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Review Article

Efficacy of Psychotherapy for Symptoms of Anxiety and Depression in People with Primary Brain Tumours: A Protocol for a Systematic Review

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ABSTRACT

Background: Emotional distress, anxiety and depression are commonly experienced following diagnosis and initial treatment of a primary brain tumour. There is uncertainty regarding the merits of psychotherapy interventions to improve well-being and decrease distress, anxiety, and depression symptoms in adults with primary brain tumours in the year following diagnosis or a recurrence. Our objective is to summarize the evidence on psychotherapy interventions to decrease distress, anxiety and depression symptoms and increase well-being in people with primary brain tumours.

Methods: We will search MEDLINE; EMBASE; PsychINFO; PsychEXTRA; Health and Psychosocial instruments (HPI); and Cumulative Index to Nursing and Allied Health (CINAHL) from 2000 to present, to identify randomized trials of psychotherapy interventions to decrease distress, anxiety, or depression symptoms and improve the well-being and emotional and psychosocial health of the patients with a primary brain tumor. The review will be confined to studies including adults with primary brain tumours. Screening, data extraction, and assessment of risk of bias and certainty of evidence will be performed in duplicate. Data will be pooled statistically were possible.

Results: We developed a protocol for a systematic review assessing the effect of psychotherapy interventions on psychological health outcomes in adults with primary brain tumours in the year following diagnosis or recurrence.

Conclusion: We hope that this review will guide psychotherapy recommendations for patient with brain tumour.

Registration number and registry name: The International Prospective Register of Systematic Reviews (PROSPERO) database (registration number: CRD42021234789).

Strengths and limitations: The effect of psychotherapy in people with primary brain tumours has not been addressed by current evidence. Methods used in psychotherapy have developed considerably in recent years making this a very timely protocol.

We will use a comprehensive and exhaustive search strategy to identify relevant articles.

This systematic review protocol follows the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guideline.

Evidence from non-randomized studies will not be included.

Keywords: Psychotherapy; Brain tumour; Rehabilitation; Anxiety

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ABBREVIATIONS

WHO: World Health Organization; CNS: Central Nervous System; CINAHL: Cumulative Index to Nursing and Allied Health; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; CBT: Cognitive Behavioural Therapy; DBT: Dialectical Behavioural Therapy; ACT: Acceptance and Commitment Therapy; ESASr: Assessment Scale revised; GAD-7: Generalized Anxiety Disorder-7; PHQ: Patient Health Questionnaire; DT: Distress Thermometer; GRADE: Grading of Recommendations Assessment, Development and Evaluation; SF-36: Medical Outcomes Study Short-Form Health Survey; FACT: Functional Assessment of Cancer Therapy; MQoL: McGill Quality of Life Questionnaire.

INTRODUCTION

Primary brain tumours are those that are intrinsic to the brain and surrounding tissue. They are classified by the World Health Organization (WHO) according to four grades. Grades I and II are less aggressive than grades III and IV [1]. Primary brain tumours become problematic for the patient's cognition and daily functioning as they grow into crucial spaces in the brain. Specifically, the tumour and its mass effects are known to interfere with physical functioning, communication *via* written and verbal language, vision, movement, judgement, and emotion [2]. Relationships, financial concerns, and the ability to keep up with one's personal responsibilities can also be affected [3, 4]. The diagnosis of severe disease may also lead to existential distress and death anxiety [5,6].

Multiple reports estimate the burden of disease of primary brain tumours, both globally but do not often separate analysis according to types of central nervous system (CNS) tumours [7]. The most recent report by Patel et al. estimates the incidence of CNS tumours globally in 2016 was 330 000, with 227 000 deaths [8]. In Canada, a recent report by The Brain Tumour Registry of Canada estimated the annual average age standardized incidence rate (ASIR) for primary brain tumours was 23.5 per 100 000 population between 2010-2015, with 35.9% malignant, and 64.1% non-malignant [7].

Given the high incidence of primary brain tumours, recent research efforts have focused on the impact of receiving the diagnosis on psychological well-being. Trejnowska et al. found that people with brain tumours experience distress related to the diagnosis, as well as symptoms of anxiety and depression, especially when the diagnosis is of an aggressive tumour, with poor prognosis [9]. Other studies have shown that emotional distress is experienced by approximately 42%-74% of people after receiving the diagnosis [10-12]. Anxiety by about 29.4%, nervousness for 22.4%, fears for 17.5% and symptoms of depression are present for 21.7% of people with brain tumours [13,14].

