

STUDY PROTOCOL

Title:

Development and Pilot Evaluation of a Rehabilitation Consult for Survivors of Head and Neck Cancer

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1.0 BACKGROUND

In contrast with other major chronic conditions such as heart disease and stroke, cancer care does not routinely integrate evidence-based rehabilitation services within the standard continuum. This protocol describes a structured process for the development, implementation, and preliminary evaluation of a novel, integrated rehabilitation intervention for survivors of head and neck cancer (HNC) called the Rehabilitation Consultation (RC). The RC program goals are to increase knowledge about rehabilitation needs and resources to meet those needs; to establish individualized rehabilitation goals for HNC survivors and personalized action plans to meet those goals; and to provide support to HNC survivors for the implementation and evaluation of action plans. The goals will be personally important to the individual survivor, and the action plans will be achievable, using resources they can access close to home rather than at the cancer centre, when possible. Additionally, the RC will be integrated into routine HNC follow-up procedures, and will be administered as soon as possible following active cancer treatment. It will be led by a professional with a background in one of the traditional rehabilitation professions, and will include the following 3 components: 1. A brief, HNC-specific functional evaluation; 2. A resource compendium; 3. Collaborative goal-setting, action-planning, and follow-up processes.

Reductions in function and quality of life are particularly high in HNC, as the disease and treatment cause more diverse and serious impairments than many other cancers. Issues include reductions in swallowing, speech, neck and upper extremity mobility, general deconditioning, fatigue, insomnia, lymphedema, neuropathies, visible facial deformity, and psychological distress [1-9]. In addition, a range of more global functional issues result, including body image dissatisfaction, cognitive and behavioural problems [10], decreased role functioning [11], decreased nutritional status [12], decreased communication [5], poor driving performance [13] and inability to return to work [14,15]. Among the 9000 new cases of HNC in Canada each year [16], an increasing proportion is among young, working-

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aged patients, primarily related to the ongoing epidemic of oropharyngeal cancer associated with Human Papillomavirus [17]. Without rehabilitation services, the influx of younger survivors may increase the societal burden of the illness through loss of employment, increased absenteeism, and the financial, social, and potentially emotional effects on their families which may include young dependents [18,19].

Cancer rehabilitation has been defined as coordinated, professional care designed to enable people to maximize physical, social and psychological function within the limits imposed by the disease and treatment effects, and to engage in personally valued activities within their social contexts [20].

Rehabilitation interventions for HNC are demonstrably safe, feasible, cost-effective, and associated with improvements in quality of life, general conditioning, swallowing, muscle function, insomnia, pain, weakness, anorexia, shortness of breath, tube-feeding dependency, hospital readmissions, depression and distress [7,21-25]. Although evidence exists to support cancer rehabilitation, services are fragmented. Rehabilitation professionals are consulted infrequently and often long after treatment ends, when chronicity of problems limits the impact of intervention [unpublished observations].

Additional barriers to accessing rehabilitation services include cost, issues between and among patients, oncology professionals and rehabilitation experts related to communication and awareness of available resources [unpublished observations]. There are clear potential benefits to a comprehensive, integrated rehabilitation consultation process that targets all HNC patients soon after primary cancer treatment is completed, improves communication among stakeholders, and provides linkages to appropriate resources. Therefore, the overall objective of this project is to develop, implement, and conduct a pilot evaluation of the RC. This current protocol is concerned with pre-testing of an alpha version of the RC and subsequent pilot testing of a beta version.

