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A randomised controlled trial of the effectiveness of a coping strategies intervention for people with head and neck cancer

Submission date 16/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/11/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/12/2007	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-75475

Study information

Scientific Title

Study objectives
Psychological distress in people with head and neck cancer. Those receiving the test intervention will have reduced psychological distress compared to those in the control group.

To test the effectiveness of the test intervention in reducing symptoms of psychological distress in people with head and neck cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Institutional Review Board of McGill University, Montreal, Canada on the 25 July 2005.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Head and neck cancer

Interventions
The test intervention is the 'Nucare program'; a psycho-educational intervention designed to teach cancer patients strategies to help them cope with having their disease. The intervention is a structured training package, delivered by trained therapists during 2-3 one-two hour sessions. The control intervention is an attention placebo in which individuals are invited to talk with the therapists concerning any problems they have with their cancer and treatment.

Trial details received 12 Sept 2005

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Psychological distress symptoms as indicated by the depression scale of the Hospital Anxiety and Depression Scale (HADS) at 4 months following randomisation.

Secondary outcome measures
1. Mean HADS anxiety and depression scale scores (measured at 8 weeks, 4, 8 months)
2. Quality of life, measured using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) Core 30 and Head and Neck (H&N35) module
3. Coping strategies (measured using the Ways of Coping Checklist)
4. Smoking and alcohol consumption behaviours
5. 2 year post-diagnosis survival
6. Recurrent head and neck cancer incidence
7. New head and neck cancer incidence
8. Cost per depression averted

Overall study start date
01/04/2005

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. Are diagnosed with a primary cancer of the head and neck region (International Statistical Classification of Diseases and Related Health Problems [ICD-9] 140-149 and 161; lip, salivary glands, tongue, floor of mouth, other mouth, oropharynx, nasopharynx, other pharynx and larynx)
2. Age 18 years and older, either sex
3. Were diagnosed 6 - 12 months previously
4. Scored greater than 7 on one or both of the anxiety and depression scales of the Hospital Anxiety and Depression Scale (HADS)
5. Are able to understand and complete either English or French language questionnaires
6. Have signed a consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
250

Key exclusion criteria
1. Are undergoing palliative or terminal care only
2. Have a previous history of malignant disease affecting other parts of their body
3. Have been diagnosed with depression and are currently undergoing any anti-depressive therapy
4. Live beyond 90 minutes traveling time by car/taxi from the site where they are recruited AND are unable or unwilling to travel to the recruitment hospital to receive the intervention as an alternative. This exclusion criterion will be used because a small proportion of patients at these clinics travel considerable distances for treatment and a limit must be made concerning the traveling time necessary for the therapists in the study.

Date of first enrolment
01/04/2005

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
Canada

Study participating centre
Faculty of Dentistry
Montreal
Canada
H3A 2B2

Sponsor information

Organisation
McGill University (Canada)

Sponsor details

3640 University St.
Montreal
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Sponsor type
Not defined

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-75475)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration