

A Self-Regulation Intervention to Improve Psychological Outcomes in Patients with Head and Neck Cancer and Their Caregivers

STUDY PROTOCOL

Overview

The proposed study is a randomised controlled trial that aims to investigate the effectiveness of a psychological intervention at reducing psychological distress, particularly depression and anxiety, in patients with head and neck cancer (HNC) and their family caregivers. 100 patients and their caregivers will be randomly assigned to a 'self-regulation' intervention or to a control condition (standard-care).

Prior to randomization, after the intervention (3 months), and again 6 months after diagnosis, patients and caregivers will complete assessments of coping, depression, anxiety, and post-traumatic stress. Patients will also complete assessments of health-related quality of life, fear of cancer recurrence, and anxious preoccupation.

Participants randomized to the 'self-regulation' intervention will participate in three 45 minutes sessions that are designed to modify illness perceptions and improve coping. These sessions will be conducted by a health psychologist and will take place at Auckland Hospital, or in patients' homes if necessary. A follow-up phone call will take place, one month after completion of the intervention sessions. The sessions will be individually delivered and tailored to the patients' and caregivers' concerns and situation.

It is anticipated that patients and caregivers assigned to the intervention condition will exhibit improvements in health-related quality of life, and reductions in depression and anxiety at 3 and 6 month follow-up, compared to patients and caregivers assigned to the control condition.

Rationale

Patients with HNC must contend with a number of unique challenges. Not only is the disease life threatening, with a five year survival rate of approximately 60% (12), but its treatment is associated with side effects that cause disfigurement and impact basic functions, such as speaking, breathing, swallowing and eating (13). This dysfunction and disfigurement can increase patients' susceptibility to psychological distress (14), which is more prevalent in patients with HNC than in patients with other types of cancer, including breast, prostate, bronchial and gastrointestinal (15,16).

Rates of depression are high across all stages of the HNC trajectory from diagnosis to 11 years post-treatment, with estimates ranging from 33-92% (1-3). In our recent studies, the rate of depression in newly diagnosed patients was 34% (4), and 41% of patients had mild to severe depression 12-18 months after diagnosis (5). Anxiety rates are also high in patients with HNC. Twenty percent of patients in our recent study experienced high levels of anxiety (4). Other research has found that anxiety is particularly prevalent at HNC diagnosis (30%), and that this can negatively impact on patients' capacity to engage and comply with treatment (8). Patients also experience significant fears of recurrence (9), and post-traumatic stress (10).

Despite these high rates of depression and anxiety, distress is often undetected by clinicians and unreported by patients themselves (17). Left untreated, depression and anxiety can exert considerable influence over post-treatment outcomes, negatively impacting physical functioning (18,19), health-related quality of life (20-24), and prognosis (6,7)(25). Depression and anxiety independently predict these outcomes after controlling for possible medical and demographic confounds (26).

The high rates of untreated depression and anxiety in patients with HNC suggest that mental health interventions are needed. Although a number of studies have investigated psychological interventions for patients with HNC, there is an absence of well-designed randomised controlled trials. A recent Cochrane review concluded that the shortcomings in the design and reporting of psychosocial interventions for patients with HNC prevent any conclusions regarding their effectiveness (27). Shortcomings include the small number of studies conducted, and methodological problems.

We aim to further research in this area. We will conduct a randomised controlled trial, and target variables (illness perceptions and coping) that have known associations with depression and anxiety in patients with HNC. We have chosen a self-regulatory intervention, based on Leventhal's common sense model of illness (28). Self-regulatory interventions aim to change the way that patients think and feel about their illness, in order to influence their coping behaviours and health outcomes (29,30). We chose this type of intervention because we found that patients consistently asked for more information about their illness and treatment so that they could cope better (4). This type of intervention aligns well with research that has shown the way in which HNC patients perceive and cope with their disease is associated with depression and anxiety (31-34). Negative illness perceptions are associated with the use of maladaptive coping strategies, such as avoidance, substance use, or behavioural disengagement (35). HNC patients who adopt these coping strategies are at increased risk of depression, anxiety, and poor HRQL (36-41). One coping strategy linked to lower anxiety and depression is 'Self-care', which involves a number of behavioural changes, particularly with respect to diet and lifestyle (41).

Research investigating the effectiveness of self-regulatory interventions has found positive results in a number of patient groups, including myocardial infarction (42,43), Type 2 diabetes (44,45), chronic low back pain (46,47), haemodialysis (48), asthma (49), and psoriasis (50). Self-regulatory interventions are also effective at modifying spouse and caregiver beliefs, with positive consequences for both their own (42) and patient health (45). Recent research has trialled a self-regulation intervention with oropharyngeal cancer patients. The AFTER intervention was conducted with patients 7 months after diagnosis and showed reductions in fear of recurrence and anxiety preoccupation compared to standard care (51).

When asked about when they would prefer a psychological intervention, patients in our observational study preferred an intervention to be before or during treatment (4). Therefore we have chosen to conduct this study with the intervention before and during treatment. We will include a broad range of head and neck cancers so the findings are widely generalizable.

