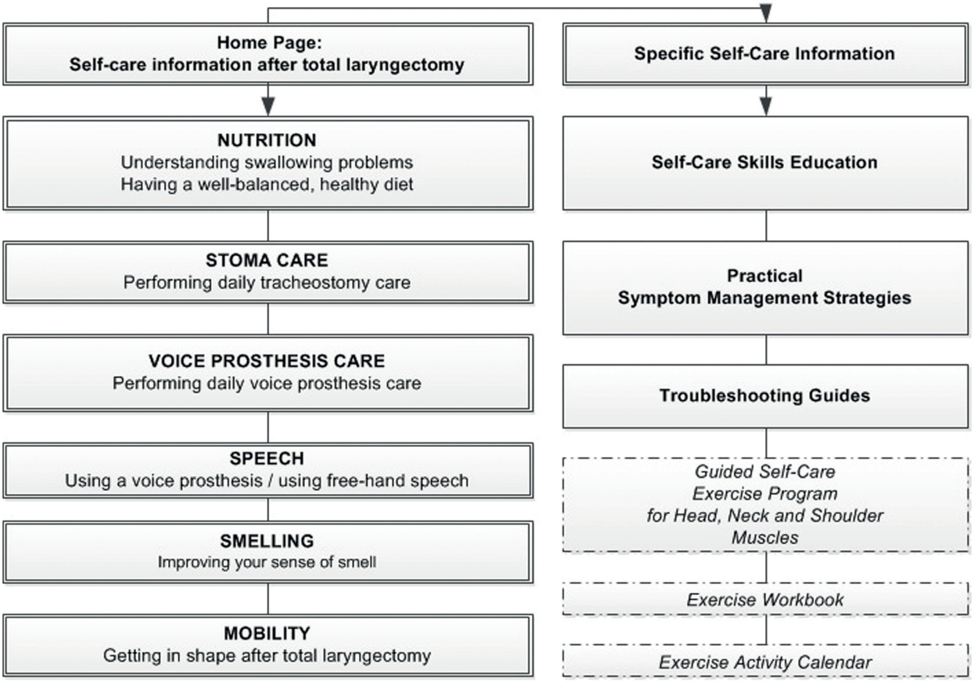

Figure 1. Content of the ITwC application. The present study focused on feasibility of the online self-care program. Participants had no access to the exercise program

Outcome measures

A study-specific survey was composed comprising items on sociodemographic and clinical factors, a quality of life questionnaire, a health literacy scale (T0 baseline assessment), and on usage and satisfaction (T1 follow-up assessment).

Uptake, usage, and satisfaction

HCP uptake (the intention to refer) was defined as the percentage of HCPs that agreed to participate and were willing to refer their patients to the education program of ITwC. TLP uptake (the intention to use ITwC) was defined as the percentage of all TLPs willing to participate (e.g., those who provided informed consent).

Self-reported usage addressed the percentage of active ITwC users (patients who logged in and visited ITwC during 2 weeks). Questions related to self-reported usage were asked the following: “Did you log in to the self-care program?”, “How much time did you spend visiting ITwC?”, and “Did you view the self-care skills demonstration videos?”

General satisfaction was based on the mean score of 4 items on (1) general impression of ITwC, (2) ease of use of ITwC, (3) willingness to use the ITwC program, and (4) satisfaction with ITwC self-care advice and strategies. All items were scored on a 10-point Likert scale ranging from "poor" or "low" (1) to "very good" or "high" (10). Furthermore, the Net Promoter Score (NPS) was calculated as an indication of satisfaction. The NPS is assessed by asking "On a scale from 0 to 10, how likely is it that you would recommend ITwC to other TLPs during the follow-up phase after TL?". Responses were scored on a 10-point Likert scale ranging from "not likely" (0) to "very likely" (10). The NPS consists of the percentage of "Promoters" (those who score 9-10) minus the percentage of "Criticasters" (those who score 0-6). The NPS ranges between −100 and +100 where a positive score is considered to be good [22].

The survey also included two open-ended questions: "How would you describe the ITwC self-care program to fellow users?" and "What could we do to improve the program?"

Moderating factors

Data were collected on gender, age, treatment modality, time since TL, education level, marital status, employment status, Internet usage, and Internet literacy, using a study-specific questionnaire. Education attainment level was categorized as primary education or less, low (lower and prevocational education), middle (secondary vocational education), and high (vocational college or university). Global quality of life was assessed using the EORTC QLQ-C30 (version 3.0), including a global Health Related Quality of Life (HRQOL) scale. In the present study, the global HRQOL scale was used. The scores of the QLQ-C30 are linearly transformed to a scale ranging from 0 to 100, with a higher score indicating a higher (i.e., more positive) level of HRQOL [23].

A Dutch translation of the Functional Communicative and Critical Health Literacy scale (FCCHL) by Ishikawa was used [24-26] to gain insight in TLPs' health literacy skills (the capacity to obtain, process, and understand basic health information and services to make sound health decisions) [27]. The FCCHL-Dutch is based on the results of two validation studies in the Netherlands [24,25] and consists of 14 statements with 4-point Likert scales (1-4). Mean scale scores were obtained by summing (reversed) item scores and dividing them by the total number of items, resulting in a score ranging from 1 (low health literacy) to 4 (high health literacy) [28].

Data analysis

Descriptive analyses were used to summarize sociodemographic and clinical characteristics of TLPs as well as the uptake, usage, and satisfaction.

The self-care education program was considered feasible in case of (1) an uptake percentage by HCPs and TLPs of more than 50%, (2) a user percentage of more than 50% of the users visiting the ITwC Web site, (3) a user percentage of more than 50% of the users viewing the demonstration videos, (4) in case of a positive Net Promoter Score, and (5) a mean general satisfaction score of at least 7 on 4 survey items. This definition of feasibility is based on adherence rates reported in previous research among head and neck cancer (HNC) patients who performed unsupervised, home-based exercises [29,30].

Associations between satisfaction (score <7 vs score ≥7) with ITwC and gender (male vs female), education level (primary education/lower vocational education vs middle/higher vocational education), marital status (cohabiting vs single), employment status (employed vs unemployed/retired), Internet literacy (insufficient/moderate vs sufficient/good/very good), Internet usage (<5 vs >5 years), treatment modality (TL as single modality treatment vs TL and (C)RT), and time since TL (recent TL vs 3 months to 2 years after TL) were examined using Fisher's exact tests. Associations between satisfaction and age, quality of life, and health literacy skills were examined using Mann-Whitney *U* tests as these variables were not normally distributed. Analyses were performed using the Statistical Package for Social Sciences (IBM SPSS Statistics 20). For all analyses, values $P \leq .05$ (two-tailed) were used as criterion for statistical significance.

Free text responses to two open-ended questions (TLPs' description of ITwC to fellow users and TLPs' recommendations to improve the ITwC program) were used as illustrations of quantitative data.

