Understanding pathways to post-traumatic growth: informing intervention development in head and neck cancer survivors.

Short title: Life after head and neck cancer

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Background
Population ageing and improving survival mean that the number of cancer survivors – people living with and beyond a diagnosis of cancer – is growing. In the UK, there are more than 2 million cancer survivors, of whom 40,000 are living with head and neck cancer (HNC).

HNC incidence rates in the North-East are higher than the national average: by 24% for men and 14% for women. This is probably due to the strong association between deprivation and HNC risk, and the intensity of deprivation in many areas of the North-East.

Survival rates are also significantly lower in HNC patients resident in deprived areas.
Moreover, deprived HNC patients report lower mood and poorer social-emotional functioning\textsuperscript{6,7}.

A cancer diagnosis is a stressful event that may have a significant and long-term psychological, social and functional adverse effects for survivors. HNC survivors may experience detrimental effects as a result of the cancer itself or following treatment. This can include impact on many functions and activities of daily living (such as speech and eating); disfigurement; and negative consequences for psychological and social wellbeing\textsuperscript{8–11}.

While most research among cancer survivors has focused on identifying problems and limitations, over the past decade, interest has grown in exploring the potential for survivors to experience positive consequences of their illness. One such positive consequence is post-traumatic growth (PTG). PTG may occur in the months and years following a traumatic event and manifest in various ways including increased appreciation for life, more meaningful interpersonal relationships, and a richer existential and spiritual life\textsuperscript{12}. However, traumatic events are insufficient in themselves to cause PTG; instead an individual must reflect on their experiences and seek to find meaning in them i.e., growth arises from adaptation to the trauma and rebuilding one’s sense of the world \textsuperscript{13}. There is a growing body of research relating PTG to cancer survivorship\textsuperscript{13–15}. In relation to HNC, Harding\textsuperscript{16} recently reviewed eight quantitative studies investigating positive psychological change/post-traumatic growth. They conclude that these studies provide evidence for some HNC survivors reporting positive effects following cancer and that higher education and cohabitation or marriage are associated with increased positive psychological change. Women and younger people also appeared to have higher levels of positive change across the studies and no clear relationships have been found with ethnicity or educational attainment. The above review does not include work published in the same year by members of the team leading this study\textsuperscript{17}. This piece of survey research represents the largest ever study of PTG in head and neck cancer survivors (583 HNC survivors resident in the Republic of Ireland) and was the first to also investigate the potential relationship between PTG and quality of life (QoL). The study established that PTG is possible in this population: 60\% of survivors reported moderate/high PTG. In multivariable analyses, female survivors, younger survivors, those
with more social support, and those who experienced cancer-related financial stress all had higher levels of PTG. There was a significant association between moderate/higher PTG and better health-related QoL in this survivor population. Thus, PTG, if it can be realised, has the potential to lead to improved outcomes for people surviving HNC. The quantitative design meant that the underlying reasons for the observed associations were unknown. We speculated that these associations may be due to differences between subgroups of survivors in: coping styles used; appraisal of stressors; perceptions about cancer; and perspectives of life stage. However, empirical evidence on these issues and their link to PTG in HNC is lacking. A small number of qualitative studies have begun to examine the lived experience of HNC survivors. Ruf, Buchi, Moergeli, Zwahlen, & Jenewein’s\textsuperscript{18} study suggested that most HNC survivors may experience some kind of positive changes. These findings are supported by Thambyrajah et al.\textsuperscript{19}, who report evidence for some positive psychological growth following treatment for cancer. However, the extent of PTG among HNC survivors and the types of changes experienced remain unclear, as do the factors that help or hinder PTG. Moreover, cultural differences in PTG have been postulated\textsuperscript{20}, so the applicability of the findings to the UK is unclear. The proposed study will, therefore, build on this work to improve understanding of the “mechanism” of PTG among head and neck cancer survivors.

**Study Aims, Research Questions and Objectives**
The aim of this study is to advance understanding of the pathways by which PTG may occur, in order to inform the development of interventions to encourage PTG in HNC survivors.

The study will address the following research questions:

1. What coping strategies do HNC survivors use?
2. What illness beliefs do HNC survivors hold?
3. Are coping, illness beliefs and psychosocial adjustment related to PTG among HNC survivors?
4. What other factors help/hinder PTG among HNC survivors?
The primary objective of the study is to conduct semi-structured interviews with HNC survivors to:

- understand survivors’ experiences of PTG;
- identify strategies used by survivors to cope with the cancer;
- describe survivors’ beliefs about their cancer;
- explore whether illness beliefs, coping styles and psychosocial adjustment are related to PTG among survivors; and
- identify other barriers and facilitators of PTG.

