Evaluation of the Making Sense of Brain Tumor Program: A randomized controlled trial of a home-based psychosocial intervention

Tamara Ownsworth[1]; Suzanne Chambers[1-4]; Ea Stewart[1]; Leanne Casey[1]; David G. Walker[5]; David H. K. Shum[1]

[1]School of Applied Psychology and Griffith Health Institute, Griffith University, Brisbane

[2]Cancer Council Queensland, Australia

[3]Health and Wellness Institute, Edith Cowan University, Australia

[4]Centre for Clinical Research, University of Queensland, Australia

[5]Newro Foundation and Briz Brain & Spine, Brisbane, Australia

Contact for correspondence:
A/Prof Tamara Ownsworth
School of Applied Psychology
Griffith University
Mt Gravatt, 4122
Australia
Email: t.ownsworth@griffith.edu.au
Ph: +61 73735 3307
Fax: +61 73735 3388

Abstract

Objective: Despite significant psychosocial morbidity, there are few controlled trials of psychological support for people with brain tumor. This study evaluated the efficacy of the Making Sense of Brain Tumor (MSoBT) program, a home-based psychosocial intervention. *Design:* A randomized controlled trial with a wait list condition. *Methods:* Fifty participants aged 17-82 years with brain tumor (54% benign) were randomly allocated to immediate treatment (n = 27) or a waitlist (n = 23). Measures included: Montgomery Asberg Depression Rating Scale (MADRS), McGill Quality of Life (MQOL) Questionnaire, Depression Anxiety Stress Scales (DASS) and Functional Assessment of Cancer Therapy-Brain (FACT-Br). The immediate treatment group received the 10-session MSoBT program while the waitlist group received usual care for 10 weeks and were then re-assessed before receiving the MSoBT program. A 6-month post-intervention follow-up was conducted. *Results:* ANCOVA adjusting for baseline functioning identified that the immediate treatment group reported significantly lower levels of depression on the MADRS (η_p^2 =.19) and higher levels of existential well-being on the MQOL (η_p^2 =.13) and functional well-being (η_p^2 =.21) and global quality of life on the FACT-Br (η_p^2 =.12) at post-assessment than the waitlist group. At 6-months follow-up participants reported significantly lower levels of depression and stress and higher existential well-being and quality of life relative to pre-intervention. *Conclusions:* The MSoBT program appears to have efficacy for enhancing psychological well-being and quality of life after brain tumor.

Keywords: cancer, oncology, brain tumor, mental health, quality of life, randomized controlled trial

Background

An estimated 256 000 people (3.4/100,000) were diagnosed with primary malignant brain and nervous system cancers worldwide in 2012 [1]. Malignant brain tumors (Grades III-IV) comprise approximately 37% of all primary brain tumors, and are associated with poorer prognosis for survival than benign tumors [2]. Although histologically non-cancerous, some benign tumors (e.g., gliomas) can recur or progress to malignant status [3, 4], and be life threatening because of their location and serious neurological effects [5].

High rates of psychosocial morbidity (30-50%) have been consistently reported in brain tumor samples [6] with reported rates of 48% and 41% for generalized anxiety disorder and depression respectively [7]. People with brain tumor commonly experience neurological symptoms, including sensory/motor dysfunction, cognitive and communication deficits, seizures and fatigue, and have related social and activity restrictions [8, 9]. Uncertainty about the future and lack of understanding of the illness are recurrent issues impacting adjustment [8-10].

The efficacy of neurorehabilitation after brain tumor has mainly been evaluated with case studies and non-randomized cohort studies [11-14]. In a pilot randomized controlled trial (RCT), Locke and colleagues [15] investigated the effectiveness of 12 sessions of cognitive rehabilitation for people with brain tumor and their caregivers. Although participants reported greater cognitive strategy use at post-intervention, there were no significant pre-post differences in quality of life or functional status. Another RCT [16] evaluated the efficacy of six sessions of computer-based attention training for people with mixed glioma (n = 140). They found significant improvements in subjective cognitive function at post-assessment and better neuropsychological outcomes at six months follow-up relative to controls. However, there were no significant gains in mental health or community integration. Thus, to date,

neurorehabilitation trials have not indicated improvements in mental health and quality of life.

