The MHK (Mitchell, Hoole, Kanatas) questionnaire: the first patient reported outcomes (PROs) instrument relating to intimacy problems following diagnosis and treatment for head and neck cancer

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Abstract

Introduction

Patient reported outcomes (PROMs) are increasingly used by clinical teams as quality indicators when assessing treatment following a diagnosis of head and neck cancer. Approximately 1/3 of patients report reduced sexual interest or enjoyment following head and neck cancer therapy. Despite that, there is no intimacy questionnaire developed specifically for head and neck cancer patients. The objective of this study was to develop the first such questionnaire, to gain an indication of the relative frequency of individual items and compare clinical characteristics such as age, stage, treatment, time since treatment, with an established head and neck cancer (HNC), health-related quality of life (HRQOL) measure (EORTC QLQ-C30 with the H&N 35 module).

Method

The development of the instrument was based on an exploratory observational study that included quantitative and qualitative methods. The qualitative element was achieved with item generation - from the perspective of the literature, patients and carers and a cross-sectional survey of HCN patients who were alive and disease free. The quantitative element comprised exploratory and confirmatory factor analysis (EFA and CFA), internal reliability assessment (Cronbach's alpha) as well as a correlational analysis.

Results

42 patients were included in the focus groups and a total of 101 patients participated in the cross-sectional survey. Patients were male and female, in relationships and single, age range 30 to 70 years. All treatment modalities were included. We demonstrate that the ability to enjoy a sex life has been adversely affected in about 50% of the sample and that this has significantly changed from before their cancer in 30% of the patients. The qualitative part of the study resulted in 22 items covering a range of domains from dry mouth, thick saliva, to loss of sensation (lips, fingertips), restricted head/neck movement, fatigue and pain. The EFA revealed four domains (physical, sensation, movement and communication) from 12 of 22 items.

Cronbach's alphas ranged from 0.62 to 0.84, and the CFA revealed good fit statistics for these domains. In terms of the EORTC QLQ-H&N35, the 4 (MHK) domains showed good levels of association with anticipated domains.

Conclusion

HNC and the associated treatment significantly adversely affects intimacy and sexuality in half the sample population. The MHK tool may be used to identify specific issues relating to intimacy in patients with a history of diagnosis and treatment for head and neck cancer. Further work is essential in order to identify its precise role and to help develop specific interventions.

Introduction

The diagnosis and treatment for head and neck cancer often have devastating consequences to patients and their families[1]. Essential parts of clinical care include the measurement of symptoms, function and HRQOL, before, during and after treatment. There are several assessment tools currently being used by clinical teams, but these tools do not yet cover all the domains required for a holistic needs assessment (HNA), which is mandatory in the UK[2]. Following advances in diagnosis and treatment cancer is recognised as behaving as a chronic disease. Patients may benefit from their partners active involvement in their care. Recent data found that being married reduced HNC patients' risk of dying from cancer by 33% [3]. In addition to providing emotional support and helping patients cope with the disease or the treatment, there is growing recognition that spousal caregivers have their own unique needs and concerns[4]. Unmet caregiver support needs have been shown to adversely affect both patient and caregiver quality of life[4]. Sexual well-being is an important aspect of patients' psychological rehabilitation[5]. The identification of the intimacy problems of patients is an essential part of relationship needs and this may become more relevant given the rapid rise of HPV related oropharyngeal cancers[6]. Problems with sexuality and intimacy in head and neck cancer are under reported[7,8]. Rogers et al (2015)[9] concluded that intimacy and sexuality problems will remain a potential unmet need unless attempts are made to advance the opportunities for patient screening. Previous work has highlighted shortcomings in the identification of problems with intimacy and sexuality in patients treated for head and neck cancer[10,11,12]. The aim of this work was to develop an intimacy questionnaire applied specifically to HNC patients.

Materials and method

For this work we followed and developed further the methodology that was previously published[13,14]. We started with the following hypothesis and objective:

Hypothesis: Using a specifically developed tool in clinical practice will help to identify patient intimacy and sexual dysfunction concerns, improve consultations between professionals and patients so that their concerns are highlighted and addressed.

Specific objective: To develop an intimacy tool specific to HNC. The development of the instrument was based on an exploratory observational study that included quantitative and qualitative methods.

This was achieved with two phases.

Phase 1: Item generation - from the perspective of the literature, clinical specialists, patients and carers.

