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BMJ Open Resilience and quality of life (QoL) of head and neck cancer and brain tumour survivors in Pakistan: an analytical cross-sectional study protocol

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ABSTRACT

Background Cancer is a devastating disease and has detrimental effects on the quality of life (QoL) of cancer survivors and interferes with their treatment compliance. The aim of the study is to assess resilience and QoL among cancer survivors and to evaluate the important factors affecting their resilience and QoL, with respect to the Pakistani cultural context.

Method and analysis A cross-sectional study will be conducted at a tertiary care hospital in Karachi, Pakistan. A minimum sample size of 250 head and neck cancers and 250 brain tumour survivors with 10% inflation for non-response rate will be required. The SD of QoL and resilience will range from 16.5 to 40.8 for head and neck cancer, and 12.7 to 34.1 for brain tumour, at 5% level of significance, with 2.5 precision. QoL will be assessed by European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30, EORTC QLQ-H&N35 and EORTC QLQ-BN20 and resilience will be evaluated by Wagnild and Young's 14-item scale. Mean±SD will be reported for resilience and QoL scores. Unadjusted and adjusted β-coefficients, with 95% CI, will be reported by using multiple linear regression analysis. Correlation analysis will also be performed using Pearson or Spearman rank correlation coefficients. A p value of <0.05 will be considered significant.

Ethics and dissemination Ethical approval has been obtained from the Aga Khan University Pakistan's Ethical Review Committee. Written informed consent will be taken from the participants by trained research assistants. A trained psychologist will provide on-spot counselling to the participants and those identified with severe depression will be referred to a psychiatrist. The study materials will be kept under lock and key and the electronic data base will be password protected and will only be accessed by the research team. The study findings will be disseminated through publications conferences and workshops and research briefs.

Trial registration number Clinicaltrials.gov registry (NCT03466762).

BACKGROUND

Globally, cancer is the second leading cause of death.¹ Approximately 70% of the deaths from cancer occur in the lower middle

Strengths and limitations of this study

- Validated measures will be used for evaluating the outcomes and the independent variables.
- The overall quality of the study will be maintained through random spot-checks.
- The study results can be generalised to all cancer patients presenting at private tertiary care hospitals in Pakistan.
- To compare the quality of life and resilience within the two groups of patients, subgroup analysis will be performed by stratification.

income countries. Head and neck cancers are the sixth most common cancers worldwide, with ~630 000 new cases diagnosed annually, causing 350 000 deaths.^{2 3} Globally, brain tumours are also a significant source of cancer-related morbidity and mortality, with an overall incidence of 4–5/100 000 cases annually, contributing to 2% of all cancer deaths.⁴ And in Pakistan ~150 000 new cases of cancer are diagnosed annually, causing 60%–80% deaths.⁵

Conventionally, the endpoints of medical care for cancer patients are focused on survival rate, local control rate or complication rate.⁶ These assessments do not capture the patients' mental and emotional well-being,⁶ although the diagnosis of cancer considerably affects a patient's emotional and psychological status.⁷

Cancer patients suffer clinically important symptoms of emotional distress such as depression and anxiety⁸ that reduces their quality of life (QoL) and resilience and interferes with their treatment compliance.^{9 10} Studies have found that cancer patients with similar diseases and treatment status have significantly different QoLs.^{11 12} It is believed that resilience is the main factor that causes

patients with similar situations to have different perceptions about their QoL.^{13 14}

Resilience is an important trait that contributes to a person's mental and physical well-being. Evidence suggests that resilience is related to motivation. This motivation to recover from physical or psychological traumatic events^{15 16} minimises the impact of risk factors, thus increasing a person's ability to deal with challenges of life.¹⁷ Resilience, thus protects against psychosocial health-related issues, such as depression, anxiety, fear and helplessness, and helps to reduce their associated negative effects.¹⁸

Resilience has an important impact on the QoL of a cancer patient. Hence, over the last few years, QoL has become an important health-related outcome measure with regard to communities and healthcare systems. This outcome measure is based on multidimensional concept that incorporates: the subjective perceptions of positive and negative aspects of cancer symptoms, physical, emotional, social, cognitive functions, the disease symptoms and the side effects of treatment.^{7 19}