A recent meta-analysis of psychological interventions for adults with cancer located no trials specifically targeting brain tumor [17]. A review of brain tumor interventions [18] identified case descriptions of psychosocial support and specialist nursing support. More recently, a systematic review of rehabilitative and supportive care interventions [19] identified an absence of controlled psychosocial interventions for people with high grade glioma and their caregivers. There is a critical need to evaluate psychosocial interventions tailored to the needs of people with brain tumor, with involvement of family members to support retention of information and strategies.

Our pilot research [10] found that people with brain tumor often had difficulty making sense of their illness (e.g., What does this mean for me? What does the future hold?). Sense-making appraisals or existential questions affect how well people can cope with and find meaning in their illness [20]. Accordingly, a useful framework for understanding the support needs of people with brain tumor is 'sense of coherence' (SOC), or people's global orientation to the world and extent to which they see the world as comprehensible, manageable, and meaningful [21]. When faced with serious illness people with strong SOC are more likely to perceive that they understand what is happening, believe they possess resources to manage the demands of the situation, and strive to find meaning in their life situation [20-22]. Higher SOC is found to promote well-being in the face of stress or illness [22], and can be enhanced through intervention [23].

Closely related to SOC, existential well-being refers to people's sense of purpose, meaning and control in life [24]. People with lower existential well-being after brain tumor have been found to experience greater symptoms of depression and poorer quality of life [25]. Guided by the SOC framework, this study investigated the efficacy of the Making Sense

of Brain Tumor (MSoBT) program for improving existential well-being, mental health and quality of life of people with brain tumor (note: caregiver data will be reported in a separate manuscript).

Methods

Participants

Over a two year period (July 2010-2012) people with primary brain tumor were recruited from hospital and community support services in Brisbane, Australia. Inclusion criteria were: aged at least 18 years, diagnosis of primary brain tumor, live within a one-hour drive of Brisbane, adequate receptive and expressive communication skills, and able to provide informed consent. A 17 year old with a malignant brain tumor who expressed interest in participating was also included, with consent also obtained from his parents. Approximately 60% of participants had a family member involved in their program, who attended 1-10 sessions (*M*= 5.4, *SD*= 3.2). Family members included the person's spouse (83.3%), parent (13.3%) and adult child (3.3%).

Fifty people with brain tumor (54% male) aged 17-82 years (*M*= 46.6, *SD*= 14.5) consented to participate in the program and completed the pre-intervention assessment. Relationship status included: married/defacto (66%), single (20%), divorced/separated (12%) and widowed (2%). Approximately half of the sample (54%) had a benign or low grade tumor and time since diagnosis ranged from 6 weeks to 18 years (*M*= 2.6 years, *SD*= 4.3). Brain tumor types included: glioblastoma multiforme (*n*= 15; 6 with recurrent tumor), oligodendroglioma (*n*=7; 4x Grade II, 3 x Grade III; 2 with recurrent tumor), astrocytoma (*n*=7, 3x Grade II, 4 x Grade III; 2 with recurrent tumor), meningioma (*n*= 6), pituitary tumor (*n*= 6), colloid cyst (*n*= 2) and craniopharyngioma (*n*= 2). Most participants (78%) received surgery, with chemotherapy (52%) and/or radiation therapy (42%) used as an adjuvant treatment or in isolation.

Design and Randomization

This study employed a randomized wait-list control design which followed CONSORT guidelines [26]. Based on a medium effect size for pre-post changes in quality of life from a previous RCT [15], a sample size of 35-40 participants per group was deemed to have sufficient power (.80) to detect significant intervention effects at an alpha level of .05. Participants were randomly allocated to the immediate or wait-list group using a pre-determined random computer-generated sequence. It was not possible to blind participants, therapists or assessors in the project. However, all outcome assessments were performed by psychologists independent of the therapy.

Assessment Measures

At the baseline assessment participants received a neuropsychological battery including tests of attention, memory, visuo-spatial skills, language and executive function (Digit Span, Hopkins Verbal Learning Test, Rey Complex Figure, Trail Making Test, and Verbal Fluency). A global neuropsychological functioning (GNF) composite was calculated for the purpose of examining the potential influence of cognitive status on intervention outcomes. Based on a previous study [27], the GNF composite was calculated by summing and averaging age-adjusted *z*-scores on each test.