2.0 METHODS/DESIGN

This project employs Intervention Mapping as an ecologically valid, structured framework to develop, implement, and evaluate the RC [26]. Intervention Mapping consists of 6 steps: 1. Needs assessment 2. Definition of program objectives 3. Selection of theory-based intervention methods 4. Production and pretesting 5. Adoption, implementation, and sustainability planning 6. Process and effect evaluation. Research staff and the investigators will oversee the project with input from an eight-member Advisory Panel, including patient and family representatives, health care professionals working in oncology, health care professionals working in rehabilitation, and representatives of the provincial cancer care system. All Intervention Mapping steps are described below. **Note that Steps 1 -4 have previously been completed or are in progress (REB # 13-6877-CE), with Steps 5-6 planned and the subject of this current proposal.**

2.1 Step 1, Needs Assessment

In the previously-completed Step 1, *Needs Assessment*, we used information gleaned from focus groups with patients, family members, and front-line health care professionals (unpublished data, manuscript under preparation) and from a scoping literature review (unpublished data, 1 manuscript submitted, 1 manuscript under preparation) to establish the rehabilitation needs of HNC survivors. The rehabilitation needs appear as Phase 2 and Phase 1 in Table 1. We next identified highly relevant and modifiable behavioural and environmental factors that contributed to the identified issues (Phase 3, Table 1), their determinants (Phase 4, Table 1), and the items targeted for change with the RC intervention (items in italics in Table 1). Finally, the following RC program goals were developed: 1. Increase knowledge of all stakeholders about rehabilitation needs and about resources to meet those needs; 2. Establish individualized rehabilitation goals and personalized action plans for HNC survivors; 3. Provide support for the implementation and evaluation of action plans; 4. Facilitate HNC survivors' access to rehabilitation professionals where it is most feasible for them.

2.2 Step 2, Definition of Program Objectives

In the previously completed Step 2, ***Definition of Program Objectives***, the resource requirements that will enable achievement of the program goals described above were specified. The specific resource requirements to be developed as components of the RC include a brief, HNC-specific functional evaluation, an online resource compendium that includes comprehensive information about rehabilitation services in Toronto and adjacent regions as well as educational modules for specific home-based exercises, a goal-setting and action planning process, and a follow-up process. The specific behavioural requirements are that the HNC survivors be confident in goal-setting and action planning, and that all stakeholders be knowledgeable about HNC rehabilitation needs and applicable resources.

2.3 Step 3, Selection of Theory-Based Intervention Methods and Practical Applications

In Step 3, ***Selection of Theory-Based Intervention Methods and Practical Applications***, the research team reviewed the work completed in Intervention Mapping Steps 1 and 2 with the Advisory Panel. Then, the research team selected behavioural change methods from the Intervention Mapping tables [26, p 357-358] that are congruent with self-management and goal-setting theories and with the RC program parameters. Additional behavioural change methods derived from the Cognitive Orientation to daily Occupational Performance (CO-OP) approach were also incorporated, specifically cognitive strategy training and guided discovery. (Polatajko & Mandich, 2004) Behavioural change methods were linked to specific change objectives and determinants. Two members of the research team (SM and CD) then identified practical applications (such as worksheets, pamphlets, websites, videos) to enact those methods. The Advisory Panel will conduct a final review of all methods and practical applications selected in Step 3 to ensure that they mesh with the program goals and resource requirements identified in Intervention Mapping Steps 1 and 2, and will make recommendations for modifications if necessary.

2.4 Step 4: Production of Program Components and Pre Testing

Figure 1 provides the expected timeline for completion of Steps 4 through 6. In Step 4, ***Production of Program Components and Pre Testing***, all components of the RC will be developed and pre-tested for

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acceptability and feasibility. The program components to be developed are as follows: a brief, HNC-specific functional evaluation; a resource compendium; collaborative goal-setting, action-planning, and follow-up processes.

The **brief HNC-specific functional evaluation** has the objectives of estimating both performance-based issues, such as swallowing or joint mobility, but also patient-determined functional and life participation issues, such as return to work or family and social role functioning. Items will be derived from the Needs Assessment completed in Step 1. The investigators and study staff will generate an initial list of items that will be reviewed for content, length, and intelligibility by the Advisory Panel, and modified as necessary.

Development of the **resource compendium** is currently underway using interviews with key informants. This piece of the RC development was initiated as part of the previously approved project (REB # 13-6877-CE). The resource compendium includes listings of rehabilitation services available in Toronto and adjoining regions that commonly refer to Toronto regional cancer centres, educational resources for patients and therapists, and materials to support the RC process, such as worksheets and pamphlets. All materials will be available online at www.hncrehab.ca and printed hard copies of materials will also be available for those survivors who have difficulty accessing the Internet.

A preliminary version of the **collaborative goal setting, action planning, and follow up processes** has been developed. All survivor/professional processes are designed to establish a strong therapeutic alliance, to engage and motivate the survivor, and to foster independence and self-management. The alpha-RC face-to-face phase (collaborative goal setting and action planning process) includes the following steps:

- A. A brief presentation (Appendix A) is given by the rehab consultant to **orient** the survivor to the reason for the consultation and the process.
- B. The rehab consultant implements the brief HNC-specific functional evaluation, and then **consults** with the survivor regarding the results. The survivor identifies the issues that are currently most important to him or her.
- C. The survivor and the rehab consultant work collaboratively to set **goals** based on issues identified by the survivor as most important to him or her. The rehab consultant teaches the survivor a global problem solving strategy, Goal-Plan-Do-Check (Meichenbaum, 1971).
- D. Using the Goal-Plan phases of the problem solving strategy, the rehab consultant and the survivor develop an action **plan** to meet the identified goals. The rehab consultant uses motivational interviewing techniques (eliciting change talk, evoking motivation to make positive changes (Miller & Rollnick, 1991) and guided discovery techniques (ask don't tell, coach don't adjust, make it obvious, and one thing at a time (Polatajko & Mandich, 2004)). Also as part of the planning process, the rehab consultant and the survivor discuss potential barriers to implementing the action plan and develop coping responses, using planning coping responses techniques (Marlatt & Donovan, 2005). The rehab consultant introduces the survivor to the resource compendium for future use, and facilitates the assembly of resources necessary to implement the survivor's plans.
- E. Telephone follow-up appointment is scheduled for between 2 and 10 weeks later, at a mutually convenient time. The survivor also has the option of attending a follow up session in person. Preferred communication strategies are set in place, and the survivor is encouraged to **execute (do)** his or her plan.

The alpha-RC telephone follow-up process includes the following steps:

- A. An email/text/or telephone reminder (as preferred by the survivor) regarding the follow-up appointment is sent 24 hours in advance.
- B. The rehab consultant phones at the designated date and time and confirms with the survivor that the appointment is still convenient.
- C. The rehab consultant re-orientes the survivor to the RC process.
- D. The rehab consultant and the survivor begin the *check* phase of goal-plan-do-check. They review the goals and the actions plans, and proceed with a discussion about the do-check portion of the problem solving strategy. The rehab consultant guides the discussion using motivational interviewing and guided discovery techniques. If the plan was successfully implemented and the goals are achieved, next steps are discussed. If the plan was not implemented or the goals were not achieved, the rehab consultant will guide the survivor to modify the plan as necessary. The rehab consultant and the survivor discuss potential barriers to implementing the newly modified action plan and develop coping responses, using techniques for planning coping responses.
- E. The need for a second follow-up appointment is discussed and, if necessary, scheduled at a mutually convenient time. If the survivor seems to be struggling, a face-to-face follow-up might be scheduled. If a follow-up is deemed unnecessary at this time, the survivor is provided with information about how to access the rehab consultant in the future, should the need arise, and discharge occurs. The rehab consultant arranges a time for the research assistant to conduct a re-assessment of the outcome measures (Research Assessment 2), as well as a semi-structured interview for participant feedback.

2.4.1 Pre Testing

2.4.1.1 Participants and Recruitment Pretesting of the alpha-RC process will be conducted using an iterative single case series of 5 to 10 survivors of HNC. Participants will be recruited from the HNC clinics at Sunnybrook Odette Cancer Centre and Princess Margaret Cancer Centre. Eligibility criterion

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are adult survivors of HNC who have completed active treatment (surgery, radiation, chemotherapy or any combination thereof) within the last year. Exclusion criteria are lack of English fluency, cognitive impairment, or concurrent major degenerative conditions likely to cause functional deterioration. Two members of the research team who are radiation oncologists (IP, Sunnybrook, and JR, Princess Margaret) will review patients scheduled for follow-up at their respective HNC clinics for eligibility, and will approach those who are eligible to ask if they are interested in learning more about a rehabilitation research project. Those who express interest will be connected with an on-site research assistant, who will provide the potential participant with additional information about the study and to answer any questions they may have. If the survivor is willing, the research assistant will obtain informed consent and schedule an assessment and alpha RC intervention time. The research assistant will provide the participant with the Brief Rehabilitation Assessment for Head and Neck Cancer Survivors (BRASH) for the patient to review and complete prior to meeting with the Rehabilitation Consultant. We anticipate that we will be able to recruit 1 participant per week.

2.4.1.2 Procedures. Participants will be required to attend 3-4 sessions that are a combination of face-to-face visits and telephone calls. Session 1: Face-to-face, at the research site (either Sunnybrook or Princess Margaret) a research assistant will conduct a pre-intervention *research* assessment (approximately 60 minutes) and then on the same day, a rehabilitation consultant, licensed physiotherapist Colleen Dunphy, will administer the face-to-face phase of alpha-RC *intervention* (approximately 90 minutes). Session 2: As a second phase of the alpha-RC *intervention* process, the rehabilitation consultant (CD) will conduct a telephone follow-up with the participant (45 to 60 minutes). Session 3: Within one week of Session 2, the participant will complete a post-intervention *research* assessment with the research assistant (approximately 60 minutes), either as a face-to-face visit at the research site, or as a telephone interview. For Session 3, it will be the participant's choice to have either a face-to-face or telephone interview, based on what is most convenient for him or her. This

choice has been put in place because many patients travel to Sunnybrook and Princess Margaret from out-of-region to receive specialized treatment for head and neck cancer, making an additional face-to-face visit very inconvenient for some. It is possible that, as part of the alpha-RC *intervention*, participants will require a second follow-up session that may occur as a second telephone call or a second face-to-face meeting. This is expected to happen rarely. The rehabilitation consultant will log any additional follow-up meetings, including type (phone or face-to-face), reason for meeting, outcome of meeting, next steps.

Participants will be remunerated \$25 for each *research* visit to the site to offset their transportation and parking costs, for a total of \$50 per participant. Additional *intervention-only* visits will not have any remuneration.

At both the pre and post intervention research assessments, the following constructs will be evaluated: function, quality of life, self-efficacy, community participation, goal attainment, and return to work status (if applicable). Additionally, the research assistant will collect data on the time to complete the assessment battery; perceived respondent burden; and ease of use of all tools. At the post-intervention assessment, the participant will be asked to complete a survey related to the content and process of the alpha-RC. Table 2 describes all tools to be used. The rehabilitation consultant (CD) will video record the face-to-face phase and audio record the follow-up telephone call so that the processes can be reviewed and analysed in depth. The following information will be extracted from these recordings: time required for each segment in the process; adherence to planned methods and theory; challenges and successes with each participant.

Descriptive analysis will be conducted; the research team will review results, and then make decisions about adaptations to the alpha-RC and finalization of the outcome measure battery. The alpha-RC will

be modified iteratively based on the information gleaned from each survivor, outcome data, and feedback from research team members. Step 4 will be considered complete when the investigators are satisfied that a version of the RC suitable for formal pilot evaluation has been developed, the beta-RC.

2.5 Step 5: Planning for adoption, implementation, and sustainability.

This is a planning step, in which a logic model will be developed to guide the initial implementation and program evaluation. Specific objectives for adoption, implementation, and sustainability will be established, and determinants of those will be considered. We will seek input on the logic model from the Advisory Panel.