Phase 2: A cross-sectional survey of HNC patients who were alive and disease free. The aim of phase 1 was to provide a working draft of intimacy issues that were relevant to HNC patients. The aim of the cross-sectional survey (Phase 2) was to gain an indication of the relative frequency of individual items and compare clinical characteristics such as age, stage, treatment, time since treatment, with an established Head and Neck cancer HRQOL measure (EORTC C30 with the H&N 35 module). During phase 1 (item generation phase) the following steps were undertaken:

I) A structured literature review of HRQOL questionnaires specific to head and neck cancer and general intimacy and sexual dysfunction tools was completed and published[11].

II) Patients were recruited prospectively from the Head and Neck clinics of the relevant hospitals and participated in 4 focus groups of 8-12 participants. All discussions were audio recorded to ensure quality.

III) National bodies – British Association of Oral and Maxillofacial Surgeons (BAOMS) and the British Association of Head and Neck Oncologists (BAHNO)were contacted to explain the background of the tool and asked to comment on the draft resulting from step III.

At the end of steps I and II, a preliminary intimacy tool was constructed highlighting the most relevant concerns patients might wish to raise in out-patient clinics. There are 2 parts to the tool. First, any existing intimacy and or sexual function issues, if present, are identified. Second, specific items which impact on intimacy after HNC and/or treatment for HNC.
The items on this preliminary tool were shown (in semi-structured interview format) to patients in 4 focus groups (step III), to identify which items had the greatest impact on daily living from the patients' point of view and the acceptability of language being used. Focus groups and semi-structured interviews were analysed concurrently with data collection to identify key themes and sub-themes by content analysis. After transcribing the interviews, relevant phrases/expressions were obtained for each of the assessed items. This was followed

by an initial qualitative reduction of the identified sentences, in which expressions that may be considered inappropriate, ambiguous or redundant were excluded. During phase 2 we conducted a prospective cross-sectional survey of HNC patients. Disease free patients with a history of HNC in the last 11 years were included. Patients with metastatic disease or with cancer at other sites were excluded from the study. Patient were identified in the head and neck clinics. Interested patients were given a study information pack. The information pack contained the HRQOL measure (EORTC 30 with the H&N 35 module (4)), appropriate consent, GP contact documentation, details about the study and the preliminary tool that was constructed in Phase 1. Patients were asked to identify items they think should be included and any items they think should be removed or could add any items they think were missing. Demographic and clinical characteristics such as age, stage, treatment, time since treatment were accessed via clinic records. For phase 1 we recruited 8-12 patients per focus group and for phase 2 we aimed for 100 patients. These figures are pragmatic and based on a literature review and retrospective audit of the experience obtained during the development of the other tools in oncology[15,16,17]. All data were entered into SPSS (Version 25.0, IBM SPSS Statistics) after the removal of all personal identifiers. Additional analyses were also carried out with RStudio using the lavaan library package. Qualitative data was audio-recorded and transcribed verbatim. Anonymous identity codes were used to assure the identity of participants was not revealed. This work was approved by; Calderdale and Huddersfield Research and Ethics Committee, the Health Research Authority Ethics Committee and Leeds Central Ethics Committee.

Instruments

Patients completed the EORTC QLQ-C30 as well as the associated Head and Neck Cancer module (H&N35). The EORTC QLQ-C30 comprises five functional scales (physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning), and eight symptoms scales (fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea). In addition to this there is one financial difficulties scale, and a global health status or quality of life scale (GHS). With the exception of the latter, all responses are scored on a 4-point Likert scale (Not at all, A little, Quite a bit, Very much). The GHS is scored on a 7-point numeric rating scale with 2 anchors: “Very poor” and “Excellent”. The H&N35 is scored in the same way as the EORTC QLQ-C30 functional

scales and consists of 15 scales covering issues particular to head and neck cancer, such as swallowing, sense problems, speech problems, dry mouth and sticky saliva. Raw scores on these instruments are converted to a 0-100 scale. For the EORTC QLQ-C30 functioning scales and GHS, higher scores indicate better functioning, whereas higher scores on the symptom scales and H&N35 indicate worse symptoms[1].

In the cross-sectional survey patients completed the EORTC QOL-C30 with the H&N 35 module in addition to the MHK tool that derived in Phase 1 of the study. This tool included some general questions relating to intimacy and sexuality, a list of treatment related complications applicable to both sexes followed by sections that are completed by male or female patients only. The four response categories on the MHK ("Not at all", "A little", "Quite a bit", "A lot") were scored on a scale from 1 to 4.

Statistics

Descriptive statistics were derived for the sample describing the patients' basic clinical details. The EORTC QLQ-C30 and H&N35 module were converted to scale scores using the published algorithms (EORTC, 2001).

Factor analysis

An exploratory factor analysis was undertaken using principal components analysis (PCA). This was applied with a varimax rotation (assuming orthogonality or no correlation between the factors) to determine the factors structure of the MHK. Factor loadings were assessed against a criterion of ≥ 0.4. Scree plot, eigen values >1 (Kaiser's criterion), and percentage variance explained were used to determine the optimal number of factors present. Cronbach's alpha was used to assess the internal reliability of the putative factors.