The McGill Quality of Life Questionnaire (MQOL [24]) is a 16-item tool that assesses physical, psychological, existential and social well-being of people with chronic illness. The total MQOL score provides a global index of quality of life. Of primary interest here, the existential subscale (MQOL-EW) consists of six items rated on an 11-point scale (0-10) with higher scores indicating greater existential well-being. Previous research [25] demonstrated the validity of this subscale for use in brain tumor.

Using the structured interview guide [28], the Montgomery-Asberg Depression Rating Scale (MADRS [29]) assessed the presence and severity of depressive symptoms. The MADRS has been found to be a valid measure of depression for people with neurological disorders [30]. The 10 items are clinician-rated on a seven-point Likert scale, ranging from 0 (no or minimal symptomatology) to 6 (maximum symptomatology), with total scores ranging from 0 to 60. A cut-off of 12 is commonly used to identify individuals with depression requiring treatment [29]. Although the MADRS has not previously been used in brain tumor research, it was considered a useful approach in this study because the semi-structured format enabled the assessor to provide clarification prompts regarding mood symptoms. Internal consistency was satisfactory for the present sample (α = .71).

The Depression Anxiety Stress Scales - 21 (DASS-21 [31]) measures symptoms of depression, anxiety, and stress. Participants rate items on a 4-point Likert scale (0= *did not apply to me at all* to 3= *applied to me very much*), with total scores multiplied by two (range: 0-42). Clinical cut-offs include: depression $\geq$10, anxiety $\geq$7, and stress $\geq$14 [31]. The DASS assesses a broader range of mood symptoms than the MADRS, and has demonstrated reliability and validity in a brain tumor sample [32].

The Functional Assessment of Cancer Therapy-Brain (FACT-Br [33]) is a validated 50-item measure of QoL for brain tumor [34]. The FACT-Brain index assesses neurological symptoms whereas the FACT General subscales assess physical, social, emotional, and functional well-being. Items are rated on a 5-point Likert scale (0= *not at all* to 4= *very much*), with higher overall scores reflecting better QoL. The main subscales of interest were emotional, functional and social well-being and FACT-General (FACT-G) total.

Intervention

The MSoBT program was designed to meet the diverse needs of people with benign or malignant tumor. The 10 one-hour weekly sessions comprised of core (sessions 1, 2 and 10) and modular components, with the latter tailored to people's goals, life situation and cognitive capacity. While the program focused primarily on the person with brain tumor, family members were encouraged to be involved to enhance their understanding of the effects of brain tumor, support strategy use by the person with brain tumor and access counselling for their own support needs. Participants who had a family member involved received a combination of individual and couple/family support sessions. During the first two sessions participants described their diagnosis, treatment and functional changes and set 3-5 related goals, which represented the focus for support. Treatment modules included psychoeducation, neuropsychological feedback, cognitive rehabilitation, psychotherapy (anxiety, anger, depression), couple and family support (communication, intimacy). Session 10 involved the client and therapist reflecting on goal progress and planning for maintaining and ongoing gains. For details regarding the MSoBT therapy manual contact the first author.

Procedure

Ethical clearance was obtained from Griffith University Human Research Ethics Committee prior to study commencement. Study advertisements were published in a brain tumor support newsletter, hospitals, neurosurgery clinics and community services. After initial telephone contact, the project coordinator conducted a home visit to obtain written informed consent. Participants were administered a neuropsychological test battery and MADRS, MQOL, FACT and DASS. Family members completed measures of caregiver strain and emotional adjustment (note: these outcomes are not reported in this paper). Outcome measures were administered face-to-face at the baseline assessment and re-assessment (wait-list controls), while post-assessment and follow-up assessments were conducted over the telephone. When

requested, the assessment was conducted over two sessions to reduce fatigue. For the telephone-based assessments participants had copies of the questionnaires and read their responses out aloud to the independent assessor. Due to the length of administration of the FACT (50 items), this measure was omitted from the follow-up assessment.