As stated in sections 2.1 and 2.2, two of the objectives of the overall study are: 1. Increase knowledge of all stakeholders about rehabilitation needs and about resources to meet those needs; 2. Facilitate HNC survivors' access to rehabilitation professionals where it is most feasible for them. To assist in this stage, head and neck cancer patients will be surveyed in clinic to determine their baseline level of awareness of rehabilitation services, where they receive any current information, and their preferences for receiving this information. Any consenting head and neck cancer patient will be eligible for the survey, but only those who meet inclusion criteria for the rest of the study will be approached for participation in the rehabilitation consult. We anticipate surveying 20-30 patients. This information will provide input into the design of adoption and implementation strategies to address the above objectives, and plan for long term sustainability. The same survey will be administered in clinic, to a separate sample of 20-30 patients, after these strategies have been implemented.

2.6 Step 6, Pilot Testing

In this step, we will implement the program evaluation plan established in Step 5, and will also include a pilot outcome evaluation to estimate the impact of the beta-RC on function and quality of life. We will implement and evaluate the beta-RC using a mixed method, single group study with a convenience sample of approximately 35 HNC survivors post primary cancer treatment, *recruited from the Princess*

*Margaret Cancer Center HNC clinics**, with inclusion and exclusion criteria and recruitment as described above in section 2.4.1. The procedures will be as described above in 2.4.1.2, with the following changes:

- a) An additional research assessment (Session 4) will be added. Session 4 will occur 1-2 months after Session 3; the participant will complete a follow-up assessment with the research assistant (approximately 60 minutes), either as a face-to-face visit or as a telephone interview. The assessment battery will be based on the tools described in Table 2.
- b) The intervention will include revisions based on feedback and observations from the pre-testing stage. The pilot testing version (beta RC) of the previously described intervention can be found in Table 3.
- c) The intervention will continue to be video recorded and reviewed by an investigator for fidelity. This will occur for the first 3 participants and then for every 5th participant who completes the intervention, starting with the 1st (1,2,3, then 8th, 13th, and so on). To explore survivor experiences with the RC, a survey will be administered during session 3, based on one-on-one semi-structured interviews carried out during the pre-testing phase. (approximately 30 minutes). The survey is included in Appendix B.

Participants will be remunerated \$25 for each *research* visit to the site to offset their transportation and parking costs. Additional *intervention-only* visits will not have any remuneration.

Quantitative data analysis will be exploratory and descriptive, and effect sizes will be calculated for all outcomes to help plan for a future, controlled trial. We will calculate means, standard deviations, and Cohen's *d* [39] effect size for normally distributed data. For non-normally distributed data, we will calculate medians, ranges, and a nonparametric effect size *r* using the formula $r^2 = z^2 / N$. [40] For qualitative analysis, all interviews will be audio recorded, transcribed verbatim, and analyzed using a

* Note that Sunnybrook-Odette will not be involved with data collection in Step 6

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two-phased, hybrid approach that is both deductive and inductive, described by Fereday and Muir-Cochrane [41]. Findings will be summarized and reported to the Advisory Panel, who will then make recommendations regarding any additional modifications to the RC. The research team will make final decisions about RC modifications and will finalize a version for future evaluation.

In order to further evaluate individual program components, and address the objectives of adoption and knowledge translation to rehabilitation professionals, the research team will evaluate the brief, head and neck specific, functional evaluation that was developed as part of the project, and described in section 2.4. Content validity will be assessed by collecting feedback from professionals in the multidisciplinary head and neck cancer site group, regarding the degree to which items of the functional assessment adequately represents relevant rehabilitation issues in the head and neck cancer population. Concurrent (convergent and divergent) validity will be assessed through comparing the results of the functional assessment to the standardized and validated FACT-H&N and SF 36 assessments, which are already being administered to study participants. Data will be analysed using the content validity index, descriptive statistics, and Spearman's rho correlation coefficients.

Assuming positive outcomes from this single group evaluation, a future, multi-site controlled trial will be designed and implemented in a future study. Results from this study will provide feasibility information, such as recruitment rates; help to define primary and secondary outcomes; and provide data to calculate sample size to ensure an adequately powered trial.