There are several positive and negative factors that can influence a cancer patient's resilience and QoL. These are: illness-related risk, which include perceived illness, ambiguity and complexity, stress of symptoms, severity of illness; family protective factors, which include perceived social support from family and socioeconomic variables; social protective factors, which include perceived social support from friends, influence of others with similar conditions and perceived support from providers; individual risk factors including evasive, emotive and fatalistic coping measures/strategies; individual protective factors,

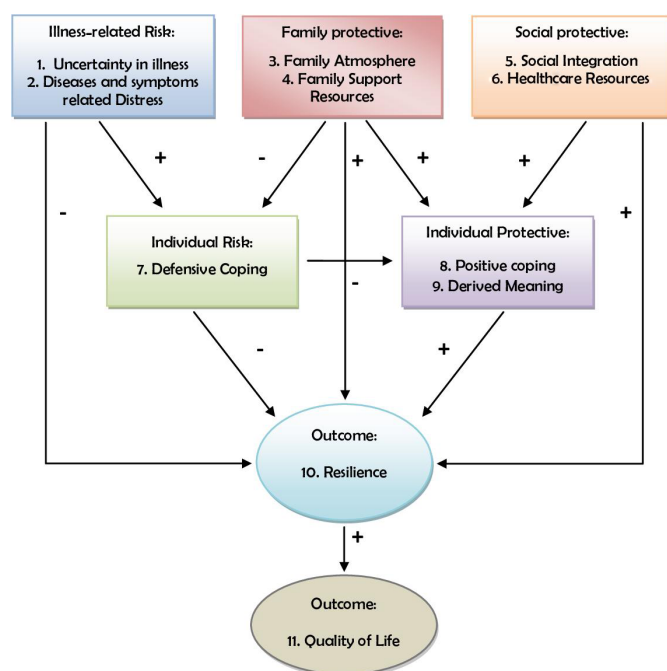


Figure 1 Conceptual framework of resilience and quality of life for cancer survivors adapted from 'the adolescent resilience model'.⁴⁷

which include confrontive, optimistic and supportant coping, along with hope and spiritual factors (figure 1).

Studies have examined the influence of psychological resilience among cancer patients.^{20 21} These studies from different parts of the world suggest that resilience is a protective factor against distress among cancer survivors^{22–26} which indicates that cancer patients with high resilience require less psychosocial support to manage their stressful conditions, as compared with those with low resilience.²⁰ One study reports that resilience mediates between cancer symptoms and distress and QoL among cancer survivors. Hence, resilience plays an important role in protecting them against the adverse effects of cancer symptoms.²² A systematic review of 24 studies on head and neck cancer patients reports that distress-related variables (depression, anxiety and distress) have a negative association with QoL outcomes.²⁷

Moreover, resilience is a critical component for QoL at all stages; during diagnosis, treatment, survivorship and palliative care. It is an important trait for promoting positive psychosocial well-being. Early identification of psychological factors associated with post-treatment QoL is essential among those at increased risk of poorer outcomes, as this can aid in the development of interventions to improve their QoL.²⁷

Limited evidence is available from the Pakistani context regarding resilience and QoL among cancer patients. To the best of the researchers' knowledge, this will be the first in-depth study to evaluate resilience and QoL among head and neck cancer and brain tumour patients in Pakistan. Resilience and QoL among them changes over time and may be modifiable towards increased well-being. This study will, therefore, enable designing of interventions in the future to improve resilience and QoL. In the light of literature, the objectives of this study are:

1. To determine the resilience and the QoL scores for head and neck cancer and brain tumour patients, at least 4 weeks post-treatment.
2. To evaluate important factors associated with resilience and QoL among head and neck cancer and brain tumour patients, at least 4 weeks post-treatment.
3. To examine the relationship between resilience and the QoL for head and neck cancer and brain tumour patients, at least 4 weeks post-treatment.