**Long-term goal of the project**

Our ultimate goal is to develop an evidence- and theory-based intervention to encourage PTG in HNCS, with the aim of improving health-related quality-of-life (QoL). The proposed study is the first step in the bottom-up development of a theoretically-based intervention to encourage PTG in HNCS; it will provide greater understanding of existing interventions, how they influence PTG, and the pathways to PTG in HNCS.

The development of interventions that may improve PTG and, hence, QoL (the ultimate goal of this project) therefore has potential to yield significant benefits for HNC patients.

**Sites**

Two NHS sites will be included: Newcastle upon Tyne Hospitals Trust and City Hospitals Sunderland NHS Foundation Trust.

Newcastle University will act as a third site, for participants recruited outside the NHS from charity support groups.

**Study Design**

Due to the explorative nature of the study, this study will use qualitative methods, namely semi-structured interviews. Qualitative methods are useful for informing understanding of the ‘how and why’ from the perspectives of research participants. Personal narratives uncovered as part of the interview process can provide increased understanding of individuals’ experiences and processes, providing insight into the nature of any change.
Interviews

Interviews will be recorded using a password encrypted audio recording device. A semi-structured topic guide will be designed to elicit detailed responses from each participant. The guide will follow existing guidelines on the design of qualitative interviews\(^\text{22}\). It will include guidance on possible areas for the interviewer to probe that are relevant to the research questions and to themes from the existing literature. The topic guide will be used flexibly by the interviewer, so that each interviewee can raise and discuss issues in a manner and order that feels natural to them and their “story”, while the interviewer can ensure that all areas of interest are discussed. The interview (and guide) will commence with a few questions designed to ease participants into the discussion (e.g. questions about themselves, their circumstances and their cancer diagnosis). The interviewer will ask “headline” open-ended questions on each area of interest on the guide; she will also develop a range of sub-questions and prompts to explore the issue in more depth. If necessary, the interviewer will rephrase a question to aid a participant’s understanding. The topic guide can evolve as interviews progress so that new issues raised will be added and covered in subsequent interviews, to ensure sufficient depth is reached.

The topic guide will cover: the participant’s experience of positive psychological changes following their cancer diagnosis; coping styles used; beliefs and perceptions about the cancer; appraisal of the cancer and other life stressors; adjustment to cancer; and its overall impact on the participant’s life and QoL. The interview will also cover social networks and social support, financial situation before and after cancer diagnosis, and psychological wellbeing (as these emerged from our quantitative research as relevant issues)\(^\text{17}\).

Participants will have an opportunity to raise at the end of the interview any topics they feel are important but that have not been captured by the questions. The participant will also be asked to complete the Post-Traumatic Growth Inventory (PTG-I), a reliable and validated quantitative instrument that measures overall PTG and growth in five dimensions: relating to others, new possibilities, personal strength, spiritual change and appreciation of life\(^\text{23}\). This will enable the team to describe the distribution of the extent of PTG among the interviewees using a widely established instrument, and to take this into account in the analysis.
Prior to initial interviews with head and neck cancer survivors, the topic guide will be discussed with a patient and participant involvement group of survivors of all cancers (based at Freeman Hospital, Newcastle) to obtain feedback on the areas covered by the interview.

Study duration and sample size
Recruitment will start from April 2019 and continue, if necessary, until the end of February 2020. Recruitment will continue until data saturation is reached, defined as no new themes arising in the last three interviews\(^2\). We anticipate 25-30 survivors will need to be interviewed.

Participants
Eligible survivors of HNC over 18 years will be identified through Head and Neck Cancer multidisciplinary teams and associated clinical and allied health professionals working in the two study sites.

*Inclusion Criteria*

Potential participants:

- will have been diagnosed with a primary HNC at least 9 months and up to 5 years ago. This time window allows for the completion of initial treatment and some time for reflection on the experience of having cancer, while ensuring that the diagnosis was not so long ago that survivors struggle to recall processes of coping and adjustment.

- must speak English. Those whose first language is not English but who speak it sufficiently well to provide informed consent and take part in an interview will be eligible.

- Potential participants who have impaired speech but who can successfully use a communication aid or written language to communicate will be eligible for inclusion in the study.