Validation

Confirmatory factor analysis was applied to further assess the factor structure of the MHK instrument. Model fit was evaluated using the root mean square error of approximation (RMSEA<0.08), and comparative fit index (CFI>0.90).

[1] EORTC QLQ-C30 Scoring Manual. Third Edition. 2001. www.eortc.be

Pearson's correlations were used to determine degree of association between the EORTC QLQ-C30, H&N35 and the MHK.

All analyses were undertaken using IBM SPSS Statistics version 25 and AMOS version 25 (IBM).

Results

Results for the initial MHK questionnaire are shown in Table 1 and 4. Forty-two patients were included in the focus groups. Each session included one hour of open discussion, led by the group and facilitated by one of the authors (JH). The groups changed the language of the questionnaire items, for example question 1 b, one group wished the language to be "compared to your sex life at its best", to another group wishing to say, "pre, your cancer" and it was agreed by all patients to use "compared to your sex life previously". For the desire for Intimacy Questions: the scale was agreed by the focus groups. The tool is now in version 10, this is with the impact of every group and feedback, as well as the final reliability and validity of relevant questions.

A total of 101 patients participated in the cross-sectional study. Table 2 shows a breakdown of the patient demographic details. As may be seen, just under 37% of the sample were female, average age was 62 years (range: 35.5 to 117.8 years). The majority of patients had surgery alone or with adjuvant treatment.

Outcome measures – EORTC QLQ-C30 and EORTC QLQ-H&N35

Complete data were available for between 84 to 89 patients (not all patients completed all of the questions) (Table 3). In general, patients reported relatively good levels of functioning and quality of life compared to reference values for patients with head and neck cancers, although slightly worse in terms of symptoms, such as fatigue and pain. Similarly, cancer-specific symptomatology was also broadly in line with reference values, although this sample of patients reported a greater degree of impairment with symptoms such as dry mouth and sticky saliva, as well as a greater use of painkillers and nutritional supplements.[2]

[2] EORTC QLQ-C30 Reference Values. 2008 (pp. 118 and 310)

Outcome measures – MHK

Table 1 shows the impact patients feel their cancer has had on their ability to enjoy a sex life. As can be seen from Q1 and Q2, the ability to enjoy a sex life has been impacted in about 50% of the sample (Q1), and this has significantly changed from previously in 30% of the patients (Q2). 19% report they did not want to engage in sex (Q3), the remaining 81% reporting they did from a little to very much.

Table 4 as may be seen, symptoms such as dry mouth, breath smelling, thick saliva, as well as loss of confidence and tiredness or fatigue were where patients reported the greatest level of problems. Patients reported fewest problems in areas such as the use of a feeding tube or an airway stoma, reflux symptoms, breathing difficulties, as well as loss of fingertip sensation and thrush or oral candida.

Factor analysis

Figure 1 shows the final factor solution for the MHK questionnaire. Items with factor loadings <0.4 were removed from the analysis: this led to the removal of 10 items, some of which (e.g. breathing difficulties, feeding tube, airway stoma) had previously been identified as having low levels of patient endorsement. The remaining 12 items accounted for 68.5% of the total variance and comprised 4 factors: “Physical” (4 items), “Sensation” (2 items), “Movement” (3) and “Communication” (3). Cronbach’s alphas for each of these factors were, respectively: 0.71, 0.84, 0.62 and 0.73, suggesting good internal reliability for the 4 factors, although “Movement” was slightly lower than the 0.70 criterion.

Validation

The results of the confirmatory factor analysis showed RMSEA of 0.082 (90% confidence intervals, CI: 0.044 to 0.116), and CFI of 0.908. Both indices suggesting good model fit for the 4-factor structure.

The Communication and Movement domains from the MHK showed a significant negative association with the Role Functioning and GHS / QoL domains on the EORTC QLQ-C30 (Table 5), suggesting that impairments in these domains has a detrimental effect on patients’ quality of life and ability to undertake usual daily activities. The Physical domain on the MHK showed significant associations with Physical, Role, Social and Cognitive Functioning, as well with both Fatigue and Pain domains on the EORTC QLQ-C30.

In terms of the EORTC QLQ-H&N35, the MHK domains showed good levels of association with anticipated domains. For instance, the Communication domain showed good associations with the Speech, and Social Contact domains on the QLQ-H&N35. Similarly, the Movement factor showed a good degree of association with the Opening Mouth domain on the QLQ-H&N35. The Physical, Sensation, Communication and Movement domains were associated with the Sexuality domain on the QLQ-H&N35.

Discussion

The work gives a detailed account of the cross-sectional study. The details and the contribution of the focus groups are beyond the scope of this paper. It is however, important to recognise their part in developing this tool and its acceptability of use, both for them and what they believe their head and neck team can do to help. The intimacy questions came from one of the authors experience in providing PST to head and neck patients over 2 years and patients concerns that have simple practical solutions that the general medical team could approach and help with. The focus groups ordered and listed what they believed was an impact on their intimacy. The results show that sexual function and intimacy are affected by head and neck cancer and/or its treatment. Patients may use this tool to highlight areas that can be improved. The principle areas of concern are not specific to psychosexual therapy and could benefit from relatively low-level education in the areas of intimacy and sexuality. This can address both why things have changed and how things could be improved.

The results from the cross-sectional study revealed a 4-factoror domain structure for the MHK. This suggests use in practice of the 4 summed domains, however the additional 10 questions are crucial to delineate the precise problem in clinical practice. One potential limitation of the study is the relatively low numbers for the factor analyses. Additional research with larger or pooled samples is required to support the factor structure of the MHK. Useful qualitative data emerging from this process included the observations that intimacy and sexual function issues are not exclusive to those in active sexual relationships. Singletons have been poorly served by previous research.[3] This study highlighted that there are problems with intimacy and sexual function in people who have had HNC whether in a relationship or not and this needs to be considered by the clinical teams supporting this group of patients. In the UK a (HNA) is a mandatory part of the patients' recovery package. Patients who indicate from their HNA an

issue with intimacy or sexual function now have a more detailed tool which will highlight more specific areas of concern that can be addressed.

Whilst our aspirations for this tool are to highlight intimacy and sexual function issues for HNC patients the MHK tool only "opens the door" for discussion of these issues. It does not direct the clinician towards solutions but it does allow patients to communicate their intimacy problems. This is very much in keeping with modern clinical care, embracing the issues around survivorship in cancer. What would be helpful to both patients and clinical teams is to have accurate patient sexual health education information[12], services to which the patients can be referred such as hospital based psychosexual therapy services or community "Relate" psychosexual services. It is also important to understand that psychosexual therapists don't necessarily have any specialist cancer knowledge and awareness of its impact on intimacy or sexual function. This, therefore, is not an issue simply to be referred out. What is important to understand is that each of the desire for intimacy questions have relatively simple interventions that could improve the patients' situation that can be delivered by the clinical head and neck team. Questionnaire 1 was used in the cross-sectional study. As a consequence of both quantitative and qualitive assessment, this was modified and the final questionnaire (Questionnaire 2) was produced.

Conclusion.

Further research in order to evaluate the MHK tool is essential. A larger patient cohort, a longitudinal approach, qualitative input, and a link to possible interventions, would each improve our understanding of the intimacy issues faced by head and neck cancer patients and suggest possible steps to improve their situation.

Conflict of interest: The authors have no conflict of interest to report.

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Questionnaire 1: This is the initial MHK questionnaire that was included in the cross-sectional study

[TYPE THE SENDER COMPANY NAME]

[TYPE THE SENDER COMPANY ADDRESS]

[Pick the date]

Initials:
D.O.B:

For the purpose of this questionnaire we define sexual activity as any stimulation of the mind or body for pleasurable erotic stimulation. This includes penetrative intercourse, masturbation, sexual fantasies and any related or similar erotic activity. Please note we have deliberately included questions applicable to both males and females as responses relevant to your partner may have a direct impact on you.
Since your cancer diagnosis please indicate which single answer most applies to you from the following questions.

1(a) Do you think that your cancer has impacted your ability to enjoy a sex life? **Yes** □ **No** □

1(b) Compared to your sex life previously, how much has this impacted on how much you enjoy it now?

Not at all □ **A little** □ **Quite a bit** □ **Very much** □

2. How often have you thought about sex with real interest or desire in the last week?
Not at all □ **A little** □ **Quite a bit** □ **Very much** □

3(a) How often do you want to engage in any form of sexual activity?
Not at all □ **A little** □ **Quite a bit** □ **Very much** □

3(b) Is this different to before your diagnosis? **Yes** □ **No** □

3(c) Is this different from your partner(s)? **Yes** □ **No** □ **Not sure** □

3 (d) Can you identify a reason why this may be different…….