METHODS

Study design

To evaluate resilience and QoL among head and neck cancer and brain tumour patients and their associated factors an analytical cross-sectional study will be conducted. Resilience and QoL will be measured at least 4 weeks post-treatment.

Study setting

The study will be conducted at the Aga Khan University Hospital (AKUH) which is a Joint Commission International Accreditation (JCIA-accredited) hospital, in

Karachi-Pakistan. Karachi is the largest metropolitan city of Pakistan, a home to all major ethnicities living in this country. Aga Khan University Hospital (AKUH) is one of the largest private tertiary care hospitals that cater to different ethnic and socioeconomic groups of population in Karachi. The participants will be recruited from the surgical/oncology clinics at AKU. It has a multidisciplinary team that provides comprehensive care to cancer patients. The proposed duration of data collection will be 4–6 months.

Study participants

Men and women aged 18 years and above, who have received treatment for brain tumour and head and neck cancer at AKUH, fulfilling the below eligibility criteria, will be recruited. According to recent data, the prevalence of head and neck cancer is escalating in Pakistan and limited information is available about their QoL brain tumour also is an understudied area in Pakistan and there is dearth of information regarding their QoL. To maintain internal validity, the participants will be studied based on assumptions pertaining to their respective group.

Eligibility criteria

Inclusion criteria

1. Individuals aged 18 years and above, who have received treatment at AKUH for head and neck cancer or brain tumour.
2. Cancer survivors living in Pakistan for at least 3 months.
3. Patients who will give consent to participate in the study.

Exclusion criteria

1. Known cases of any psychiatric illness leading to disability (eg, manic disorder, schizophrenia and so on) as confirmed by medical records, will be excluded from the study as they may be on medications that might distort the results.
2. Patients on antidepressants prescribed by a psychiatrist
3. Participants with physical comorbidities, stroke and renal failure, will be excluded because these are debilitating diseases that will distort the results. Patients with Cardiovascular Diseases (CVD)/heart disease, diabetes or Chronic Obstructive Pulmonary Disease (COPD) will not be excluded as every 4th Pakistani suffers from cardiovascular risk factors. If patient with these conditions are excluded, the majority of the participants will be ineligible and the required sample size will not be achieved. However, these comorbid conditions will be adjusted during analysis.

Sampling technique

Purposive sampling technique will be used for selecting the participants. The target population, that is, brain tumour and head and neck cancer patients who have received cancer treatment, will be approached by trained research assistants. The research assistants will be informed about the possible study participants who will

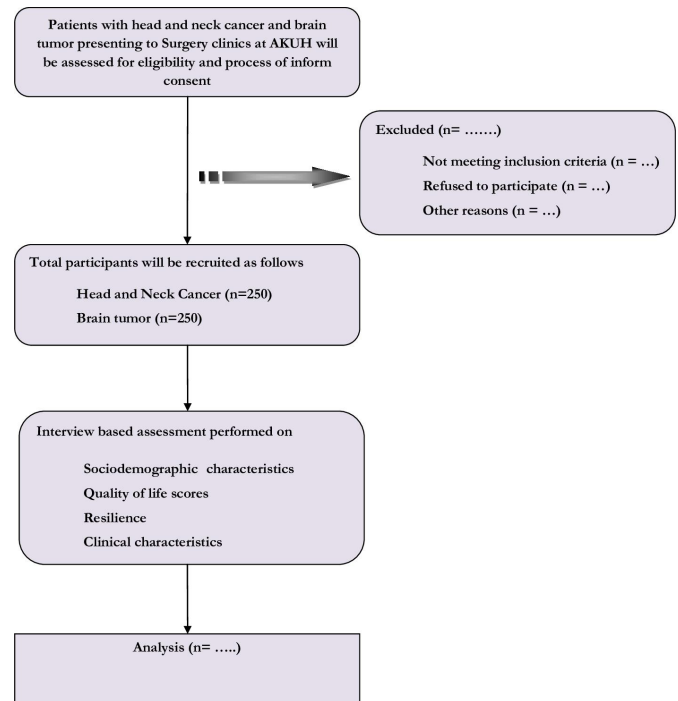


Figure 2 Participants recruitment plan flow diagram.

be coming in for their appointment, by the nurse. On the day of appointment, the participants will be screened for eligibility and if they fulfil the eligibility criteria and give consent to participate, they will be enrolled in the study (figure 2).