3.0 DISCUSSION

This project brings together the diverging views of rehabilitation specialists, focused on long-term real-world function, with those of cancer specialists, focused on acute treatment and episodic symptom management. We have set out to bring those views together to develop a clinically effective and cost-

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effective rehabilitation intervention that integrates seamlessly with an existing cancer care system.

Survivors of HNC have among the most complex rehabilitation needs of all cancer patients because of the anatomical complexity of the head and neck region. The RC is expected to improve knowledge and uptake of rehabilitation resources and strategies in survivors of HNC, and thereby improve function and quality of life. The RC will be designed to ensure the components are readily modifiable for use beyond the regional cancer centres within which they were developed. Further, we believe that HNC serves as an ideal incubator for development of the RC. If it is effective in cancer patients with such high and diverse needs, it is expected that this project will produce a toolkit that will be adaptable for other types of cancer in other jurisdictions.

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Table 1: Intervention Mapping Step 1, Needs Assessment Logic Model

	Phase 4: Determinants	Phase 3: Behavioural and Environmental Factors	Phase 2: Body Structures and Functions	Phase 1: Function and Health
				➔
Modifiable	<p><i>Awareness of rehab needs/risk</i></p> <p>Communication style</p> <p>Coping style</p> <p><i>Healthcare team engagement and buy-in</i></p> <p><i>Knowledge about association among needs/issues</i></p> <p><i>Knowledge about condition</i></p> <p><i>Knowledge about metacognitive strategy use</i></p> <p><i>Knowledge about symptom management and resources</i></p> <p><i>Local processes</i></p> <p>Physician referral processes</p> <p><i>Physician support and participation (awareness of rehab consult, recommendations and clearance)</i></p> <p>Pre-existing mood/behavior</p> <p><i>Self efficacy</i></p>	<p><i>Action planning</i></p> <p>Addictions – presence or absence</p> <p>Attitudes/biases towards HNC survivors</p> <p><i>Availability of and access to relevant resources (particularly clinicians)</i></p> <p>Community resources</p> <p>Coping habits</p> <p><i>Developing strategies</i></p> <p><i>Dietary habits</i></p> <p><i>Energy Budgeting</i></p> <p><i>Exercise habits</i></p> <p><i>Expectations</i></p> <p><i>Goal setting and action planning</i></p> <p><i>Health care professionals knowledge about rehab and head and neck cancer treatment</i></p> <p><i>Problem solving</i></p> <p><i>Rehab resources</i></p> <p><i>Self regulation/self evaluation</i></p> <p><i>Substance use, particularly smoking, - presence</i></p>	<p>Aesthetic outcomes</p> <p>Body image/body satisfaction</p> <p>Cardiovascular capacity</p> <p>Chewing/mastication</p> <p>Cognitive impairments</p> <p>Dental issues</p> <p>Digestive system functioning</p> <p>Dry mouth</p> <p>Fatigue</p> <p>Fibrosis</p> <p>Instrumentation care (eg. Trach, feeding tube, etc)</p> <p>Intimacy</p> <p>Joint mobility</p> <p>Late effects</p> <p>Lymphedema/edema</p> <p>Mental health (eg. Anxiety, depression, mood)</p> <p>Mouth opening</p> <p>Muscle strength</p> <p>Range of motion (ROM) – neck, upper extremity, mouth/jaw</p> <p>Neuropathies/Sensory issues</p> <p>Pain</p>	<p><i>Decreased employment</i></p> <p><i>Decreased functional status (Activities of Daily Living or ADLs)</i></p> <p><i>Decreased health status</i></p> <p><i>Decreased participation and engagement in personally-meaningful life areas</i></p> <p><i>Decreased psychosocial function</i></p> <p><i>Decreased role function</i></p>

		<i>or absence</i>	Personality changes Respiratory issues Senses (ie. Smell, taste, touch, sight, hearing) Sexuality Speech Swallowing Voice Weight loss	
Difficult to Modify	Age Disease site Education level Personality Sex Socioeconomic status/finances Treatment received	Culture (of survivor) Familial/caregiver support Geographic location – rural vs urban Hospital type (eg cancer centre vs tertiary care centre) Language Living/workplace conditions (e.g. exposure to second-hand smoke, exposure to carcinogenic substances at work unknowing or without proper protection gear, etc.)		