RESULTS

Uptake

During the study period of 1 year, HCPs of 6 out of 9 centers agreed to participate, representing 5 academic and one nonacademic center(s), and recruited TLPs (HCP uptake rate of 67%). Reasons for not participating were as follows: inability to get in contact with a HCP (*n*=1), inability to recruit TLPs (*n*=1), and other ongoing research projects (*n*=1). Of 92 eligible TLPs, 75 agreed to participate (82%). Of the 17 TLPs who refused participation, 4 were not interested (3 TLPs who recently underwent TL (recent TLPs), and 1 TLP who underwent TL between 3 months and 2 years prior (later TLP)) and 13 TLPs had no time to participate (4 recent TLPs and 9 later TLPs). In total, 55 out of 75 TLPs who were willing to participate returned the T0 survey and were provided with a login code for the ITwC application (TLP uptake rate 73%).

Usage

Among the 55 TLPs, 38 logged in and visited ITwC. The usage percentage was 69%. Of these 38 users, mean age was 65 years, and the majority was male (76%). Most were middle to higher educated (58%), and most were treated with TL in combination with radiotherapy (61%). Fifty percent was treated less than 3 months earlier. More details on the sociodemographic and clinical characteristics are provided in Table 1.

Table 2 shows TLPs' self-reported usage of ITwC. Approximately half (55%) spent less than 60 min using ITwC, 29% spent 60-90 min, and 16% spent more than 90 min during the study period of 2 weeks. The majority valued the time spent as exactly right (89%), (strongly) agreed that ITwC is beneficial in managing self-care (69%), and reported no problems while performing self-care (89%). Furthermore, demonstration videos were viewed by 84% (32/38) of TLPs. One TLP (3%) stated not being able to view the videos because of technical problems, two TLPs (5%) reported not to know how to start the videos, and three TLPs (8%) were not interested.

Satisfaction

Of the 38 TLPs asked, 84% were satisfied with the overall ITwC self-care program (mean score 7.4, SD 1.2), 74% evaluated ITwC as user-friendly (mean score 7.3, SD 1.9), and 74% of TLPs were enthusiastic about ITwC (mean score 7.0, SD 1.3). Most TLPs were satisfied with the specific self-care advice and strategies (79%; mean score 7.1, SD 1.2). Overall, satisfaction was 66% (average score of ≥7 (scale 1-10) on 4 items) with ITwC (mean average score 7.2, SD 1.1). The NPS was positive (+5), consisting of 25% Promoters, and 20% Criticasters.

Table 3 shows more details on TLPs' perceived satisfaction. The majority was (very) satisfied with the quantity (76%) and comprehensibility (93%) of the information provided in ITwC and did not need help using ITwC (82%). Most would like to be introduced to ITwC before TL (37%) or before hospital discharge (32%). The majority of patients preferred the online format of ITwC (71%), would like to continue using the website (87%), and (strongly) agreed that photos and videos were of additional value (90%).

Moderating factors

Satisfaction with ITwC was significantly associated with (higher) education level (*P*=.004) and (higher) health literacy skills (*P*=.038). Satisfaction with ITwC was not significantly associated with gender (*P*=.46), age (*P*=.50), marital status (*P*=1.00), employment status (*P*=1.00), Internet literacy (*P*=.10), Internet usage (*P*=.06), treatment modality (*P*=.46), time since TL (*P*=1.00), and quality of life (*P*=.75).

Table 1. Characteristics of study participants (*n*=38)

Characteristic	**Mean age, y (range)**
Age	65 (46-78)
Gender	**n (%)**
Male	29 (76)
Female	9 (24)
Marital status	
Cohabiting	30 (79)
Single	8 (21)
Education [a]	
Primary education	3 (8)
Low	13 (34)
Middle	12 (32)
High	10 (26)
Employment status	
Retired	17 (45)
Employed	12 (32)
Unemployed	9 (24)
Treatment	
Total laryngectomy	11 (29)
Total laryngectomy / radiation therapy	23 (61)
Total laryngectomy / chemoradiation	4 (10)
Time since total laryngectomy	
< 3 months	19 (50)
3 months - 2 years	19 (50)
Internet usage since	
>5 years	26 (68)
<5 years	12 (32)
Self-assessed Internet literacy skills	
Very good	3 (8)
Good	7 (18)
Sufficient	12 (32)
Moderate	11 (29)
Insufficient	5 (13)
Global quality of life (EORTC QLQ C-30)	**Mean (SD)** 75.0 (16.4)
Total health literacy scores (FCCHL-Dutch)	37.0 (9.0)

[a] low = lower and prevocational education
middle = secondary vocational education
high = vocational college or university

Table 2. TLPs' self-reported ITwC usage (*n*=38)

	n (%)
Time spent on 'ITwC' during two weeks	
< 60 minutes	21 (55)
60-90 minutes	11 (29)
> 90 minutes	6 (16)
Time spent on 'ITwC' was perceived as	
Too short	1 (3)
Exactly right	34 (89)
Too long	2 (5)
Much too long	1 (3)
To perform ITwC self-care strategies and advice is beneficial in managing my self-care	
Strongly disagree	0
Disagree	2 (5)
Neutral	10 (26)
Agree	23 (61)
Strongly agree	3 (8)
Any problems while performing self-care strategies and advice?	
No	34 (89)
Yes	4 (11)

User feedback and general recommendations

In general, TLPs reported to be satisfied with ITwC. One user mentioned specific self-care behavior changes, such as "After reading the troubleshooting guide I was able to manage some problems with my voice prosthesis on my own, and I did not have to contact the hospital." Other users described the self-care education program as "a must," "everything you always wanted to know," "supportive information," "a guide," "very interesting," "necessary information," and "practical information".

TLPs gave some helpful recommendations to improve the program. A section with "frequently asked questions" (FAQ) was recommended. Some TLPs would like to read other TLPs' experiences after TL. Suggestions were made to develop an application for a smartphone with links to an online store with tracheostomy products and accessories. A section with the latest news on tracheostomy filters, covers, adhesive patches, and (freehand) voice prostheses was also recommended. Furthermore, one TLP would like to have a help desk available to address any issues on work, relationship, sexuality, travelling, and general psychosocial aspects after TL. One TLP mentioned that he missed information on excessive flatulence, bloating, burping, edema, and on how to cope with and get support after TL.