Sample size calculation

Head and neck cancer

The sample size has been calculated based on mean QoL and resilience scores for head and neck cancer patients from previous studies. It has been calculated using one population mean formula, based on a SD range of 16.5–40.8, 5% level of significance with precision of 2.5, and by adjusting the sample size for 10% non-response rate. The minimum sample size has been estimated to be 250.^{6 14 28–31}

Brain tumour

The sample size has been calculated based on previously reported estimates for QoL and resilience among patients with brain tumours. It has been calculated using one population mean formula, based on a SD range of 12.7–34.1, 5% level of significance with precision of 2.5, and by adjusting the sample size for 10% non-response rate. The minimum sample size has been estimated to be 250.^{32–35}

Assessment tools

Resilience (Wagnild and Young's 14 items)

Resilience is the ability to rebound or spring back, the power of something to resume its original shape or position after compression or bending.³⁶ Resilience is also defined as the 'capacity of individuals exposed to a negative event, to maintain stability and healthy physical and

psychological functioning. It is a defense mechanism, which permits people to grow in the face of adversity.³⁷ The resilience tool that will be used has two versions; a long 25-item and short 14-item scale, using a 7-point rating likert scale. It comprises the five core characteristics of resilience, which include purposeful life, perseverance, equanimity, self-reliance and existential loneliness.³⁸ A high score represents better resilience. The respondent's choice ranges from 1 (strongly disagree) to 7 (strongly agree). The scale uses total scores rather than scores of individual items. To measure resilience, the validated Urdu version of the resilience scale 14 (RS-14), which indicates moderate negative correlation of resilience with depression and anxiety ($r=-0.31$), and moderate positive significant correlation of resilience with life satisfaction ($r=0.40$) will be used. The test-retest correlation coefficients and Cronbach's alpha for RS-14 are 0.49 and 0.76, respectively.³⁹

QoL (EORTC QLQ-C30, EORTC QLQ-H&N35 and EORTC QLQ-BN20)
QoL is defined by the WHO as 'Individual's perceptions of their position in life in the context of the culture and value systems and their goals, expectations, standards and concerns'.⁴⁰ The QoL of the cancer survivors will be assessed by the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 tool.⁴¹ It is composed of multi-item scales and single-item measures. These include five functional scales, three symptom scales, a global health status QoL scale and six single items. All the scales and single-item measures scores range from 0 to 100. A high score on the scale represents a higher response level. Specific questionnaires will also be administered to evaluate the QoL of patients with brain tumours and head and neck cancer via EORTC QLQ-BN20 and EORTC QLQ-H&N35, respectively. Since the tool has not been validated in Urdu, therefore, in this study content validation will be conducted through a panel of experts and the content validity index (CVI) will be calculated. The panel of experts will comprise head and neck surgeons, neurosurgeons, an oncologist, an epidemiologist, a biostatistician and a psychologist. They will be asked to provide their expert suggestions for improving the tool according to the Pakistani cultural context, in Urdu. Each and every expert will rate the tool regarding the relevancy and clarity of each question. The responses will be rated on a scale from not relevant to highly relevant. Based on expert scores, the CVI will be calculated. CVI quantifies the level of content validity by calculating the percentage agreement between experts.⁴² CVI of >0.8 indicates high level of agreement among the experts.⁴³ Permission has been granted by the QoL tool developers for content validation.

Sociodemography and clinical characteristics

The information on demographic variables will be collected on aspects like; age, gender, ethnicity, education, family status, number of people actively working, monthly household income and employment status

of the individuals. The socioeconomic determinant will include education, occupation and family income. Information on comorbid conditions such as hypertension, diabetes, cardiovascular disease, addiction history (including smoking and substance abuse) will also be evaluated. Data on important major recent life events, such as death of child, spouse or any other event that has affected their lives will also be collected. Clinical characteristics and management of brain tumour and head and neck cancer will also be assessed by taking information from the patients on tumour type, site of tumour, type of surgery, type of chemotherapy and/or radiotherapy.