Data analysis

The data were screened and managed for missing scores and relevant statistical assumptions. Participant attrition was managed according to intention-to-treat principles [35], and all participants were analyzed according to their group allocation. Potential covariates and baseline comparability of the groups was investigated. ANCOVAs were employed to investigate between-group differences on outcomes for the intervention group and wait list controls using endpoint means (post-assessment) and adjusting for baseline functioning and relevant covariates in each analysis. For all participants who received the MSoBT intervention, paired *t*-tests were used to compare levels of functioning at pre-intervention (i.e., assessment conducted just prior to the intervention) and six months follow-up. Subgroup analyses were conducted for participants with benign tumor and malignant tumor to examine changes in functioning between the pre-intervention and six-month follow-up assessments.

Results

Participant Flow

As shown in Figure 1, 61 inquiries were received over the two year recruitment period. Of the 50 individuals who consented to participate, 27 were allocated to the immediate group and 25 completed the MSoBT program (1 died and 1 experienced rapid decline). Of the 23 participants allocated to the wait-list group, 19 completed the MSoBT program. Two withdrew during the wait list period due to work and family commitments, and two withdrew

during their therapy program (1 due to rapid decline and 1 did not feel he was benefiting). Overall, 44 people completed the 10-session MSoBT program and post-assessment (25 immediate & 19 waitlist). Thirty-six participants completed the 6-month follow-up assessment (3 died, 2 had serious functional decline and 3 could not be contacted).

Covariates and Baseline Comparability

There was no significant association between number of sessions attended by family members and post-intervention outcomes. However, family member involvement in the program (coded: yes/no) was significantly related to post-intervention depression on the MADRS and FACT social/family well-being. Significant correlations were found between time since diagnosis and MADRS (r = .32, p<.05); age and MQOL-EW (r = .31, p<.05) and total MQOL (r = .34, p<.05); GNF and FACT emotional well-being (r = .37, p<.01), FACT functional well-being (r = .32, p<.05) and FACT-G (r = .35, p<.05); gender (r = .32, p<.05) and education (r = -.34, p<.05) and DASS depression. There were no significant differences between the intervention and wait-list groups on age, education, gender, time since diagnosis, tumor location, malignancy (benign tumor: 55% in immediate group vs. 52% in wait-list group) or global neuropsychological status (p>.05). However, significant baseline differences were found on four outcome measures (see Table 1). Relative to wait-list controls, the intervention group reported significantly lower levels of existential well-being (MQOL-EW: t = 2.20, p< .05), quality of life (total MQOL; t = 2.46, p<.05; FACT-G: t = 2.19, p<.05), and emotional well-being (FACT; t = 2.36, p <.05).

Between-Group Differences at Post-Assessment

Results of ANCOVAs comparing endpoint means (post-assessment) and adjusting for baseline functioning and relevant covariates are presented in Table 2. Intervention

participants reported significantly lower levels of depression on the MADRS and higher existential well-being, functional well-being and quality of life (FACT-G) at post-assessment compared to wait-list controls (p<.05). There were no significant between-group differences at post-assessment on social/family well-being, emotional well-being (FACT), overall quality of life (MQOL), depression (DASS), anxiety and stress (p>.05). Effect sizes ranged from small (.03) to large (.21) [36].

Pre-Intervention and Six Months Follow-up

For all participants who received the MSoBT (n = 44), paired t-tests indicated that, relative to pre-intervention, at six months follow-up participants reported significantly lower levels of depression on the MADRS (pre-intervention M= 13.78, SD= 6.4; follow-up M= 7.37, SD= 6.7, t = 6.37, p<.001, d= .98) and DASS (pre-intervention M= 13.35, SD= 10.3; follow-up M= 8.00, SD= 8.7, t = 3.18, p<.01, d= .56), and significantly higher levels of existential well-being (pre-intervention M= 6.21, SD= 1.9; follow-up M= 7.16, SD= 1.7, t = -2.91, p<.01, d= .53) and overall quality of life (pre-intervention M= 6.51, SD= 1.7; follow-up M= 7.38, SD= 1.8, t = -3.02, p<.01, d= .50) on the MQOL. Further, levels of stress significantly decreased on the DASS (pre-intervention M= 17.89, SD= 9.8; follow-up M= 12.89, SD= 9.6, t = 2.71, p=.01, d= .52) while the reduction in anxiety between pre-intervention (M= 10.27, SD = 8.6) and follow-up (M= 7.67, SD = 8.9) approached significance (t = 1.86, p= .07, d= .30).