4(a) Do you feel that since your cancer diagnosis that your relationship with your partner has changed? (ie more of a carer than a partner)
Not at all □ **A little** □ **Quite a bit** □ **Very much** □

4(b) Would you like help/advice to discover a non-sexual and close relationship back with your partner,

Not at all □ **A little** □ **Quite a bit** □ **Very much** □4(c)
Would you like help/advice to discover your sexual relationship back with your partner
Not at all □ **A little** □ **Quite a bit** □ **Very much** □

For females:

1(a) Do you vaginally lubricate during sexual intercourse?
Not at all □ **Sometimes** □ **Often** □ **Always** □

1(b) Has this changed since your cancer treatment?
Yes □ **No** □ **Unsure** □
If Yes, do you have a reason why?.....

2(a) How often do you become aroused either mentally or physically and then lose interest?
Daily □ **Weekly** □ **Monthly** □ **Other (please state)……..**

2(b) Has this changed since your diagnosis of cancer?
Yes □ **No** □ **Unsure** □

If changed is it: 1) Better □ **2) worse** □

2(c) Has this changed since your treatment for cancer?
Yes □ **No** □ **Unsure** □

If changed is it: 1) Better □ **2) worse** □

3(a) Do you experience difficulty to achieve an orgasm?
Not at all □ **A little** □ **Quite a bit** □ **Very much** □

3(b) Is this different since your cancer treatment?
Yes □ **No** □ **Unsure** □

3(c) Is this important to you?
Yes □ **No** □ **Unsure** □

4. Are you: 1) Menstruating □ 2) Pre-menopausal □ 3) Menopausal □

For males:

1, How difficult is it for you to achieve a full or partial erection?

Not at all □ **A little** □ **Quite a bit** □ **Very much** □

a. Was this sufficient for penetrative sex? **Yes** □ **No** □
b. Is this different to before your cancer? **Yes** □ **No** □
c. Is this different to after your cancer treatment? **Yes** □ **No** □

2(a) Do you experience difficulty in achieving an orgasm?

Yes □ **No** □ **Unsure** □

2(b) Is this different since your cancer treatment?

Yes □ **No** □ **Unsure** □

If Yes, do you have a reason why?.....

2(c) Is this important to you?

Yes □ **No** □ **Unsure** □

2(d) Do you experience erections on waking in the morning?

Not at all □ A little □ Quite a bit □ Very much □

3(a) How often do you become aroused either mentally or physically and then lose interest?

Daily □ **Weekly** □ **Monthly** □ **Other (please state)……..**

3(b) Has this changed since your diagnosis of cancer?

Yes □ **No** □ **Unsure** □

If changed is it: 1) Better □ **2) Worse** □

3(c) Has this changed since your treatment for cancer?

Yes □ **No** □ **Unsure** □

If changed is it: 1) Better □ **2) Worse** □

Do any of the following affect your desire for intimacy (please tick):

Dry mouth	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Breath smelling	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Thick saliva	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Breathing difficulties	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Restricted tongue movement	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Loss of feeling in your lips	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Loss of control of lip suction	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Loss of feeling in your tongue	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Feeding tube	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Airway stoma	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Loss of confidence	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Anxiety	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Reflux	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Restricted neck movement	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Restricted head movement	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Scars from surgery	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Loss of sensation in fingertips due to chemotherapy	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Communication/speech difficulties	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Tiredness/exhaustion/fatigue	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Pain	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Thrush/oral candida	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □

Questionnaire 2: The final MHK questionnaire following the cross-sectional study

[TYPE THE SENDER COMPANY NAME]

[TYPE THE SENDER COMPANY ADDRESS]

[Pick the date]

Initials:
D.O.B:

For the purpose of this questionnaire we define sexual activity as any stimulation of the mind or body for pleasurable erotic stimulation. This includes penetrative intercourse, masturbation, sexual fantasies and any related or similar erotic activity. Please note we have deliberately included questions applicable to both males and females as responses relevant to your partner may have a direct impact on you.
Since your cancer diagnosis please indicate which single answer most applies to you from the following questions.

1(a) Do you think that your cancer has impacted your ability to enjoy a sex life? **Yes** □ **No** □

1(b) Compared to your sex life previously, how much has this impacted on how much you enjoy it now?

Not at all □ **A little** □ **Quite a bit** □ **Very much** □

2. How often have you thought about sex with real interest or desire in the last week?
Not at all □ **A little** □ **Quite a bit** □ **Very much** □

3(a) How often do you want to engage in any form of sexual activity?
Not at all □ **A little** □ **Quite a bit** □ **Very much** □

3(b) Is this different to before your diagnosis? **Yes** □ **No** □

3(c) Is this different from your partner(s)? **Yes** □ **No** □ **Not sure** □

3 (d) Can you identify a reason why this may be different…….