Items in *italics* are targeted for change.

Items in the “Determinants” column refer to both clinician and provider, where applicable, unless otherwise stated.

Table 2. Outcome Measures

Construct	Instrument(s)	Description and Psychometric Properties
Health-related Quality of Life	Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) [42,43]	SF-36 a widely used, generic, patient-report measure created to assess health-related quality of life (HRQOL). It consists of 8 domains: Physical Functioning, Role limitations due to Physical problems, Bodily Pain, General Health Perceptions, Social Functioning, General Mental Health, Role limitations due to Emotional problems, and Vitality. SF-36 has been widely tested, and, with the exception of the Social Functioning subscale, has excellent internal consistency and interrater reliability; SF-36 has adequate to excellent convergent validity with a number of functional and HRQoL scales.
	The Functional Assessment of Cancer Therapy-Head and Neck Version 4 (FACT-H&N) [44]	Self-report reliable and valid quality of life questionnaire. The scale consists of a core FACT-G (General) questionnaire that covers four domains: physical, social/family, emotional, and functional. The scale is supplemented by a head and neck cancer specific subscale. Items are rated on a 0 (<i>Not at all</i>) to 4 (<i>Very much</i>) Likert scale and scores are calculated to produce subscale scores for each domain. It is reliable and valid in patients with HNC, scores correlating with treatment status and global performance status.
Participation	Reintegration to Normal Living Index (RNL) [45]	The RNL consists of 11-items covering areas such as recreational and social participation, community mobility, family roles and other relationships. It has high internal consistency, moderate interrater reliability, and is correlated with measures of quality of life and well being.
Self-Efficacy	HNC RC Self-Efficacy Tool	There was no existing tool which adequately measured self-efficacy as it relates to the goals of this study. Therefore, a self-efficacy tool was created, using a 0-100 rating scale, based on Bandura (2006) "Guide to Constructing Self-Efficacy Tools" to measure the confidence of participants to achieve outcomes specific to this study. This tool is included as Appendix D.
Return to Work	Radiation Therapy Oncology Group (RTOG) Work Status Questionnaire [47]	The RTOG Work Status Questionnaire is a brief, patient-report tool that takes less than 5 minutes to complete. It was designed for use in RTOG trials, and psychometric properties have not been tested, but meets content validity criteria and sensibility criteria.
Goal Attainment	Goal Attainment Tool	Participants are asked about how well they currently perform a stated goal, which they develop in consultation with the rehabilitation consultant, how satisfied they are with this performance, and their confidence they can do the goal, and rate these on a scale of 0-100. A score of 0 represents low performance/satisfaction, and 100 represents the highest level of performance/satisfaction. This tool is included as Appendix C.
Patient Perspective Intervention Process	Rehab Consult Process Survey	Items for this survey were derived from questions posed in interview format during an earlier testing phase. 17 statements are scored using a 3-point Likert-type scale. Statements concerns intervention process issues such as timing, ease of use, and value of specific consult segments. This can be found in Appendix B.