Subgroup Analyses for Participants with Benign and Malignant Tumors

As shown in Table 3, paired t-tests indicated that, relative to pre-intervention functioning, at the six month follow-up participants with benign tumor reported significantly lower levels of depression on the MADRS (p<.001) and DASS (p=.014) and lower levels of stress (p=.036). There were no significant differences in existential well-being (p=.11), overall quality of life

on the MQOL (p=.06) or anxiety (p=.09) for the benign subgroup. For participants with malignant tumor there was a significant decrease in depression levels on the MADRS (p=.001) between the pre-intervention and follow-up assessment, but not in levels of depression, anxiety or stress on the DASS (p<.10). However, levels of existential well-being and overall quality of life on the MQOL significantly improved (p<.05) between the pre-intervention and follow-up assessments.

Discussion

The findings indicate that the MSoBT intervention was effective for improving existential and functional well-being and reducing depressive symptoms as assessed by clinical interview. There were no significant differences at post-assessment between the immediate and wait list groups on measures of social/family well-being, anxiety or stress. At six months follow-up participants generally reported significantly better psychological well-being and quality of life than pre-intervention levels.

In addition to the lower than optimal sample size, a potential explanation for the non-significant effects for social/family well-being is that only 60% had a family member involved in therapy. Further, their involvement varied from regular attendance (e.g., focusing on communication and intimacy) to a single session (e.g., psycho-education). The pattern of significant findings on the MADRS and non-significant findings on the DASS and emotional well-being on the FACT suggests that the impact of the intervention was greatest for mood symptoms assessed via a clinical interview. The MADRS items (viz., sadness, loss of interest, reduced initiation) overlap with, but differ from DASS items. Further, as a clinician-administered tool, assessors were able to clarify symptom presence and severity on the MADRS. The DASS anxiety scale mainly assesses physical symptoms that may directly arise from brain tumor or treatment, which could have affected its sensitivity to detect change.

The FACT emotional well-being subscale assesses emotional reactions (e.g., losing hope and worry) [33], which although related, differ from the MQOL existential well-being items, which assess sense of purpose, meaning and control [24]. The improvement in existential well-being indicates that the MSoBT intervention supported people to make sense of and find meaning in their life situation. Further, the gains in functional well-being suggest that participants were more able to derive fulfilment in life and accept their illness. Associations among existential well-being, depression and quality of life have been highlighted [25]; however, previous interventions have not demonstrated gains in psychological well-being [15, 16]. The integration of cognitive rehabilitation and psychotherapy and goal-directed focus of the MSoBT intervention may have provided greater scope to address diverse issues impacting on people's mental health and quality of life.

Due to the lack of control group at follow-up, the functional gains between the pre-intervention and six month follow-up assessments cannot be solely attributed to the MSoBT intervention. In particular, other services participants concurrently accessed was not monitored, which is an important consideration for future research. The subgroup analysis indicated that people with both benign and malignant tumors reported improvement in psychological well-being (albeit across different measures) relative to pre-intervention functioning. Caution is needed when interpreting these findings because many participants lost to follow-up experienced tumor recurrence and functional decline. Nonetheless, given the relatively high retention rate (81%) between the post-assessment and six month follow-up, the findings provide some positive indications of long-term benefits of psychosocial support for this population.

A key study limitation is that the sample size was lower than desirable, thus affecting statistical power. Further, although GNF was a covariate in relevant analyses, the influence of specific cognitive deficits (e.g., memory) on outcomes was not examined and is important

to consider in future research. A paper on patient and therapy-related factors related to reliable change outcomes after the MSoBT intervention is in preparation.