Table 3. TLPs' perceived satisfaction

	n (%)
The quantity of information is (*n*=38)	
Dissatisfactory	3 (8)
Neutral	6 (16)
Satisfactory	26 (68)
Very satisfactory	3 (8)
The comprehensibility of information is (*n*=38)	
Dissatisfactory	0
Neutral	3 (8)
Satisfactory	31 (82)
Very satisfactory	4 (11)
Needed help during ITwC visit? (*n*=38)	
No	31 (82)
Yes, I contacted the researcher or a HCP	7 (18)
Added value of ITwC to self-care advice offered during hospital stay? (*n*=38)	
Not at all	1 (3)
Little	20 (52)
Much	16 (42)
very much	1 (3)
ITwC should be introduced (*n*=38)	
Before TL	14 (37)
After TL	3 (8)
Before hospital discharge	12 (32)
After hospital discharge	5 (13)
Other	4 (11)
Preferred format of ITwC (*n*=38)	
Online	27 (71)
Book	11 (29)
Prefer to continue to use ITwC (*n*=38)	
Yes	33 (87)
No	4 (11)
No response	1 (3)
Photos and videos are of added value (*n*=32)	
Disagree	0
Neutral	3 (9)
Agree	26 (81)
Strongly agree	3 (9)
Comprehensible information through photos and videos (*n*=32)	
Strongly disagree	0
Disagree	0
Neutral	0
Agree	30 (94)
Strongly agree	2 (6)

DISCUSSION

The aim of this study was to investigate the feasibility of an online self-care education program ITwC in terms of HCPs' and TLPs' uptake, TLPs' usage and satisfaction, and to identify factors associated with user satisfaction. Results revealed that implementing a self-care education program such as ITwC in a TL care setting is feasible both for HCPs and TLPs. In general, most participants were satisfied with ITwC.

HCPs' uptake rate (67%) in our study is much higher compared to an earlier Dutch study evaluating an electronic health information support system for HNC patients, in which only 25% of the general practitioners used the system [31]. Recently, it has become clear that by eliciting the viewpoints of clinical providers early in the process of developing new eHealth applications, eventual uptake can be improved [32,33]. Expert-user involvement (HCPs) throughout all aspects of the development may have helped to ensure that ITwC adequately meets end-users' needs and is perceived to be easy to adopt [17]. The same holds for end-user involvement (TLPs) in ITwC design which may explain high TLPs' uptake rate of 73% in the present study.

Among patients with HNC, acceptability of Internet-based programs is growing [34]. About 54% of HNC patients use the Internet to find information about their treatment and on how to maintain their health in the future [35]. In the present study, TLPs' usage rate of 69% was somewhat higher compared to earlier studies on usage of eHealth interventions to provide support and education to HNC patients (55-64%) [29,31,33]. It should be kept in mind, however, that in our study, patients were selected on having access to the Internet. Nevertheless, still, 29% preferred to receive ITwC via a book format, while 71% preferred the online version. Therefore, we also developed an ITwC book format, with a DVD with video animations, video demonstrations of self-care skills, and exercises. TLPs who are recruited in the multicenter randomized controlled trial are now either offered the online ITwC program or the ITwC book format with a DVD.

In the present study, satisfaction with the online self-care program ITwC was associated with a higher education level and with higher health literacy skills. These findings are consistent with the literature [36,37]. Those with lower education levels are shown to be considerably less likely to seek for health information online compared to those with a higher educational level [38]. A lower subjective health literacy is associated with less perceived information provision and lower information satisfaction [39,40]. To comprehend written health information, a person must have certain reading and health literacy levels [41]. HNC patients are known to have lower educational levels [42], have poor health literacy, have difficulties interpreting commonly used written health information, feeling inadequately informed. As a result, they feel dissatisfied with their care and with the information received [43]. Sites for HNC patients containing reliable information pitched at an appropriate reading level are rare, and the quality varies [44]. Visual cues and the use of alternative media may aid comprehension when people have difficulty understanding the text. In ITwC multimedia, self-care information (photos, video animations, and video demonstrations of self-care skills) was offered in addition to the written information, which may have contributed to high patient satisfaction [45]. By applying a participatory design approach, ITwC was designed to meet end user's needs, with information pitched at an appropriate reading level.

In the present study, some helpful recommendations to improve the ITwC program were made by end users. One TLP mentioned to miss information on specific self-care strategies. However, these guides and strategies were already provided for and may have been overlooked. Clearer navigation instructions were therefore added to the menu, and meaningful subheadings were used.

A limitation of this study is that although various attempts were made to get in contact with interested TLPs by email or telephone, a number of TLPs (*n*=17) dropped out prior to completing the T1 survey.

Results of this feasibility study are encouraging and support the initiation of a randomized controlled trial. A randomized controlled trial is now ongoing, aiming to investigate the efficacy of an online exercise program to support early rehabilitation of TLPs.

CONCLUSION

The online self-care education program ITwC supporting early rehabilitation was feasible among TLPs with access to the Internet. Satisfaction with the online self-care education program was associated with educational level and health literacy skills.

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7

GENERAL DISCUSSION

The aim of the research described in this thesis was to investigate the usefulness of (eHealth) self-management interventions supporting rehabilitation among HNC patients. Furthermore, more insight was acquired into the influencing factors that are related to the usefulness of these interventions.

The three main (eHealth) self-management interventions described in this thesis were (1) 'OncoQuest' (OQ), an application to monitor HRQOL in clinical practice, (2) 'Head Matters' (HM), a multimodal guided self-care exercise intervention to prevent speech, swallowing and shoulder problems in HNC patients during and after radiotherapy alone or in combination with chemotherapy, and (3) 'In Tune without Cords' (ITwC), a self-care intervention to support the rehabilitation of TLPs.

The results of the studies conducted are integrated, whereby the focus lies on the usefulness in terms of usability, feasibility, uptake, usage, satisfaction of, and adherence to (eHealth) self-management interventions, and factors associated with usefulness. The results are discussed and linked to prior research to highlight new insights. Furthermore, the methodological considerations, strengths and limitations of the studies are discussed. The implications of the findings for clinical practice, and directions for future research are described. This section will end with a final conclusion.

Main findings and prior research

Providing (eHealth) self-management interventions can lead to people living with chronic illnesses gaining control of their illness, and can improve patients' overall quality of life [1]. However, few evidence-based self-management interventions for cancer patients, and specifically for HNC patients, are available to meet this need [2]. As a result relatively little information is known about the usefulness of these interventions in the HNC patient population. Therefore, between 2009 and 2014 we set out to develop, and to conduct research on (eHealth) self-management interventions to support the rehabilitation of HNC patients, guided by a participatory design approach [3-5].

In this thesis the results of the studies conducted showed that (eHealth) self-management interventions are useful to support the rehabilitation of HNC patients. This success can in all likelihood be attributed to a participatory design approach, leading to acceptable, user-friendly, and feasible (eHealth) self-management interventions. Using a participatory design approach places high value in the on-going involvement of intended users during design and evaluation elements. To maximize the probability of use and adoption, it is deemed crucial to obtain feedback from key stakeholders (e.g., patients, health care professionals (HCPs)) regarding the usability of a new intervention [6-8]. For the development of all three self-management interventions (OQ, HM, and ITwC) a participatory design approach was applied. The development process and usability evaluations of ITwC specifically were described in more detail in **chapter 5**. By using a 3-phase development life-cycle method, stakeholder input and feedback were incorporated into the development stages. Phase I consisted of input on content and delivery of OQ, HM, and ITwC, and in Phase II prototypes were developed, and underwent refinement following usability testing (Phase III). The applied participatory approach proved valuable and provided important insights into end users' and expert users' perceived usefulness of the (computerized or web-based) self-management tools (**chapter 2, 3, 5, and 6**).

The next phase in a developmental cycle of a new intervention is to investigate the feasibility in clinical practice. Although recent reviews suggest that computerized or web-based self-monitoring and self-management interventions are promising approaches, suboptimal usage, low uptake in patients and HCPs [9-12], and perceptions of limited utility among HCPs are identified [13]. The data as described in this thesis, do however, support the conclusion that computerized self-monitoring of symptoms and quality of life issues using OQ appeared to be feasible. In addition, study results revealed high uptake (73%-83%), high usage (69%), and high levels of satisfaction (66%-84%) in HNC patients, and high uptake in HCPs (67%), supporting the feasibility of self-management interventions, such as HM, and ITwC in clinical practice. Expert user and end user involvement throughout all aspects of the development may have helped to ensure that the intervention adequately meets end users' needs, was perceived easy to adopt, and was useful for patients and HCPs (**chapter 2-6**).

Some of the most notable limitations of eHealth self-management tools are low uptake, and high attrition rates [14,15]. Results from studies focusing on exercise interventions among cancer survivors show that exercise adherence is a challenge [16,17]. In contrast, study results presented in this thesis demonstrated that 6-week adherence to the prophylactic home-based exercise program HM among HNC patients during primary or adjuvant (C)RT was reasonable to high (64%-70%). In spite of the challenging burden of undergoing daily RT, the majority of HNC patients (58%) had moderate to high levels of exercise performance, suggesting that a multimodal home-based guided self-management intervention including self-monitoring strategies ((online) diary keeping) can be offered to HNC patients prior to RT. Exercise performance levels were not significantly associated with age, gender, tumor site, tumor stage, HM format or coaching sessions. However, especially in patients treated with SW-IMRT in combination with chemotherapy exercise performance levels were most frequent low compared to those treated with SW-IMRT only. CRT significantly increases symptom severity, as reported in the literature [18], which may explain this finding (**chapter 3 and 4**).

eHealth interventions may improve patients' HRQOL and well-being, and may support patient self-management [10,19]. However, those benefits will only accrue to patients if the technology is accepted and perceived as useful. Relatively little is known about patient-, and HCP-related factors that are likely to contribute or limit successful uptake and usage of, and adherence to eHealth (self-management) interventions. It is suggested that when users of an eHealth intervention perceive the intervention as disadvantageous or functionally incompatible with their needs, they will be less likely to accept the technology [20]. Furthermore, it is deemed important to clarify the role of HCPs in the delivery of eHealth services, including endorsement, promotion and facilitation [1,21]. HCPs emphasize that adequate training and support are needed, both for patients and themselves in order to enable self-management [22]. As described in this thesis the level of satisfaction of HNC patients receiving information via an eHealth self-management intervention was associated with (higher) educational level and (higher) health literacy skills (**chapter 6**). This is in line with previous findings [23]. Differences in perceived usefulness of (eHealth) self-management interventions may indicate potential inequalities in patients' engagement with the health care system [24], specifically if such interventions would only be available to those with advanced eHealth literacy skills [25]. First and foremost, in order to increase the likelihood that patients will experience the potential benefits of eHealth interventions, the technology must be designed such that system applications are in consonance with patients' needs [20].

Important other factors facilitating or limiting the usefulness of (eHealth) self-management interventions in clinical practice were identified, and described in **chapter 3 and 4**. Using qualitative research methods, information was generated regarding factors perceived to facilitate (e.g., increased physical condition, feeling motivated) and factors perceived to impede (e.g., a decreased physical condition, treatment-related factors) exercise adherence among HNC patients treated with primary or adjuvant (chemo) radiation. When studying these factors using quantitative research methods, only chemotherapy in combination with SW-IMRT was identified as a limiting (treatment-related) factor on exercising.

Methodological considerations

While the studies presented in this thesis add to the existing, yet limited literature on the subject of (eHealth) self-management interventions to support patients with HNC, there are some important limitations with regard to the methodologies applied.

First, no information was obtained from patients who refused to participate, or who dropped out prior to completing post intervention surveys. It is likely that negative experiences and barriers to accessibility and acceptability were under-reported, because studies were largely concerned with the experiences of those currently using and accessing interventions, rather than those who either do not engage initially or do not continue to engage. Information from a non-participating group of patients would give a more balanced view of the perceived barriers to self-management interventions, and to interventions' feasibility. Second, usage of, and adherence to various self-management interventions were self-reported, and therefore, may be subject to bias. Self-reports should ideally be supplemented using objective sources of data, such as usage statistics (number of log-ins, time spent online). In an attempt to minimize bias, exercise logs in the form of diaries were completed daily.

This thesis also has several important strengths. In current research, increased attention is paid to the development of eHealth interventions based on participatory development. First, we pioneered (eHealth) self-management interventions for HNC patients, aiming to improve or optimize HRQOL. In the studies described in this thesis, methods to support the participation of stakeholders (e.g., HNC patients, HCPs), co-creation, and user-centered persuasive design techniques were used [26,5]. Second, we also monitored usage, uptake, acceptability and usability of these new interventions in clinical practice. User-produced knowledge was gathered to determine how well the new (eHealth) self-management interventions would be received

[27]. Having the target population and clinical settings involved in the process of assessing the usability and acceptability of an intervention is a critical component of intervention development research [28]. A third strength of this thesis is that factors associated with self-care exercise performance were explored by using qualitative and quantitative research methods. Fourth, we identified factors that either impede or facilitate the usefulness, and implementation of eHealth applications in clinical practice, providing directions for future studies.

Implications for clinical practice

Using self-management strategies may help HNC patients with the practical and functional implications of the consequences of HNC treatment over the longer term [29], and may lead to increased engagement in care [30,31,20). However, major knowledge gaps remain around adherence to, and patient engagement with (eHealth) self-management in clinical practice [32,33]. Study results described in this thesis imply that the (eHealth) interventions such as OQ, HM, and ITwC are useful to support HNC patients' self-management and rehabilitation. HCPs advantageously use (eHealth) self-management interventions as tools for promoting self-care [34]. It is deemed crucial that the introduction of (eHealth) self-management interventions is provided by a care professional who is a credible source for patients. As described in **chapter 3 and 5** speech therapists considered themselves to be the most suitable to introduce self-management interventions such a HM and ITwC. In their opinion eHealth applications cannot replace a face-to-face encounter, and should be used as an adjunct also known as 'blended care', i.e. face-to-face consultations supported by web-based interventions or web-based interventions supported by face-to-face consultations [35,36]. Research is needed to identify and anticipate if and how eHealth services will affect clinical interactions and activities [27].

Despite the high prevalence of Internet access in the Netherlands and advantages of eHealth interventions including multimedia presentation, easy updating of the information provided and tailoring, we think booklet formats of HM and ITwC self-management interventions (with DVDs with video exercise demonstrations) are still required. Results of the studies conducted in this thesis showed that many participants preferred to receive the intervention via a book format. For a part of the (HNC patient) population (with higher age and lower socioeconomic status) an online intervention is not useful, because of low (eHealth) literacy skills.

Directions for future research

Through the studies described in this thesis a better understanding of the (factors associated with) usefulness of (eHealth) self-management interventions among HNC patients was achieved. However, the potential of early (eHealth) self-monitoring and self-management interventions in HNC patients should be further explored in future research. The treatment of HNC not only imposes significant structural, functional, and cosmetic burdens upon those affected, but many patients already have high symptom levels before treatment begins. The key to optimizing patients' wellbeing and therapeutic outcomes is monitoring symptoms, and early identification of individuals at risk of symptoms from the diagnosis on [37]. Monitoring symptoms would aid in the evaluation of the symptomatic benefit or burden of interventions [38], and would inform us about the required optimal timing for specific symptom interventions, management strategies in the pre-treatment setting, and patient education and preparedness [37,39]. Assessing patient-reported symptoms routinely before treatment commences is important, and emphasizes the need for symptom management in parallel with disease treatment [38]. As described in this thesis, a computerized monitoring system can be used for this purpose, but further research is warranted.

It is well known that exercise adherence in cancer survivors is a challenge. In order to facilitate and/or improve exercise adherence we developed guided home-based multimodal (paper, online, DVD) (prophylactic) self-management interventions, targeting to smoothen the transition from hospital to home, and enabling HNC patients to perform exercises in the comfort of their own homes, on their own time. However, further research is needed to gain a complete understanding of (prophylactic) exercise adherence and the multitude of factors that contribute to poor exercise adherence. Furthermore, research is needed to assess the impact of (combined) coaching strategies (home-based vs supervised, face-to-face vs email and/or telephone contact). Research is also needed to investigate the efficacy of (eHealth) self-management interventions on HRQOL. Important issues to consider are how self-management is viewed, and which outcomes are prioritized and valued by patients and HCPs [32]. At the patient level, outcome measures should include patient empowerment, compliance with treatment and follow-up advice, satisfaction with care, and HRQOL. At the professional level, relevant outcome measures would be workload and job efficiency, awareness of patients' symptoms and functional limitations, and satisfaction with the care process [40,41]. Future studies should also provide information on how new (eHealth) self-management interventions can be implemented and maintained in clinical practice [42], using the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation and Maintenance) [43].

The three main (eHealth) self-management interventions described in this thesis (1) OncoQuest (OQ), (2) Head Matters (HM), and (3) In Tune without Cords (ITwC) proved to be useful, feasible, and satisfactory in clinical practice, especially for HNC patients with higher educational levels, with higher health literacy skills, and to those not treated with chemotherapy.

The results in this thesis can guide future research on developing and evaluating other useful (web-based) self-management interventions to support HNC patients.

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SUMMARY

SUMMARY

The main aim of this thesis was to investigate the usefulness of three (eHealth) self-management interventions in clinical practice (1) ‘OncoQuest’ (OQ), an application to monitor HRQOL, (2) ‘Head Matters’ (HM), a multimodal guided self-care exercise intervention to prevent speech, swallowing and shoulder problems in HNC patients during and after radiotherapy (RT) alone or in combination with chemotherapy, and (3) ‘In Tune without Cords’ (ITwC), a self-care intervention to support the rehabilitation of TLPs. The usefulness of these interventions supporting the rehabilitation of HNC patients was investigated, and insights were gained into the factors influencing the usefulness of these interventions.

The purpose of the first study was to evaluate the usefulness of OQ to monitor speech and swallowing outcomes and its impact on QoL and emotional well-being in HNC patients in an outpatient clinic (**chapter 2**). At baseline (at time of diagnosis) and at first follow-up (1 month after end of treatment) HNC patients completed the EORTC QLQ-C30 and QLQ-H&N35 questionnaires and the Hospital Anxiety and Depression Scale, using OQ. No speech or swallowing problems at baseline or follow-up were noted in 23% (speech) and 41% (swallowing) of patients. Twenty-one percent (speech) and 19% (swallowing) had problems at baseline and returned to normal scores at follow-up, while 16% (speech) and 19% (swallowing) had normal scores at baseline but developed problems at follow-up. Forty percent (speech) and 21% (swallowing) had persistent problems from baseline to follow-up. At baseline, speech problems were significantly related to tumor site and emotional distress. At baseline and follow-up, swallowing problems were significantly related to QoL and emotional distress. At follow-up, speech problems were significantly related to QoL, emotional distress, and swallowing problems. It was concluded that monitoring speech and swallowing problems through OQ in an outpatient clinic is feasible. Many patients reported speech and swallowing problems, negatively affecting their HRQOL and emotional well-being.

In the second study the feasibility of HM was investigated, a multimodal guided self-help exercise program (**chapter 3**). During a 6-week course of RT many HNC patients have to endure radiotherapy-induced toxicity, negatively affecting patients’ HRQOL. Pretreatment counseling combined with self-help exercises can be provided to inform patients and possibly prevent them from having speech, swallowing, and shoulder problems, and a stiff neck during and after treatment. Participating HNC patients (*n*=33) were asked to follow HM targeting prevention of deterioration of speech, swallowing, and shoulder function during and after treatment with RT alone or in combination with chemotherapy. HM was offered in three different formats, a leaflet, an online and a booklet format. Weekly coaching was provided by a speech and swallowing therapist. Patients filled out a diary to keep track of their exercise activity. To gain insight into possible barriers and facilitators to exercise adherence, reports of weekly coaching sessions were analyzed by two coders independently using qualitative research methods. Results from this study indicated that the guided self-help exercise program HM is feasible among HNC patients undergoing primary or postoperative RT (combined with chemotherapy) with high uptake (83%) and reasonable adherence rates (64%). The majority of participants (58%) performed at least the minimum number of exercises during 6 weeks, and had moderate to high levels of exercise performance. Exercise performance level was not significantly associated with age (*P*=.50), gender (*P*=.42), tumor subsite (*P*=1.00) or tumor stage (*P*=.20), treatment modality (*P*=.72), or Head Matters format (web-based or paper) (*P*=1.00). Based on the analysis of reports of weekly coaching sessions, patients' perceived barriers to exercise were a decreased physical condition, treatment-related barriers, emotional problems, lack of motivation, social barriers, and technical problems. Patients' perceived facilitators included an increased physical condition, feeling motivated, and social and technical facilitators. The conclusion was that HM, a multimodal guided self-help exercise program is feasible for HNC patients undergoing (chemo) radiation.