4(a) Do you feel that since your cancer diagnosis that your relationship with your partner has changed? (ie more of a carer than a partner)
Not at all □ **A little** □ **Quite a bit** □ **Very much** □

4(b) Would you like help/advice to discover a non-sexual and close relationship back with your partner,

Not at all □ **A little** □ **Quite a bit** □ **Very much** □4(c)

Would you like help/advice to discover your sexual relationship back with your partner

Not at all □ **A little** □ **Quite a bit** □ **Very much** □

Do any of the following affect your desire for intimacy (please tick):

Dry mouth	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Breath smelling	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Thick saliva	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Breathing difficulties	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Restricted tongue movement	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Loss of feeling in your lips	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Loss of control of lip suction	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Loss of feeling in your tongue	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Feeding tube	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Airway stoma	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Loss of confidence	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Anxiety	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Reflux	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Restricted neck movement	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Restricted head movement	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Scars from surgery	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Loss of sensation in fingertips due to chemotherapy	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Communication/speech difficulties	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Tiredness/exhaustion/fatigue	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Pain	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □
Thrush/oral candida	**Not at all** □	**A little** □	**Quite a bit** □	**A lot** □

For females: 

1(a) Do you vaginally lubricate during sexual intercourse?
Not at all □ **Sometimes** □ **Often** □ **Always** □

1(b) Has this changed since your cancer treatment?
Yes □ **No** □ **Unsure** □
If Yes, do you have a reason why?.....

2(a) How often do you become aroused either mentally or physically and then lose interest?
Daily □ **Weekly** □ **Monthly** □ **Other (please state)……..**

2(b) Has this changed since your diagnosis of cancer?
Yes □ **No** □ **Unsure** □

If changed is it: 1) Better □ **2) worse** □

2(c) Has this changed since your treatment for cancer?
Yes □ **No** □ **Unsure** □

If changed is it: 1) Better □ **2) worse** □

3. Are you: 1) Menstruating □ 2) Pre-menopausal □ 3) Menopausal □

For males:

1 How difficult is it for you to achieve a full or partial erection?

Not at all □ **A little** □ **Quite a bit** □ **Very much** □

a. Was this sufficient for penetrative sex? **Yes** □ **No** □
b. Is this different to before your cancer? **Yes** □ **No** □
c. Is this different to after your cancer treatment? **Yes** □ **No** □

2 Do you experience erections on waking in the morning?

Not at all □ A little □ Quite a bit □ Very much □

3(a) How often do you become aroused either mentally or physically and then lose interest?

Daily □ **Weekly** □ **Monthly** □ **Other (please state)……..**

3(b) Has this changed since your diagnosis of cancer?

Yes □ **No** □ **Unsure** □

If changed is it: 1) Better □ **2) Worse** □

3(c) Has this changed since your treatment for cancer?

Yes □ **No** □ **Unsure** □

If changed is it: 1) Better □ **2) Worse** □

Table 1- indicating the impact patients feel their cancer has had on their ability to enjoy a sex life.

X1aEnjoy sex life				
		Frequency	Percent	Valid Percent
Valid	Not at all	46	45.5	51.1
	Quite a bit	1	1	1.1
	Very much	43	42.6	47.8
	Total	90	89.1	100
Missing		11	10.9	
Total		101	100	

X1b Impact sex life				
		Frequency	Percent	Valid Percent
Valid	Not at all	26	25.7	30.2
	A little	32	31.7	37.2
	Quite a bit	18	17.8	20.9
	Very much	10	9.9	11.6
	Total	86	85.1	100
Missing		15	14.9	
Total		101	100	

X2Sexual desire				
		Frequency	Percent	Valid Percent
Valid	Not at all	24	23.8	27.9
	A little	31	30.7	36
	Quite a bit	26	25.7	30.2
	Very much	5	5	5.8
	Total	86	85.1	100
Missing		15	14.9	
Total		101	100	

X3a Sexual activity				
		Frequency	Percent	Valid Percent
Valid	Not at all	16	15.8	19
	A little	37	36.6	44
	Quite a bit	26	25.7	31
	Very much	5	5	6
	Total	84	83.2	100
Missing		17	16.8	
Total		101	100	

3bSex life (change)				
		Frequency	Percent	Valid Percent
Valid		17	16.8	16.8
	No	55	54.5	54.5
	Yes	29	28.7	28.7
	Total	101	100	100

3cPartner sex life				
		Frequency	Percent	Valid Percent
Valid		26	25.7	25.7
	No	26	25.7	25.7
	Not Sure	35	34.7	34.7
	Yes	14	13.9	13.9
	Total	101	100	100

X4a Relationship change				
		Frequency	Percent	Valid Percent
Valid	Not at all	34	33.7	41.5
	A little	29	28.7	35.4
	Quite a bit	17	16.8	20.7
	Very much	2	2	2.4
	Total	82	81.2	100
Missing	99	19	18.8	
Total		101	100	