Table 3: Pilot (beta) testing version of Rehabilitation Consult Process

Name	Process Steps	Methods
Orientation	A. A brief orientation (Appendix A) is given by the rehab consultant to orient the survivor to the reason for the consultation and the process.	Advance Organizer
Consultation	B. The rehab consultant reviews the brief HNC-specific functional evaluation (BRASH), and then consults with the survivor regarding the results. The survivor identifies the issues that are currently most important to him or her. If the participant has no goals, the rehabilitation closes the session by reinforcing that the options available if he/she has issues arising at a later time, and providing information on accessing the resource compendium.	Goal-setting Individualization Therapeutic alliance Facilitation Participatory problem solving
Goal-setting	C. The survivor and the rehab consultant work collaboratively to make goal statements based on issues identified by the survivor as most important to him or her. The rehab consultant administers a goal attainment tool (Appendix D) wherein the participant rates his or her current performance, satisfaction, and confidence with the goals.	Goal-setting Individualization Therapeutic alliance Facilitation Participatory problem solving Cognitive strategy training
Teach cognitive strategy	D. The rehab consultant teaches the global problem solving strategy, Goal-Plan-Do-Check (Meichenbaum, 1971).	
Action Planning, Planning Coping Responses, and Introduction to Resources	E. Using the Goal-Plan phases of the problem solving strategy, the rehab consultant and the survivor develop an action plan to meet the identified goals. The rehab consultant uses motivational interviewing techniques (eliciting change talk, evoking motivation to make positive changes (Miller & Rollnick, 1991) and guided	Individualization Therapeutic alliance Facilitation Participatory problem solving Motivational interviewing techniques Framing Guided discovery Implementation intentions Planning coping responses

	<p>discovery techniques (ask don't tell, coach don't adjust, make it obvious, and one thing at a time (Polatajko & Mandich, 2004)). The rehab consultant reviews the rehabilitation resources of which the survivor may already be aware, or accessing. The rehab consultant reviews the study website (resource compendium) (www.hncrehab.ca), with the survivor, for future use, and facilitates the assembly of resources previously unknown to the survivor, which are necessary to implement the survivor's plans. Also as part of the planning process, the survivor identifies potential barriers to implementing the action plan and develops coping responses, using planning coping responses techniques (Marlatt & Donovan, 2005), all facilitated by the rehabilitation consultant.</p>	Verbal persuasion
Execution	<p>F. Facilitated by the rehab consultant, the survivor reviews his or her goals and action plan for clarity, and is encouraged to execute (do) his or her plan. Follow-up appointment is scheduled for between 2 and 10 weeks later, at a mutually convenient time. This may be in person, or via telephone, as per survivor's preference.</p>	Implementation intentions Planning coping responses
Follow-Up Process		
Reminder	<p>A. A telephone reminder regarding the follow-up appointment is made 24 hours in advance.</p>	Advance organizer Individualization
Re-Orientation	<p>B. The rehab consultant phones at the designated date and time and confirms with the survivor that the appointment is still convenient. The rehab consultant re-orient the survivor to the RC process.</p>	Facilitation Individualization
Checking	<p>C. The rehab consultant and the survivor begin the check phase of goal-plan-do-check. They review the goals and the rehab consultant</p>	Self monitoring of behavior Individualization Goal setting Motivational interviewing

	<p>re-administers the goal attainment tool. Subsequently, the actions plans are reviewed and they proceed with a discussion about the do-check portion of the problem solving strategy. The rehab consultant guides the discussion using motivational interviewing and guided discovery techniques. If the plan was successfully implemented and the goals are achieved, next steps are discussed. If the plan was not implemented or the goals were not achieved, the rehab consultant will guide the survivor to modify the plan as necessary. The rehab consultant and the survivor discuss potential barriers to implementing the newly modified action plan and develop coping responses, using techniques for planning coping responses.</p>	<p>techniques Self monitoring of behaviours Self re-evaluation Goal setting Implementation intentions Planning coping responses Guided discovery Verbal persuasion</p>
<p>Discharge or Further Follow-up</p>	<p>D. The need for a second follow-up appointment is discussed and, if necessary, scheduled at a mutually convenient time. If the survivor seems to be struggling, a face-to-face follow-up might be scheduled. If a follow-up is deemed unnecessary at this time, the survivor is provided with information about how to access the rehab consultant in the future, should the need arise, and discharge occurs.</p>	<p>Individualization Facilitation Guided discovery Verbal persuasion Implementation intentions Planning coping responses</p>

Figure 1: Timeline