In the third study adherence, and exercise performance levels and its associated factors in HNC patients (*n*=50) following HM during and after treatment with SW-IMRT (combined with chemotherapy) ((C)SW-IMRT) were investigated (**chapter 4**). Adherence (percentage of patients who kept up exercising) and exercise performance level (categorized as low: ≤1, moderate: 1-2, and high: ≥2 time(s) per day, on average) were assessed using patient-completed diaries. Associations between 6- and 12-week exercise performance levels (low vs moderate/high), and age, gender, tumor site and stage, treatment, format, amount of coaching sessions and baseline HNC specific symptoms (EORTC QLQ-H&N35) were investigated. Changes in exercise performance levels in relation to each of these symptoms (at weeks 1 to 6, and at 12 weeks) were analyzed. Six- and 12-week adherence rates were 70% and 38% respectively. Exercise performance levels were most frequent low (during 6 weeks: 40%; during 12 weeks: 54%), and decreased over time (during 6 weeks: 34% moderate and 26% high; during 12 weeks: 28% moderate and 18% high). The addition of chemotherapy to SW-IMRT (CSW-IMRT) was the only factor significantly associated with low exercise performance level during six weeks (*P*=.015) and 12 weeks (*P*<.001). The conclusion was that adherence to a guided home-based prophylactic exercise program was high during (C)SW-IMRT but dropped afterwards. Exercise performance levels varied and were especially low in patients treated with chemotherapy in combination with SW-IMRT.

In **chapter 5** the development process of a web-based self-care program (ITwC) for patients after total laryngectomy according to a participatory design approach was described. A needs assessment was conducted with laryngectomees (*n*=9) and their partners (*n*=3) by means of a focus group interview. In 4 focus group sessions, a requirement plan was formulated by a team of health care professionals (*n*=10) and translated into a prototype. An eHealth application was built including illustrated information on functional changes after total laryngectomy as well as video demonstrations of skills and exercises. Usability of the prototype was tested by end users (laryngectomees; *n*=4) and expert users (speech therapists; *n*=10). Interviews were held to elicit the intention to use and the desired implementation strategy. Six main self-care topics were identified: (1) nutrition, (2) tracheostomy care, (3) voice prosthesis care, (4) speech rehabilitation, (5) smell rehabilitation, and (6) mobility of head, neck, and shoulder muscles. Speech therapists expressed concerns regarding tailored exercises, indicated a positive intent to implement the intervention in routine care, and expressed a need for guidance when implementing the intervention. End users and expert users appreciated the content completeness and multimedia-based information built into the application. The participatory design is a valuable approach to develop a self-care program to help meet users' needs.

In **chapter 6** the feasibility of ITwC, and factors associated with satisfaction were investigated in clinical practice. HCPs were invited to participate and to recruit TLPs. TLPs were informed on the self-care education program ITwC after which they gained access. A study specific survey was used (at baseline T0 and post intervention T1) on TLPs' uptake. Usage, satisfaction (general impression, willingness to use, user-friendliness, satisfaction with self-care advice and strategies, Net Promoter Score (NPS)), sociodemographic, and clinical factors were analyzed. HCPs of 6 out of 9 centers (67% uptake rate) agreed to participate and recruited TLPs. In total, 55 of 75 TLPs returned informed consent and the baseline T0 survey and were provided access to ITwC (73% uptake rate). Thirty-eight of these 55 TLPs used ITwC and completed the T1 survey (69% usage rate). Most (66%) TLPs were satisfied (i.e., score ≥7 (scale 1–10) on 4 survey items) with the self-care education program (mean score 7.2, SD 1.1). NPS was positive (+5). Satisfaction with the self-care education program was significantly associated with (higher) educational level and health literacy skills (P=.004, P=.038, respectively). No significant association was found with gender, age, marital status, employment status, Internet use, Internet literacy, treatment modality, time since total laryngectomy, and quality of life. The online self-care education program ITwC supporting early rehabilitation was feasible in clinical practice. In general, TLPs were satisfied with the program.

In the general discussion (**chapter 7**) of this thesis the main findings, methodological considerations, and implications for clinical practice were described, followed by directions for future research. The general conclusion of this thesis was that applying a participatory design approach has led to useful, user-friendly and feasible (online) self-management interventions and that OQ, HM, and ITwC proved to be useful, feasible, and satisfactory in clinical practice. Results of the studies conducted showed that part of the HNC patients prefer to receive the intervention via a book format. Therefore, HM and ITwC were also made available via a book format with DVDs of video exercise demonstrations, but it is expected that this may increase intervention costs. Through the studies described in this thesis a better understanding of the usefulness of (eHealth) self-management interventions among HNC patients was achieved, but the potential of these interventions should be further explored. More research is needed to increase adherence and to gain insight into the multitude of factors that contribute to poor exercise adherence. Also, more research on the efficacy and cost-effectiveness, as well as the implementation of these new interventions in clinical practice is warranted.

SAMENVATTING (SUMMARY IN DUTCH)

Het hoofddoel van dit proefschrift was om de bruikbaarheid te onderzoeken van drie (eHealth) zelfmanagement interventies in de klinische praktijk (1) 'OncoQuest' (OQ), een touch screen computersysteem om kwaliteit van leven te monitoren, (2) 'Halszaken' (HZ), een multimodaal begeleid zelfzorgprogramma ter preventie van spraak-, slik- en schouderproblemen bij hoofd-halskankerpatiënten tijdens en na radiotherapie (in combinatie met chemotherapie) en (3) 'Verder zonder Stembanden' (VZS), een zelfzorgprogramma ter ondersteuning van de revalidatie van patiënten na een totale laryngectomie. De bruikbaarheid van deze interventies ter ondersteuning van het herstel van hoofd-halskankerpatiënten werd onderzocht, en inzicht werd verkregen in factoren die de bruikbaarheid beïnvloeden.

In de eerste studie (**hoofdstuk 2**) werd in de polikliniek het monitoren van spraak- en slikproblemen bij hoofd-halskankerpatiënten door middel van OQ geëvalueerd (*n*=67). Op baseline (op moment van diagnose) en bij de eerste follow-up (1 maand na beëindiging van de behandeling) vulden hoofd-halskankerpatiënten via OQ de EORTC QLQ-C30 en QLQ-H&N35 en de Hospital Anxiety and Depression Scale (HADS) in. Geen spraak- of slikproblemen op het moment van diagnose (baseline) of follow-up werden gerapporteerd door 23% (spraak) en 41% (slikken) van de patiënten. Eenentwintig procent (spraak) en 19% (slikken) van de patiënten had problemen op de baseline maar niet meer op follow-up, terwijl 16% (spraak) en 19% (slikken) geen problemen had op de baseline maar wel op follow-up. Persisterende spraak- of slikproblemen van baseline tot follow-up werd gerapporteerd door respectievelijk 40% en 21% van de patiënten. Spraakproblemen op baseline waren significant gerelateerd aan tumorlocatie en psychische distress. Slikproblemen op baseline en follow-up waren significant gerelateerd aan kwaliteit van leven en psychische distress. Spraakproblemen op follow-up waren significant gerelateerd aan kwaliteit van leven, psychische distress en slikproblemen. De conclusie was dat het monitoren van spraak- en slikproblemen via OQ in een polikliniek haalbaar is. Veel patiënten rapporteren spraak- en slikproblemen, welke een negatieve invloed hebben op kwaliteit van leven en emotioneel welbevinden.