The management of patients with primary brain tumours frequently involves cognitive rehabilitation, primarily focusing on optimizing levels of functioning, and health related quality of life [15,16]. Improvements to emotional well-being, while being an important primary goal, may come about as a result of cognitive rehabilitation due to its correlation with increased functioning, quality of life and decreased distress [17-21]. Researchers contend that coping with the emotional distress, anxiety, and depression associated with a brain tumour diagnosis and treatment can be further aided by social supports and formal psychotherapy interventions [15,22]. Psychotherapy is a primarily talk-based therapy, with a goal of working with people to change thoughts, feelings, mood, or behaviours to improve and maintain mental health and well-being [21]. In therapy people may share emotions and thoughts in a confidential setting and information on coping strategies may be shared.

The Pan-Canadian Practice Guideline recommends psychotherapy for any cancer patients with distress, anxiety, and depression [23]. Unfortunately, the efficacy of targeted psychosocial interventions and psychotherapies among patients with the specific diagnosis of primary brain tumour has not received individualized attention [24]. No systematic reviews have been done to examine the evidence for psychotherapy for increasing well-being, decreasing emotional distress, or decreasing depression and anxiety symptoms in the population, despite the findings that these symptoms are linked to decreased quality of life [23]. Advances in both psychotherapy and in brain tumour diagnosis and treatment have occurred and there is an expectation of and need for growth in the supports and therapies provided to brain tumour patients, necessitating a search for evidence to guide treatment choices. Herein, we propose methods for a systematic review of randomized control trials to assess the effect of psychotherapy interventions on psychological health outcomes in adults with primary brain tumours in the year following diagnosis or recurrence.

METHODS AND ANALYSIS

General methods

We will use standard Cochrane methods and report the systematic review according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [25,26]. The protocol has been registered in The International Prospective Register of Systematic Reviews (PROSPERO) database (registration number: CRD42021234789).

Search strategy

We will develop a comprehensive search strategy with the help of a health science librarian. The search will incorporate related terms and synonyms for the following: Brain, neoplasm, cancer, tumour, malignancy, the diagnostic names of primary brain tumours (including glioma, glioblastoma, astrocytoma), therapy, psychotherapy, and the names of psychotherapy types (e.g. Cognitive Behavioural Therapy (CBT), Dialectical Behavioural Therapy (DBT), Acceptance and Commitment Therapy (ACT), mindfulness-based therapy, solution-focused therapy, interpersonal therapy, and narrative therapy). Our search will also include Medical Subject Heading Terms (MeSH) equivalents for the previously mentioned terms in our search strings. We will inlcude the Cochrane highly sensitive search strategy to identify randomized trials [27].

Data sources

The following electronic databases will be searched for works publish between the years 2000 to present: MEDLINE; EMBASE; PsychINFO; PsychEXTRA; Health and Psychosocial instruments (HPI); Cumulative Index to Nursing and Allied Health (CINAHL); the Cochrane Library (CENTRAL) and Campbell Collaboration's Social, Psychological, Educational and Criminological Trials Register (C2-SPECTR). We decided to search databases beginning from the year 2000 to capture recent developments in the past 20 years in field of psychotherapy. The WHO International Clinical Trials Registry Platform will also be searched for on-going trials.

We will also search the websites and conference proceedings (from 2000 to present) from the following organizations: the Canadian Association of Psycho-oncology, the American Psychosocial Oncology Society; the British Psychosocial Oncology Society, the European Society for Psychosocial Oncology, The European Society for Medical Oncology, the American Society of Clinical Oncology, the Canadian Cancer Society, and the Society for Neuro-oncology.

Finally, we will contact experts in the field to enquire about on-going and unpublished trials that were not captured by our search.

ELIGIBILITY CRITERIA

Study design

We will include Randomized Controlled Trials (RCTS) that report on the efficacy of psychotherapy for symptoms of anxiety, depression, distress, and well-being for people who have had a diagnosis of a primary brain tumour or recurrence within the previous year. Cluster RCTs will be included. RCTs with additional information about other types of cancer will be included, provided that the outcomes for patients with primary brain tumours are reported separately.

Participants

We will include RCTs of psychotherapy interventions, provided to participants aged 18 years and over. Participants may be out-patients, or in-patients in a hospital or rehabilitation program. RCTs with participants from any geographic region will be eligible.

Interventions

RCTs of structured psychotherapy interventions will be included. This includes but is not limited to newly created manualized programmes, Cognitive Behavioural Therapy (CBT), Dialectical Behaviour Therapy (DBT), Acceptance and Commitment Therapy (ACT) or mindfulness-focused therapy, where a stated and measured aim is to decrease distress, anxiety or depression symptoms or improve the well-being and emotional and psychosocial health of the participant. We will include individual, family and group therapy modalities. Interventions may be delivered by an individual professional or interdisciplinary team, with training in the psychotherapy method. This may include clinicians from nursing, social work, psychology, or medicine. Interventions may be delivered in any setting, including the patient's home, in community settings, hospital or rehabilitation, by in-person, virtual meetings or telephone.

We will include studies with comparisons of the psychotherapy intervention to usual care, wait list, or to active controls, (e.g., a different therapeutic intervention, as a direct comparison). Where a therapy is provided as part of a combined program, for example CBT within a cognitive rehabilitation program, the group will be added to the psychotherapy group. Where possible, if psychotherapy stand-alone program studies are available, as well as psychotherapy within a program, these will be considered.

OUTCOMES

The primary health outcomes of interest are anxiety, depression, sense of well-being, and distress level, as reported by the authors.

Secondary health outcomes of interest are health related quality of life, sleep, or fatigue. Eligible studies will have data on at least one of the primary or secondary outcomes using a validated measure [21].

Examples of validated tools that have been used to measure symptoms of anxiety in patients with brain tumours include the Edmonton Symptom Assessment Scale revised (ESASr) and the Generalized Anxiety Disorder-7 items (GAD-7) [28]. Validated tools used to measure depression symptoms in people with brain tumours include the ESASr, Patient Health Questionaire-9 (PHQ), and PHQ-2 and the Beck Depression Inventory-II [29,30]. The Distress Thermometer (DT) and Depression, Anxiety and Stress Scale (DASS-21) are a validated tool for evaluating distress [31]. The DT and Centre for Epidemiological Studies Depression scale have been used to measure well-being [32].

Examples of validated measures of health-related quality of life that have been used in brain tumour populations include the Medical Outcomes Study Short-Form Health Survey (SF-36) Functional Assessment of Cancer Therapy-General (FACT-G) Functional Assessment of Cancer Therapy-Brain (FACT-Br) Functional Assessment of Cancer Therapy – Fatigue (FACT-F), McGill Quality of Life Questionnaire (MQoL) EORTC Quality of Life scales (QLQ-BN-20 and QLQ-C) and the Piper Fatigue Scale [33-39].

Screening

Two authors will independently critically appraise citations to determine whether they should be included in the review. Each will review the titles and abstracts of studies found in literature search and will select studies for full text screening based on design, participants, interventions, and outcome measures. Eligible studies and studies for which eligibility for full text screening cannot be ascertained from the abstract will be moved forward for full text review.

Data extraction and management

We will create, pilot, and test a full text screening and data extraction form on 5% of the full text articles. Excluded studies will be documented in table. Two reviewers will independently extract data from the studies chosen for inclusion, and both authors will verify data extracted. We will extract data related to the study methods, participants, interventions, comparisons, and outcomes. If the authors disagree on the data abstracted, this will be resolved through discussion or by involvement of a third extractor. We will use the Kappa statistic to measure agreement between authors [40].

The identification, screening and inclusion of studies will be summarized using the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram [25]. We will report findings for all primary and secondary outcomes using a summary of findings table. We will reach out to authors to request missing information relevant to our review.

Assessment of methodological quality (Risk of bias

We will assess risk of bias of each included study using the Cochrane Risk of Bias 2 tool [41]. We will be interested in the effects of assignment to a treatment arm (i.e., intention to treat), and will apply the tool to all the primary and secondary outcomes. Though, unlikely, we will use adapted versions of the tool for cluster RCTs. Each data extractor will complete the risk of bias assessment independently. The tool examines risk of bias based on five domains: the randomization process; deviations from the intended intervention; missing outcome data; measurement of the outcome; and selection of the reported result. For each domain, a judgment of high risk of bias, low risk of bias or some concerns can be made for each domain. A final judgment will be made for the overall risk of bias for each outcome using the built in signaling questions and algorithm. Risk of bias data will be extracted using the recommended excel sheet and presented as a figure.

We will utilise the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool to assess the quality of the body of evidence [42]. The quality of evidence for each outcome will be rated as high, moderate, low, or very low/ uncertain.

META ANALYTIC APPROACH

Measures of treatment effect

We will use Review Manager 5 (RevMan 5) to analyse our data. For continuous data measured on the same scale we will calculate weighted mean difference. If the data is measured on different scales, we will calculate the standardized mean difference. For binary data we will present the Risk Ratio (RR) and odds ratio (OR). The results will be presented with 95% confidence intervals.

Certainty of the evidence

We will assess the certainty of the evidence using the GRADE (Grading of Recommendations Assessment, Development and Evaluation approach) approach. Certainty of evidence will be defined as the extent to which we are confident that the estimate of effect for each outcome is close to the quantity of interest. Certainty could be rated as high, moderate, low, or very low. Certainty of evidence may be compromised by poor design, indirectness, unexplained heterogeneity, imprecision, and publication bias. The overall rating of risk of bias will be used to make the summarize certainty of evidence. We will use the GradePro software to create Summary of Findings tables [43].