Table 2: Demographical information of patients included in the cross-sectional study

		Count	Percent	
	Male	64	63.4	
Sex				
	Female	37	36.6	
		Mean	Min	Max
Age	Male	62.2	40.39	117.83
	Female	62.3	34.52	85.82
	Overall	62.3	34.52	117.83
Clinical Diagnosis	Oral cavity all sites		56	
	Oropharynx		14	
	Larynx		12	
	Head and Neck (site not specified but included lip, malignant parotid disease, hypopharynx and nasopharynx)		19	

Treatment modality

Surgery:		22
Surgery with adjuvant radiotherapy or Chemo-radiotherapy:		34
Radical radiotherapy:		13
Primary chemo-radiotherapy:		22
Not recorded		10

T_Staging	T0	3	3
	T1	21	20.8
	T2	40	39.6
	T3	10	9.9
	T4	13	12.9
	TX	3	3
	Not recorded	11	10.9
N_Staging			
	N1	9	8.9
	N2	26	25.7
	N2A	8	7.9
	N2C	6	5.9
	NO	41	40.6
	Not recorded	11	10.9
M_Staging			
	M0	100	
	MX	1	

Table 3: EORTC responses of patients in the cross-sectional study

EORTC QLQ-C30		Mean	Std. Deviation	N	Min	Max
Physical Functioning	**PF**	83.8	19.76	87	13.33	100
Role Functioning	**RF**	75.5	30.37	89	0	100
Social Functioning	**SF**	73.9	30.30	88	0	100
Cognitive Functioning	**CF**	80.9	21.52	88	0	100
Emotional Functioning	**EF**	74.3	23.85	88	0	100
Global Health Status (Quality of Life)	**QL**	66.5	21.76	89	8.33	100
Fatigue	**FA**	31.8	25.93	87	0	100
Pain	**PA**	31.8	25.93	87	0	100
Nausea & Vomiting	**NV**	7.8	13.12	88	0	66.67
Dyspnoea	**DY**	16.1	28.03	89	0	100
Sleeplessness	**SL**	31.8	30.88	87	0	100
Appetite	**AP**	25.0	32.06	88	0	100
Constipation	**CO**	20.1	28.38	88	0	100
Diarrhoea	**DI**	7.1	19.12	89	0	100
Finance	**FI**	18.6	33.47	88	0	100
H&N35						
Pain	**HNPA**	30.1	25.87	87	0	100
Swallowing	**HNSW**	22.8	24.36	87	0	100
Senses problems	**HNSE**	20.1	25.29	88	0	100
Speech problems	**HNSP**	22.7	24.22	86	0	100
Trouble with social eating	**HNSO**	29.6	29.95	85	0	100
Trouble social contact	**HNSC**	9.6	14.69	83	0	66.67
Less sexuality	**HNSX**	24.6	33.68	84	0	100
Teeth	**HNTE**	19.5	28.34	89	0	100
Opening mouth	**HNOM**	22.1	30.13	89	0	100

Dry mouth	**HNDR**	49.4	37.98	89	0	100
Sticky saliva	**HNSS**	37.5	38.21	89	0	100
Coughing	**HNCO**	29.2	30.49	89	0	100
Felt ill	**HNFI**	16.9	24.68	89	0	100
Pain killers	**HNPK**	65.1	47.94	86	0	100
Nutritional supplements	**HNNU**	43.0	49.80	86	0	100
Feeding tube	**HNFE**	17.6	38.35	85	0	100
Weight loss	**HNWL**	34.1	47.69	85	0	100
Weight gain	**HNWG**	17.6	38.35	85	0	100