In de tweede studie werd de haalbaarheid van HZ onderzocht, een multimodaal begeleid zelfzorgprogramma (**hoofdstuk 3**). Veel hoofd-halskankerpatiënten ervaren radiotherapie-geïnduceerde toxiciteit en dit heeft een negatieve invloed op hun kwaliteit van leven. Voordat de radiotherapie begint kan counseling worden aangeboden, gecombineerd met zelfhulpoefeningen ter voorkoming van spraak-, slik- en schouderklachten en klachten van een stijve nek. Aan deelnemers werd gevraagd het oefenprogramma HZ te volgen om verslechtering van de spraak-, slik- en schouderfunctie te voorkomen. HZ was beschikbaar in drie formats: een folder, een website, en een boekje. Coaching werd wekelijks aangeboden door een logopedist. Patiënten vulden een dagboek in om hun oefenactiviteit bij te houden. Om inzicht te krijgen in de eventuele belemmerende en faciliterende factoren die van invloed kunnen zijn op het (blijven) oefenen, werden verslagen van de coaching sessies door twee onafhankelijke onderzoekers geanalyseerd met behulp van kwalitatieve onderzoeksmethoden. Bij de 33 hoofd-halskankerpatiënten die primaire of postoperatieve radiotherapie (gecombineerd met chemotherapie) ondergingen en meededen aan de studie, bleek dat de begeleide zelfzorgoefeningen door 83% werd gestart en dat 64% gebruik bleef maken van het oefenprogramma tijdens de bestralingsperiode. De meerderheid van de patiënten (58%) had ten minste het minimum aantal oefeningen uitgevoerd gedurende 6 weken, en had een matig tot hoog oefenniveau. Het oefenniveau was niet significant geassocieerd met leeftijd (*P*=.50), geslacht (*P*=.42), tumor locatie (*P*=1,00), tumor stadium (*P*=.20), behandelmodaliteit (*P*=.72), of HZ format (online of papier) (*P*=1.00). Op basis van de analyses van de verslagen van de wekelijkse coaching sessies werden door patiënten belemmerende (een verminderde fysieke conditie, behandeling-gerelateerde barrières, emotionele problemen, gebrek aan motivatie, sociale barrières en technische problemen) en faciliterende factoren (verbeterde lichamelijke conditie, motivatie, en sociale en technische faciliterende factoren) gerapporteerd. De conclusie is dat een begeleid zelfzorgprogramma zoals HZ, met coaching op afstand, kan worden aangeboden aan hoofd-halskankerpatiënten tijdens (chemo)radiatie.

In de derde studie, waarbij 50 hoofd-halskankerpatiënten behandeling ondergingen met intensiteit gemoduleerde radiotherapie, waarbij de slikstructuren zoveel mogelijk gespaard werden (SW-IMRT) (gecombineerd met chemotherapie) ((C)SW-IMRT), werden de therapietrouw van het oefenprogramma HZ tijdens en na de bestraling, het niveau van oefenen, en de factoren die daarop van invloed zijn onderzocht (**hoofdstuk 4**). Therapietrouw van het oefenprogramma (percentage van patiënten die bleven oefenen) en het niveau van oefenen (gecategoriseerd als laag: ≤1, matig: 1-2, en hoog: ≥2 maal per dag, gemiddeld) werden gebaseerd op de door de patiënt ingevulde dagboeken. Associaties tussen 6-wekelijks en 12-wekelijkse oefenniveaus (laag vs. gemiddeld/hoog), en leeftijd, geslacht, tumorlocatie, tumor stadium, behandeling, HZ oefenformat, aantal coaching sessies en specifieke symptomen van hoofd-halskankerpatiënten (EORTC QLQ-H&N35) werden onderzocht. Veranderingen in het oefenniveau met betrekking tot elk van deze symptomen (tijdens week 1 tot en met week 6) en tijdens week 12 werden geanalyseerd. De therapietrouw gedurende 6 en 12 weken was respectievelijk 70% en 38%. Het oefenniveau tijdens 6 weken was laag bij 40% van de patiënten en tijdens 12 weken bij 54% van de patiënten. Matige en hoge oefenniveaus tijdens 6 weken werden respectievelijk door 34% en 26% van de patiënten behaald en deze daalden tijdens 12 weken: 28% matig en 18% hoog. De combinatie van chemotherapie met SW-IMRT (CSW-IMRT) was de enige factor die significant geassocieerd was met een laag oefenniveau tijdens 6 weken (*P*=.015) en 12 weken (*P*<.001). De conclusie is dat de therapietrouw van HZ hoog was tijdens (C)SW-IMRT, maar dat deze na afloop van de behandeling daalde. De niveaus van oefenen varieerden, en het oefenniveau was lager bij patiënten die behandeld werden met chemotherapie in combinatie met SW-IMRT.

In **hoofdstuk 5** werd het ontwikkelproces volgens een participatieve benadering van een online zelfzorgprogramma voor patiënten na een totale laryngectomie (‘Verder zonder Stembanden’ (VZS)) beschreven. Een behoeftenonderzoek werd uitgevoerd bij gelaryngectomeerden (*n*=9) en hun partners (*n*=3) door middel van een focusgroep. Door een team van zorgverleners (*n*=10) werd in 4 bijeenkomsten een programma van eisen opgesteld. De 6 belangrijkste zelfzorgonderwerpen werden geïdentificeerd: (1) voeding, (2) stomazorg, (3) prothesezorg, (4) spraakrevalidatie, (5) reukrevalidatie, en (6) de mobiliteit van hoofd-, hals- en schouderspieren. Bevindingen van beide studies werden vertaald in de ontwikkeling van een prototype van het online zelfzorgprogramma. Het prototype werd gebouwd, waarin illustraties van de functionele aanpassingen na een totale laryngectomie evenals videodemonstraties van vaardigheden en oefeningen werden opgenomen. Bruikbaarheid van het prototype werd getest door eindgebruikers: gelaryngectomeerde patiënten (*n*=4) en zorgverleners (logopedisten; *n*=10). Logopedisten uitten hun bezorgdheid met betrekking tot op maat gemaakte oefeningen, hadden een positieve intentie om de interventie naast de standaard zorg te gebruiken, en rapporteerden behoefte te hebben aan begeleiding bij de implementatie van de interventie. Gelaryngectomeerde patiënten en logopedisten waardeerden de compleetheid van de multimedia informatie. Het participatieve ontwerp bleek een waardevolle aanpak om een zelfzorgprogramma te ontwikkelen dat voldoet aan de behoeften van de gebruikers.