Unit of analysis

The unit of analysis will be the individual. If we find cluster RCTs or other group-based allocation studies, we will incorporate them in our meta-analysis using the generic inverse variance approach, if their analysis accounts for clustering. If their analysis does not account for clustering, we will compute the effective sample size, by dividing the sample size by the design effect. The design effect is given as 1 (M-1) × ICC; where M is the average cluster size and ICC is the intracluster correlation coefficient. These approaches are described in detail in the Cochrane Handbook [44].

Missing data

We will contact authors of included studies to request clarification and missing data during the data extraction phase. We will also search secondary publications about the same study for missing data and complementary information.

Assessment of heterogeneity

We will assess clinical heterogeneity (participants, interventions, comparisons, outcomes). If studies are similar enough, we will combine them and perform a meta-analysis and assess statistical heterogeneity using the Chi^2 test for homogeneity, with a level of significance of p less than 0.1. We will use the I2 statistic to quantify inconsistency, and regard heterogeneity as substantial if I2 is greater than 50% [25,45].

Assessment of reporting biases

The Cochrane Collaboration Risk of Bias 2.0 tool will be used to assess selective outcome reporting. If there are more than ten studies to include, we will assess publication bias using a funnel plot [25]. We will assess funnel plots visually to assess for asymmetry, and if found we will analyze further to explore it.

Data synthesis

Data will be pooled using a random-effect meta-analysis. We will treat the random-effects summary as the average range of possible treatment effects and will discuss the clinical implications of trial differences. Weighted mean or standardized mean differences will be reported for continuous outcomes and risk ratios for binary outcomes alongside 95% confidence intervals. Our primary analysis will include all eligible studies irrespective of risk of bias, which will be explored in a sensitivity analysis. RevMan software will be used for statistical analyses [46].

Sub-group analysis and investigation of heterogeneity

We will conduct a homogeneity test to query if the differences in the results of each trial could have been expected by chance. If we find significant unexplained statistical heterogeneity, we will investigate this with a subgroup analysis. Sources of heterogeneity among studies in this review may include the type of therapy intervention; duration of therapy and time to follow-up; differences in the timing of the start of therapy following surgery and adjuvant treatment; differences in participants (e.g. studies may include a mix of patients with primary benign and malignant brain tumours); participants may also differ in the amount of cognitive deficits and pre-existing psychiatric illness prior to diagnosis of the tumors; and the therapist may differ by professional background. We will explore these differences as subgroups if the data are available. We will investigate whether age, gender and geographical differences (e.g., in acceptance and use of psychotherapy or socioeconomic status) may be sources of heterogeneity. We hypothesize that longer and early treatments from more skilled providers may have a greater effect. We also believe that individual based interventions may be more effective. All other subgroup analyses are exploratory and will be restricted to the most relevant.

Sensitivity analysis

We will investigate studies that have a high risk of bias with sensitivity analysis. We will also explore the impact of fixed-effects or random-effects analyses for outcomes with no statistical heterogeneity, where either approach could be valid.

Patient and public involvement statement

To the best of our knowledge no outcome sets have been published for this topic. The authors used their collective clinical expertise to identify the outcomes of interest for the review [24].

DISCUSSION AND CONCLUSION

Currently there are few individual studies that offer data on this research question. However, the results of this review will summarize evidence of the effect of psychotherapy (and specific psychotherapy techniques) on symptoms of anxiety and depression among those diagnosed with primary brain tumour, a population for which no summary currently exists. If the evidence is sufficient, it may be used to recommend specific psychotherapy techniques, or improve the quality of psychotherapy interventions offered to patients with primary brain tumours. This will be of upmost importance among this population, which has well-recognized challenges with emotional distress, anxiety, and depression. Finally, the assessment of the quality of evidence in this review may identify gaps in knowledge that can guide future research efforts.

ETHICS

All studies to be included in this review will have been published and received ethics approval. Therefore, ethics approval is not required for this review. However, for this review we will record whether included studies completed an ethics review, so as to avoid publication of data obtained *via* unethical means.

DISSEMINATION

The findings of this review will be disseminated as peer-reviewed manuscripts, conference abstracts and academic rounds to inform healthcare providers, patients, policy-makers, researchers and other interested end-users.

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AUTHOR'S CONTRIBUTIONS

LS conceived and designed the review protocol and wrote the manuscript. TB type-set the manuscript. All authors critically revised the manuscript for important intellectual content and approved the final manuscript. LM supervised this project.

CONFLICT OF INTERESTS

Conflict of Interest: None to report.

REVIEW STATUS

Search strategy in development.

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