The design of our intervention includes caregivers. This is because caregivers of patients with HNC also experience high rates of distress (11). Our study found that 30% of HNC caregivers' responses indicated depression, and 19% indicated high anxiety (4). Other research has found

that HNC caregivers experience worse psychological health and higher levels of anxiety than the patients for whom they are caring, as well as the general population (11).

Illness perceptions and coping have explained between 35% and 49% of the variance in psychological distress of those caring for patients with oesophageal cancer (52). Furthermore, HNC caregivers who use avoidant coping report more anxiety and depression than those who use other coping strategies (33,52). HNC caregiver perceptions can even influence psychological distress in the patients for whom they are caring (32). These findings suggest that efforts to reduce HNC patients' distress should consider not only the perceptions and coping strategies used by patients, but also those of their caregivers.

Objectives/ Research Questions

The primary objective of the research is to reduce depression and anxiety in patients with HNC. Secondary objectives are to improve patients' quality of life, and reduce post-traumatic stress, as well as reduce caregiver depression and anxiety.

The research questions are:

- Can a self-regulation intervention decrease depression and anxiety in patients with HNC?
- Can the intervention improve patients' quality of life and reduce post-traumatic stress?
- Can the intervention improve the mental health of patients' caregivers?
- Can these changes be maintained over time?

Methods

HNC patients who have been admitted to Auckland City Hospital for treatment (surgery, radiotherapy, surgery followed by radiotherapy, or chemo-radiotherapy) will be approached and informed about the study. Inclusion criteria will include patients of any age with a diagnosis of any cancer site/type in the head and neck region within the last four weeks. Exclusion criteria will include: lack of English language, treatment with palliative intent, or comorbidities that would interfere with participation (including cognitive impairment, significant physical disability, or severe psychiatric conditions). Informed consent will be gained from all participants.

The AFTER intervention trial found an effect size of $d=.7$ for reducing anxiety pre-occupation in patients with HNC (51). Setting power of 0.80, and an alpha of .05, G-power software (53) indicates that a total sample of 68 participants would be needed to detect this effect. Since not all patients will have caregivers who can participate, we will aim to recruit a total of 100 patients and 70 caregivers, to give us sufficient power to detect an effect of this size.

A randomised controlled trial will be conducted. Patients and their caregivers will be randomly assigned to receive either standard care plus a self-regulation intervention or to standard care alone. Prior to randomization, at 3 months, and again 6 months after diagnosis, patients and caregivers will complete assessments of coping (54), illness perceptions (55), depression (56), anxiety (57), fear of recurrence (58) and anxious preoccupation, post-traumatic stress (PDS)(59), and health-related quality of life (HRQL)(60).

Those randomized to the 'self-regulation' intervention will participate in three 45-minute sessions and a 30-minute telephone call, over the space of three months. The sessions will be conducted by a health psychologist and will take place at Auckland Hospital, or in patients' homes if necessary. The sessions will be standardised, individually delivered, and individually tailored. Session one will be before treatment, session two during treatment, and session three will be near the end of treatment, and the telephone call one month later. The sessions will address patients' and caregivers' illness perceptions, including causal beliefs, provide education about cancer and treatment, and discuss and normalise concerns. Coping techniques will be taught, including relaxation skills and self-care. A personal action plan will be developed, with coping strategies and plans for when and where to implement these. Concerns about the future will be covered and referrals to on-going support will be made if necessary.

Analysis

Primary outcome measures will be: 1) change in depression pre- to post-intervention, and 2) change in anxiety pre- to post-intervention. Analysis of Covariance will be carried out comparing groups on change scores, controlling for baseline measurements.

Timeline

January-March: Ethics approvals obtained (submitted Feb 3)

April-May: Preparation of intervention materials.

June 2014 June 2015: Patient and caregiver recruitment

November 2015: Last of six month follow-ups completed

December 2015: Analysis of data

January 2016: Dissemination of results

Impact of Research and Maori and Cultural Minority Groups in New Zealand

Maori are at increased risk of all cancers compared to non-Maori, including HNC (61). This may be partially attributable to the high rates of smoking in Maori, which are significantly higher than other ethnic groups (62). Smoking is the biggest risk factor for HNC (63,64). Not only is the incidence of HNC higher in Maori compared to non-Maori; Maori also tend to present with more advanced HNC and are at increased risk of death from the disease (65).

In New Zealand, Maori have the highest level of mental disorder overall, as well as the highest level of specific mental disorders compared with non-Maori and non-Pacific individuals (66). From 2009-2010, the age-standardised rate of Maori mental health-service use was higher than all other cultural groups. Disparities in mental health outcomes between Maori and non-Maori are continuing to widen (66). Maori patients with HNC are therefore likely to be at increased risk of experiencing poor mental health outcomes, and this research may be particularly relevant for these patients. The inclusion of family members may be particularly appealing to Maori, as whanau-orais an important component of health (67).

Dissemination of Results

It is anticipated that results of the proposed study will be published in international scientific peer-reviewed journals, and presented at local and international conferences.

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