Clinical Implications

This study provides preliminary support for integrating cognitive rehabilitation and psychotherapy approaches to improve mental health and quality of life for people with brain tumor. The home-based MSoBT intervention aimed to reduce barriers to attending therapy (e.g., transport, fatigue); however, this restricted the intervention to a metropolitan area. Flexible delivery intervention modes (e.g., telephone-based) needs to be evaluated, along with interventions focusing on family members.

More broadly, it is recommended that standards for psychosocial support be developed for brain tumor. A tiered model of service delivery [37] could be evaluated in which the level and type of intervention is varied according to people's clinical presentation. At a minimum, it may be recommended that people with brain tumor and family members receive access to information, and screening of psychological distress and functional impairment. This assessment can determine suitable levels of psychosocial support in conjunction with medical treatment, including community support (e.g., help-line, support groups), low intensity psychological intervention, multi-disciplinary rehabilitation, mental health care plan, and family system interventions [6, 37].

Acknowledgements

The researchers gratefully acknowledge the funding and support of the Cancer Council Queensland. We would also like to thank the following people for their expertise and support in the study: Valmai Goodwin, Sarah Thompson, Vivien Biggs, Katherine Horrigan, Cassandra Shields, Megan Broughton, Kim Nash, Elizabeth Goadby, Jacob Cooney and Paul Finnegan. The authors have no conflicts of interest to declare.

References

1. Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC Cancer Base No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: http://globocan.iarc.fr, accessed on 03/03/2014.
2. Central Brain Tumor Registry of the United States (CBTRUS; 2012). CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2004-2008 (March 23, 2012 Revision). Source: Central Brain Tumor Registry of the United States, Hinsdale, IL. website: www.cbtrus.org
3. Yeh SA, Ho JT, Lui CC, Huang YJ, Hsiung CY, Huang EY. (2005). Treatment outcomes and prognostic factors in patients with supratentorial low-grade gliomas. *British Journal of Radiology* 2005; **78**:230–235.
4. Louis DN, Ohgaki H, Wiestler OD, Cavenee WK, Burger PC, Jouvet A, Kleihues P. The 2007 WHO classification of tumours of the central nervous system. Acta Neuropathologica 2007; **114**:97–109.
5. Adelbratt S, Strang P. Death anxiety in brain tumour patients and their spouses. *Palliative Medicine* 2000; **14:**499–507.
6. Ownsworth TL, Hawkes A, Steginga S, Shum D, Walker D. A biopsychosocial perspective on adjustment and quality of life following brain tumour: A systematic evaluation of the literature. *Disability & Rehabilitation* 2009; **31:**1038-1055.
7. Arnold SD, Forman LM, Brigidi BD, Carter KE, Schweitzer HA, Quinn HE, et al. Evaluation and characterization of generalized anxiety and depression in patients with primary brain tumors. *Neuro-Oncology* 2008; **10:**171-181.
8. Lidstone V, Butters E, Seed P, Sinnot C, Beynon T, Richards M. Symptoms and concerns amongst cancer outpatients: Identifying the need for specialist palliative care. *Palliative*

Medicine 2003*;* **17:**588-595.

9. Klein M, Taphoorn MJB, Heimans JJ, Van der Ploeg HM, Vendertop WP, Smit EF, et al. Neurobehavioral status and health-related quality of life in newly diagnosed high-grade glioma patients. *Journal of Clinical Oncology* 2001; **19**:4037-47.
10. Ownsworth T, Chambers S, Hawkes A, Walker DG, Shum D. Making sense of brain tumour: A qualitative investigation of personal and social processes of adjustment. *Neuropsychological Rehabilitation* 2011; **21:**117-137.
11. Duval J, Coyette F, Seron X. Rehabilitation of the central executive component of working memory: A reorganization approach applied to a single case. *Neuropsychological Rehabilitation* 2008; **18:**430-460.
12. Sherer M, Meyers C, Bergloff P. Efficacy of postacute brain injury rehabilitation for patients with primary malignant brain tumours. *Cancer* 1997; **80**:250-57.
13. Marciniak CM, Sliwa JA, Heinemann AW, Semik BA. Functional outcomes of persons with brain tumors after inpatient rehabilitation. *Archives of Physical Medicine and Rehabilitation* 2001; **82**:457-463.
14. Greenberg E, Treger I, Ring H. Rehabilitation outcomes in patients with brain tumors and acute stroke: Comparative study of inpatient rehabilitation. *American Journal of Physical Medicine and Rehabilitation* 2006; **85**:568-573.
15. Locke DEC, Cerhan JH, Wu W, Malec J, Clark MM, Rummans TA, Brown PD. Cognitive rehabilitation and problem-solving to improve quality of life of patients with primary brain tumors: A pilot study. *Journal of Supportive Oncology* 2008; **6**:383-391.
16. Gehring K, Sitskoorn MM, Gundy CM, Sikkes SA, Klein M, Postman TJ et al. Cognitive rehabilitation in patients with gliomas: A randomized controlled trial. *Journal of Clinical Oncology* 2009; **22**:3712-3722.