*Exclusion Criteria*

Participants should not be:

- patients who are on the palliative care pathway.
• those with severe psychological or social problems that would make it inappropriate to contact the individual (in the view of the referring member of the multidisciplinary team).
• individuals with significant communication difficulties, cognitive impairment or memory difficulties that render them unable to take part in an interview.

Potential participants will be selected using purposive sampling with strata of age and sex. We will aim to obtain as diverse a sample as possible in terms of cancer site, type of treatment and socioeconomic status (via first section of postcode). This will help ensure heterogeneity in the sample and elicitation of diverse experiences and views.

Recreation procedures
We will work with each participating site to develop recruitment processes that minimise staff time while maximising recruitment. Potential participants who meet the eligibility criteria will be told about the study by a member of the head and neck cancer team. This will either be in person (during a review appointment or clinic visit) or via an introductory letter sent to people on the head and neck cancer clinical caseload who meet the recruitment criteria (e.g. those due to attend for a routine follow-up appointment in the coming month). Each eligible person will receive the patient information sheet (PIS) and a reply slip for providing their contact details (and preferred method of contact) should they be interested in finding out more about the study or taking part. The recruiting member of the head and neck cancer team may also make a follow up phone call to find out whether the person has been able to consider the study information. If the individual has any questions about the study or what it involves, they will be free to ask someone in the clinical team or to contact the study coordinator directly; the co-ordinator’s details will be included on the PIS. The HNC team will record that they have approached the patient in their electronic record, to ensure that they are not re-approached if they have elected not to participate. If the individual would like to take part, would like to find out more about the study, or is willing to speak to the study co-ordinator about potential participation, they can (i) complete the reply slip and leave it will a member of the clinical team to pass onto the study coordinator; (ii) complete the reply slip and return it by post to the study coordinator; (iii) indicate to someone in the clinical team that they are happy for their contact details to...
be passed to the study coordinator; or (iv) contact the study coordinator directly by email or telephone (using a dedicated study NHS email address and phone number, which will be provided on the PIS). Patients will be informed that they are free to choose to refuse to participate and, if they do so, they will not be asked again to take part.

The study coordinator will then contact responders via their preferred method of contact to answer any questions and determine whether they are (still) interested in taking part in the study. If so, she will then arrange an interview at a time convenient for the interviewee. A range of interview options will be offered including over the phone, in-person, or video call via WhatsApp messenger or Zoom (a service that allows video calls to take place within a web-browser).

Should this initial approach fail to identify sufficient participants for the study, recruitment will be undertaken within two HNC support groups with links to the region. These are: 1) The Northern Head and Neck Cancer Charity (www.northernhancc.org) and 2) The Swallows Head and Neck Cancer Support Group (www.theswallows.org.uk). Recruitment will follow the same process with the initial information either (i) delivered by the study coordinator following a visit to discuss the research with support group members or (ii) via an introductory letter sent to the group leader, along with sufficient participant information sheets to distribute to interested group members.

Consent procedures

A copy of the consent document will be sent to participants via post or email once a date for interview is agreed. The participant information sheet can be re-sent if required. As we anticipate the majority of the interviews will be held over the phone or via video chat, the consent process will be audio recorded. The researcher will read each step of the consent document to the participant and ask them to confirm whether they understand and agree to this part of the process. For phone/video interviews, the person will be asked to state verbally that they understand each step of the document and the researcher will initial on their behalf. For in-person interviews, the person will initial each step and sign the document. The stand-alone audio file recording of the consent process will be transferred as soon as is practical to Newcastle upon Tyne Hospitals secure drives. A paper copy record of the consent form will be held securely in the local site file.

Study protocol Version 1 (14/05/2019). IRAS: 259676. NUTH R&D 8659
As part of the consent process, participants will be asked to consent to the researcher clarifying the details of their head and neck cancer diagnosis and treatment with their clinical team. Experience suggests that patients do not always know the precise details of, for example, their cancer site or the treatment(s) they have had; such information is important to be able to document participants’ characteristics. Therefore, it will be sought in a standardised way for each participant from their medical records. The medical record abstraction will be done by a member of the clinical team.

Finally, participants will be asked whether they would like to receive a summary of the findings of the research once the study is over. Those who would like to receive this information will be asked how they would like to receive the information. Their preferred means of contact will be retained separately from the consent forms and solely for the purposes of sharing the study results.

Reimbursement
Participants will be given (or will be sent by post) a £20 high-street voucher to thank them for their time and help; those who were interviewed face-to-face will be offered reimbursement of any out-of-pocket costs.