Table 4: Responses to the initial version of the MHK questionnaire

	Count						%					
Items / Response Category	**Not at all**	**A little**	**Quite a bit**	**A lot**	**Total**	**Missing**	**Not at all**	**A little**	**Quite a bit**	**A lot**	**Total**	**Missing**
Dry Mouth	38	18	12	21	89	12	37.6	17.8	11.9	20.8	88.1	11.9
Breath Smelling	62	14	9	3	88	13	61.4	13.9	8.9	3.0	87.1	12.9
Thick Saliva	51	16	11	10	88	13	50.5	15.8	10.9	9.9	87.1	12.9
Breathing Difficulties	70	8	6	3	87	14	69.3	7.9	5.9	3.0	86.1	13.9
Restricted tongue movement	57	17	8	5	87	14	56.4	16.8	7.9	5.0	86.1	13.9
Loss of feeling (lips)	71	10	2	5	88	13	70.3	9.9	2.0	5.0	87.1	12.9
Loss of control (lip suction)	68	12	3	5	88	13	67.3	11.9	3.0	5.0	87.1	12.9
Loss of feeling (tongue)	61	12	8	7	88	13	60.4	11.9	7.9	6.9	87.1	12.9
Feeding tube	75	4	2	5	86	15	74.3	4.0	2.0	5.0	85.1	14.9
Airway stoma	80	1	-	1	82	19	79.2	1.0	0.0	1.0	81.2	18.8
Loss of confidence	50	20	14	4	88	13	49.5	19.8	13.9	4.0	87.1	12.9
Anxiety	49	23	9	5	86	15	48.5	22.8	8.9	5.0	85.1	14.9
Reflux	76	8	3	1	88	13	75.2	7.9	3.0	1.0	87.1	12.9
Restricted neck movement	59	21	7	1	88	13	58.4	20.8	6.9	1.0	87.1	12.9
Restricted head movement	70	16	2	-	88	13	69.3	15.8	2.0	0.0	87.1	12.9
Scars from surgery	68	13	5	2	88	13	67.3	12.9	5.0	2.0	87.1	12.9
Loss of sensation (fingertips)	83	3	-	-	86	15	82.2	3.0	0.0	0.0	85.1	14.9
Communication (speech difficulties)	67	10	9	2	88	13	66.3	9.9	8.9	2.0	87.1	12.9
Tiredness (exhaustion / fatigue)	41	27	16	5	89	12	40.6	26.7	15.8	5.0	88.1	11.9
Pain	55	24	7	3	89	12	54.5	23.8	6.9	3.0	88.1	11.9
Thrush (oral candida)	74	8	4	2	88	13	73.3	7.9	4.0	2.0	87.1	12.9

Figure 1: This includes details of the final factor solution for the MHK questionnaire.

	Component			
Item / Factors	**Communication**	**Physical**	**Sensation**	**Movement**
Dry mouth	-	0.528	-	-
Breath smelling	-	0.786	-	-
Thick saliva	-	0.791	-	-
Restricted tongue movement	0.833	-	-	-
Loss of feeling (lips)	-	-	0.881	-
Loss of control (lip suction)	-	-	0.850	-
Loss of feeling (tongue)	0.740	-	-	-
Loss of confidence	-	0.433	-	0.566
Restricted neck movement	-	-	-	0.702
Restricted head movement	-	-	-	0.801
Communication speech difficulties	0.660		-	-
Tiredness (exhaustion/ fatigue)	0.402	0.544	-	-
Extraction Method: Principal Component Analysis.				
Rotation Method: Varimax with Kaiser Normalization.				

Table 5: Associations between the initial MHK and EORTC QLQ-C30 and H&N Module

Domains	PF	RF	SF	CF	EF	QL	FA	PA	NV	DY	SL	AP	CO	DI	FI
Communication	-0.093	**-.311****	-0.201	-0.078	-0.043	-.237*	0.17	0.17	-0.017	0.069	-0.033	0.044	0.137	-0.107	0.093
Physical	**-.305****	**-.405****	**-.298****	**-.329****	-0.084	**-.395****	**.387****	**.387****	0.11	0.141	0.078	0.201	**.220***	**.240***	0.14
Sensation	-0.134	**-.272***	**-.363****	-0.18	-0.004	-.217*	**.275***	**.275***	0.131	0.096	0.112	0.074	0.188	**.331****	0.143
Movement	-0.15	**-.222***	-0.177	**-.224***	-.213*	**-.294****	**.273***	**.273***	**.306****	**.337****	**.286****	**.227***	**.284****	**.214***	**.240***

Domains	HNPA	HNSW	HNSE	HNSP	HNSO	HNSC	HNSX	HNTE	HNOM	HNDR	HNSS	HNCO	HNFI	HNPK	HNNU	HNFE	HNWL	HNWG
Communication	**.251***	**.390****	**.257***	**.399****	**.355****	**.299****	**.275***	-0.001	0.196	0.102	0.149	0.176	0.057	**.221***	**.292****	**.292****	0.009	0.031
Physical	**.280****	**.306****	**.441****	**.300****	**.425****	**.229***	**.369****	0.015	0.161	**.294****	**.345****	**.238***	0.147	0.176	**.338****	**.250***	0.104	0.101
Sensation	**.306****	0.184	**.277****	0.166	0.213	**.253***	**.240***	-0.122	0.166	0.155	0.075	0.021	-0.001	**.229***	0.112	0.023	0.032	-0.06
Movement	**.390****	0.167	**.215***	0.152	**.225***	**.273***	**.361****	-0.001	**.336****	0.201	0.111	0.104	**.251***	**.253***	0.207	-0.016	0.106	-0.036

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).