In **hoofdstuk 6** werden de haalbaarheid van VZS en de factoren die samenhangen met tevredenheid onderzocht in de klinische praktijk. Zorgverleners werden gevraagd om deel te nemen aan de studie en patiënten die een totale laryngectomie hadden ondergaan werden uitgenodigd om VZS te gebruiken. Een studie specifieke vragenlijst werd gebruikt (op baseline T0 en post interventie T1) om de "uptake" te onderzoeken: gebruik, tevredenheid (algemene indruk, bereidheid om te gebruiken, gebruiksvriendelijkheid, tevredenheid met de zelfzorgadviezen en strategieën, Net Promoter Score (NPS)), sociaal demografische en klinische factoren werden geanalyseerd. Zorgverleners van 6 van de 9 centra (67%) die gevraagd waren deel te nemen stonden positief tegenover deelname en verklaarden gelaryngectomeerde patiënten te willen werven. In totaal 55 van 75 patiënten (73%) ondertekenden het informed-consentformulier en vulden de baseline vragenlijst in, waarna toegang tot VZS werd verleend. Achtendertig van deze 55 patiënten gebruikten daadwerkelijk VZS en stuurden de T1 vragenlijst retour (gebruikerspercentage van 69%). De meeste patiënten (66%) waren tevreden (dat wil zeggen, score ≥7 (schaal 1-10) op de 4 items) met het zelfzorg- en educatieprogramma (gemiddelde score 7.2, SD 1.1). De NPS was positief (+ 5). Tevredenheid met het zelfzorg- en educatieprogramma was significant geassocieerd met een (hoger) onderwijsniveau (*P*=.004), en (hogere) gezondheidsvaardigheden (*P*=.038, respectievelijk). Er werd geen significante associatie gevonden met geslacht, leeftijd, burgerlijke staat, werkgelegenheid status, Internet gebruik, Internet geletterdheid, behandelmodaliteit, tijd sinds totale laryngectomie, en kwaliteit van leven. Het online zelfzorg- en educatieprogramma VZS ter ondersteuning van vroege revalidatie in de klinische praktijk was haalbaar.

In de algemene discussie (**hoofdstuk 7**) van dit proefschrift werden de belangrijkste bevindingen, voorafgaand onderzoek, de methodologische aspecten en implicaties voor de klinische praktijk beschreven, gevolgd door aanbevelingen voor nader onderzoek. De algemene conclusie van dit proefschrift was dat het toepassen van een participatieve ontwerpbenadering heeft geleid tot gebruikersvriendelijke, en haalbare (eHealth) zelfmanagement interventies en dat OQ, HZ en VZS bruikbaar, nuttig, haalbaar en bevredigend bleken te zijn in de klinische praktijk. Uit de resultaten van het uitgevoerde onderzoek is gebleken dat een aantal deelnemers de voorkeur geeft aan een interventie in boekformaat. Daarom is het wenselijk om HZ en VZS ook in boekformaat aan te bieden in combinatie met demonstraties van de oefeningen via DVD. De verwachting is wel dat dit zal leiden tot hogere interventiekosten. De in dit proefschrift beschreven onderzoeksresultaten leiden tot een beter begrip van de bruikbaarheid van (eHealth) zelfmanagement interventies voor patiënten met hoofd-halskanker. Echter, de mogelijkheden van deze interventies moet nader worden onderzocht. Meer onderzoek is nodig om therapietrouw van een (preventief) oefenprogramma te verhogen en om de veelheid aan factoren die van invloed zijn op het (blijven) oefenen in kaart te brengen. Verder onderzoek is ook nodig naar de (kosten)effectiviteit van de ontwikkelde interventies, alsmede de structurele implementatie van deze interventies in de klinische praktijk.

DANKWOORD

DANKWOORD

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LIST OF PUBLICATIONS

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Cnossen IC, van Uden-Kraan CF, Eerenstein SE et al (2016) A participatory design approach to develop a web-based self-care program supporting early rehabilitation among patients after total laryngectomy. Folia Phoniatrica et Logopaedica 67(4):193-201.

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Cnossen IC, van Uden-Kraan CF, Witte BI et al (submitted). Prophylactic exercises among head and neck cancer patients during and after swallowing sparing intensity modulated radiation: adherence and exercise performance levels of a 12-week guided home-based program.

ABOUT THE AUTHOR - OVER DE AUTEUR

ABOUT THE AUTHOR

Ingrid Christine Cnossen was born on May 8th, 1963 in Sneek, the Netherlands. In 1980 she completed her secondary education (HAVO) at Bogerman College, Sneek. She completed her bachelor degree in Speech and Language Therapy in 1989. From 1990 until 2000 she worked as a speech therapist at the Medical Center Leeuwarden. From January until May 2000 she was a lecturer at the Hanze University College (Speech an Language Therapy) in Groningen. From November 2002 until December 2004 she lived in St. Petersburg, Florida, together with her husband and two children, and volunteered at the Shorecrest Preparatory School in St. Petersburg. She was a speech therapist at a nursing home (Lindendael, Hoorn; between 2005 and 2009) and a general hospital (Medical Center Alkmaar; between 2008 and 2009). In 2009 she obtained her Master's Degree in 'Evidence Based Practice' at the University of Amsterdam, the Netherlands. In March 2009, she started as a speech therapist researcher / clinical epidemiologist at the Department of Otolaryngology-Head and Neck Surgery of VU University Medical Center, Amsterdam. She coordinated the development and evaluation of the research projects 'Head Matters', and 'In Tune without Cords' as described in this thesis. From March until August 2015 she worked as a PhD candidate advisor at the AMC Graduate School. From November 2015 she works as a speech therapist at the Noord West Ziekenhuisgroep, Alkmaar. She is married with Tjebbe and together they have two children: Hidde (19) and Marit (17).

OVER DE AUTEUR

Ingrid Christine Cnossen is geboren op 8 mei 1963 in Sneek. Ze behaalde in 1980 haar HAVO-diploma en in 1989 het diploma Logopedie en Akoepedie. Van 1990 tot 2000 was zij werkzaam als klinisch logopedist in het Medisch Centrum Leeuwarden. Van januari tot mei 2000 was zij docent aan de Hanzehogeschool Groningen (Academie voor Logopedie). Van november 2002 tot december 2004 woonde zij samen met echtgenoot en kinderen in St. Petersburg, Florida. Van 2005 tot 2009 werkte zij als logopedist in verpleeghuis Lindendael te Hoorn en van 2008 tot 2009 in het Medisch Centrum Alkmaar. In 2009 rondde zij haar universitaire master opleiding in ‘Evidence Based Practice’ af aan de Universiteit van Amsterdam. In maart 2009 begon zij als logopedistonderzoeker / klinisch epidemioloog op de afdeling KNO/hoofd-halschirurgie in het VUmc. Zij coördineerde de ontwikkeling en de evaluatie van de onderzoeksprojecten ‘Halszaken’ en ‘Verder zonder stembanden’, zoals beschreven in dit proefschrift. Van maart tot augustus 2015 was zij promovendiadviseur aan de AMC Graduate school. Vanaf november 2015 werkt zij als logopedist bij de Noord West Ziekenhuisgroep, locatie Alkmaar. Ze is getrouwd met Tjebbe en samen hebben zij twee kinderen: Hidde (19) en Marit (17).