17. Faller H, Schulaer M, Richards M, Heckl U, Weis J, Kuffner R. Effects of psycho-oncologic interventions on emotional distress and quality of life in adult patients with cancer: Systematic review and meta-analysis. *Journal of Clinical Oncology* 2013; **31**:782-93.
18. Salander P. Facilitating interventions and/or relationships in malignant brain tumors. *Advances in Therapy* 2010; **27**:17-27.
19. Piil K, Juhler M, Jakobsen J, Jarden M. Controlled rehabilitative and supportive care intervention trials in patients with high-grade gliomas and their caregivers: a systematic review. *BMJ Support Palliative Care* 2014; doi: 10.1136/bmjspcare-2013-000593
20. Strang S, Strang P. Spiritual thoughts, coping and 'sense of coherence' in brain tumour patients and their spouses. *Palliative Medicine* 2001; **15**: 127-34.
21. Antonovsky A. The salutogenic model as a theory to guide health promotion. *Health Promotion International* 1996; **11:**11-18.
22. Eriksson M, Lindstöm B. Validity of Antonovsky's sense of coherence scale: a systematic review. *Journal of Epidemiology and Community Health* 2005; **59**;460-466
23. Ando M, Natsume T, Kukihara H, Shibata H, Ito S. Efficacy of mindfulness-based mediation therapy on the sense of coherence and mental health of nurses. *Health* 2011; **3**:108-122.
24. Cohen SR, Mount BM, Strobel MG, Bui F. The McGill Quality of Life Questionnaire: A measure of quality of life appropriate for people with advanced disease. *Palliative Medicine* 1995; **9**;207-219
25. Pelletier G, Verhoef MJ, Khatri N, Hagen N. Quality of life in brain tumour patients: the relative contributions of depression, fatigue, emotional distress, and existential issues, *Journal of Neuro-Oncology* 2002; **57**:41-9.

26. Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *Annals of Internal Medicine* 2010; **152**:726-732.

27. Ownsworth T, Dwan T, Chambers S, Walker D, Shum D. The moderating effect of estimated pre-morbid IQ on the relationship between neuropsychological status and subjective well-being after brain tumor. *Journal of Psychosomatic Research* 2014; **76**:257-260.

28. Williams JB, Kobak KA. Development and reliability of a structured interview guide for the Montgomery–Asberg Depression Rating Scale (SIGMA). The British Journal of Psychiatry 2008; **192**:52-58.

29. Montgomery, S. A., & Asberg, M. (1979). A new depression scale designed to be sensitive to change. *British Journal of Psychiatry, 134*, 382-389.

30. Andersson S, Krogstad JM, Finset A. Apathy and depressed mood in acquired brain damage: relationship to lesion localization and psychophysiological reactivity. *Psychological Medicine* 1999; **29**:447–456.

31. Lovibond S, Lovibond P. Manual for the Depression Anxiety Stress Scales. 2nd ed. Psychology Foundation: Sydney; 1995.

32. Ownsworth T, Little T, Turner B, Hawkes A, Shum D. Assessing emotional status following acquired brain injury: The clinical potential of the depression, anxiety and stress scales. Brain Injury 2008; **22**:858–69.

33. Cella DF, Tulsky DS, Gray G, Sarafian B, Linn E, Bonomi A, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *Journal of Clinical Oncology* 1993; **11**:570–9.