Psychosocial characteristics

The participants' depression and anxiety will be assessed using the Hospital Anxiety and Depression Scale (HADS),⁴⁴ and social support will be determined via the Enriched Social Support Instrument (ESSI).⁹

Hospital anxiety and depression (HADS)

The Hospital Anxiety and Depression Scale (HADS) will be administered to assess depression and anxiety among the participants. This tool was developed to assess depression, anxiety and emotional distress among patients who were treated for a variety of clinical problems. HADS encompasses 14 items, equally subdivided into two scales, one measuring anxiety and the other depression. For instance, the item 'Worrying thoughts go through my mind' assesses anxiety, whereas the item 'I have lost interest in my appearance' evaluates depression. All the responses are on an ordinal four-point scale.⁴⁴ To measure anxiety and depression, the Urdu version of HADS will be used.⁴⁵

Social support by ESSI

Social support can ease the coping process, or help people overcome or adapt to a stressful event. The ESSI is a 7-item scale that primarily measures functional social support and emotional support. A total score of 18 or less on items 1, 2, 3, 5 and 6 is considered as low social support.⁹ To assess social support, the validated Urdu version of ESSI, with a CVI for relevance, and clarity of 0.95 and 0.97, respectively, and Cronbach's alpha 0.82⁴⁶ will be used.

Explanatory questions to evaluate culturally relevant theme

Lastly, an explanatory questionnaire will be administered to examine the factors that have affected the lives of the cancer patients and also to examine the different coping tactics used by the patients and their families to combat this disease.

Statistical analysis

Analysis will be performed using the STATA V.12. Descriptive statistics will be computed for categorical variables by computing their frequencies and percentages, and the quantitative variables will be computed by their mean \pm SD/median (IQR), as appropriate. Mean scores will be reported for resilience and QoL. The multiple

linear regression technique will be used to evaluate the effect of independent variables on the outcomes—resilience and QoL for head and neck patients and brain tumour patients. Adjusted β -coefficients with 95% CI will be reported. A p value of <0.05 will be considered statistically significant. To assess the relationship between resilience and QoL, correlation analysis will also be performed, using the Pearson or Spearman rank correlation coefficients as appropriate.

Ethical considerations

Participants will be recruited from the surgical/oncology clinics of AKUH. Written informed consent will be taken from the participants by trained research assistants, after explaining the study procedure and its potential risks and benefits to them.

In this particular study, the participants might feel anxious/uncomfortable during the interview, especially when their stress and depression level will be evaluated. To overcome this, proper training will be given to the research team for sensitive questions. On spot counselling by a trained psychologist will be provided to the participants identified as having depression. Those patients identified with severe depression especially with suicidal intentions will be referred to a psychiatrist.

Strict confidentiality and privacy rules will be maintained and the participants' information will be kept confidential. Interviews will be conducted in a separate room. All study materials containing personal identifiers will be kept in a locked file cabinet. A unique study identification number will be assigned to each participant. Data will be entered in a password-protected electronic database that will only be accessible by the research team.

Patient and public involvement

This will be a cross-sectional study design and the participants will be interviewed, regarding their sociodemographic factors, anxiety, depression, resilience and QoL, by trained research assistants.

The study findings will be disseminated to different stakeholders, such as healthcare professionals, rehabilitation experts, psychologists and cancer patients through: publications at local, national and international journals, presentations at conferences and workshops and through research briefs.

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Contributors NZ conceived the study, wrote and critically reviewed the manuscript. WK directly overlooked all aspects of study, wrote and critically reviewed the manuscript. SSB and KA intellectually contributed to the study. IA, AAJ and NA reviewed the study for overall quality and design robustness. MK and AE assisted as experts and informed aspects of development of the study intellectually. All authors have contributed intellectually to this manuscript. All authors have read and approved the final manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Study protocol is approved by Aga Khan university ethical review committee with ERC # 5154-Sur-ERC-17.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement There are no data in this work. No data are available.

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