Study withdrawal
The rights of individuals to change their mind about participation in the study and/or withdraw without giving a reason will be respected. Participants may withdraw their consent at any time. If they do so, their personal data will be destroyed as soon as possible. If the participant withdraws during the interview, the partial transcript will be discarded. If a participant decides to withdraw after the interview has been completed and wishes their transcript to be destroyed, this will be done. Consent forms will be retained but will be marked as a withdrawn participant.

Feedback of study results
Participants will be asked at the time of interview whether they wish to receive a summary of the study findings. If so, their personal details will be retained for this purpose; only the study co-ordinator (and named members of the research team) will have access to these personal details and the preferred means of contact will be stored separately from consent forms.
forms and from electronic or paper copies of the interview transcripts. If the interviewee does not want a copy of the summary of findings, their personal details will be destroyed once the details of their HNC diagnosis and treatment have been abstracted from their medical records.

Assessment and management of risk
It is recognised that participating in a qualitative interview about experiences of head and neck cancer survivorship may have emotional consequences for interviewees. If an interviewee does not wish to answer any question during the interview, this will be respected. They will also be made aware that they are free to ask for the recording device to be stopped or the interview to be paused or to cease. If a participant becomes distressed, the researcher will ask whether they would like her to contact someone (e.g., a family member, friend, GP, or consultant) on their behalf. Following all interviews, participants will be provided with a document entitled ‘What happens next?’ that will advise that they contact their GP or a member of the cancer care team if they have questions on their cancer. The debrief sheet will also contain a list of sources of local and national charitable support (e.g. Samaritans, MacMillan).

Head and neck cancer survivors may experience difficulties with speech and communication either as a result of their cancer or its treatment. For example, they may have difficulty producing clearly articulated speech or with being loud enough to be understood. The interviewer will make suitable adjustments such as:

- Conducting interviews in person rather than over the phone if this is preferred by the participant to maximise communication,
- Allowing participants sufficient time to convey a message,
- Being alert for signs of distress,
- Offering breaks during the interview or more than one session if needed,
- Ensuring any communication aid equipment that belongs to the participant is available (e.g., amplifier, voice output communication aid),
- Offering participants with very limited speech the option to be interviewed in person and to type their responses to interview questions on a laptop.
• Repeating back to the participant what has been understood, both to clarify the content of impaired speech, and to support later analysis.

Data management
Audio recordings of interviews will be a separate file from recording of consent. They will be recorded using an encrypted (password protected) device. Participants will be advised prior to taking part that the interview is an anonymous process and that if they disclose any identifiable information, this will be removed from the anonymised transcription prior to analysis. The audio files containing the interviews will be transferred as soon as possible from the encrypted recording device to be held on password protected drives at Newcastle University. The audio files will then be transferred in order to be transcribed verbatim by an external transcription company. The company we use (www.typeitwritetranscription.co.uk) are an approved service provider to the university and are committed to protecting the privacy of their clients and to fulfilling recent GDPR requirements. Audio files will be encrypted during transfer with the password for decryption provided separately via email or phone. Once transcribed, files will be deleted from type it write transcription’s systems and anonymized transcripts will be stored on Newcastle University drives. Newcastle University IT systems enable access to files to be restricted to members of the project team holding secure log-on credentials and IT administrators. The original audio recordings will be kept during the analysis period to allow researchers to return to the data if needed, e.g., to check how intonation might have contributed to meaning or to listen again to impaired speech. Following analysis the audio files will be permanently deleted from Newcastle University computers.

Data analysis
Analysis of the transcripts will be ongoing and iterative; early interviews will help inform the content of future interviews to ensure sufficient depth is reached. The transcripts will be analysed using the framework approach to qualitative data (Braun & Clarke, 2006; Ritchie, Lewis, McNaughton Nichols, & Ormston, 2003). To ensure analytical rigour, the study coordinator and another member of the research team will independently review and code transcripts of the first few interviews then discuss coding to arrive at a consensus coding.
scheme. These codes will be applied to the remainder of the interviews, being careful to incorporate any new codes and themes as they are identified in the data. Use of the framework method will allow comparisons to be make between younger and older survivors, males and females, and those with different scores on the post-traumatic growth inventory. Dr Vincent Deary will be available for consultation on issues related to health psychology. Following analysis, we will attempt to develop a conceptual model of the pathways to PTG for HNC survivors. The study will be complete when the interviews are completed and analysed and papers resulting from the analysis are written, submitted for publication and accepted.

References