34. Janda M, Steginga SK, Langbecker D, Dunn J, Walker D, Eakin EG. Quality of life among patients with a brain tumour and their carers. *Journal of Psychosomatic Research* 2007; **63**:617-623.

35. Gupta SK. Intention-to-treat concept: a review. *Perspectives in Clinical Research* 2011; **2**:109–112.

36. Cohen J. *Statistical power analysis for the behavioral sciences* (2nd ed.). Lawrence Erlbaum Associates: Hillsdale, NJ, 1998.

37. Hutchison S, Steginga SK, Dunn J. The tiered model of psychosocial intervention in cancer: A community based approach. *Psycho-Oncology* 2006; **15**:541-6.

Table 1

Descriptive Data on Outcomes at Baseline and Post-Assessment and Re-Assessment

Measure	Intervention (n = 27)		Wait list controls (n = 23)	
	M(*SD*)		*M*(*SD*)	
	Baseline (pre)	Post-assessment	Baseline (pre)	Re-assessment
MADRS	14.88 (7.2)	10.16 (9.9)	11.86 (5.3)	13.10 (6.0)
MQOL-				
Existential	5.67 (2.1)	7.10 (1.96)	6.83 (2.0)	7.03 (1.8)
Total	5.97 (2.1)	6.92 (2.2)	7.19 (1.4)	7.18 (1.34)
FACT-				
Social/family	17.35 (6.4)	16.92 (6.6)	18.87 (5.8)	19.87 (5.6)
Functional	14.08 (5.5)	17.44 (5.9)	16.53 (4.9)	14.7 (4.8)
Emotional	13.40 (5.7)	16.52 (5.2)	17.21 (5.1)	16.43 (5.0)
General	62.09 (19.7)	69.92 (22.2)	72.82 (13.8)	70.88 (13.7)
DASS-				
Depression	15.68 (11.6)	10.96 (11.1)	9.89 (7.6)	10.01 (6.9)
Anxiety	10.56 (9.8)	9.84 (8.18)	9.22 (6.3)	9.44 (7.8)
Stress	17.68 (11.2)	14.40 (11.1)	15.83 (9.6)	14.22 (8.6)

DASS = Depression Anxiety Stress Scales; FACT = Functional Assessment of Cancer Therapy; MQOL = McGill Quality of Life; MADRS: Montgomery Asberg Depression Rating Scale

Table 2.

Between Group Differences at Post-Assessment for the Immediate and Wait-List Control Groups (baseline = initial assessment for all participants; post-assessment = post-intervention assessment for the immediate group and re-assessment for wait list controls)

			Group (immediate vs wait list)	
	Covariates	*F*	*F*	Effect size ($\eta\rho^2$)
MADRS			8.32**	.17
	Baseline	30.11***		
	Time since diagnosis	2.31		
	Family involvement	3.52		
MQOL-EW			5.49*	.13
	Baseline	35.82***		
	Age	1.79		
MQOL-Total			3.21	.08
	Baseline	37.08***		
	Age	1.80		
FACT				
Social			1.77	.04
	Baseline	73.60***		
	Age	3.42		
	Family involvement	6.11*		
Functional			10.40**	.21
	Baseline	24.37***		
	GNF	0.28		
Emotional			3.78	.09
	Baseline	30.41***		
	GNF	4.82*		
General			5.37*	.12
	Baseline	69.73***		
	GNF	4.12*		
DASS				
Depression			1.92	.05
	Baseline	35.60***		
	Gender	2.16		
	Education	0.55		
Anxiety			1.07	.03
	Baseline	83.71***		
Stress			2.31	.06
	Baseline	78.74***		

*p<.05, **p<.01, ***p<.001.

Table 3

Subgroup Analyses Comparing Functioning at Pre-Intervention and Six-Month Follow-up for Participants with Benign and Malignant Tumors

Measure	Benign tumor (*n*= 26)				Malignant tumor (*n*= 18)			
	M(*SD*)		*t*	*d*	*M*(*SD*)		*t*	*d*
	Pre-intervention	Follow-up			Pre-intervention	Follow-up		
MADRS	14.38 (6.3)	8.71 (7.6)	4.62***	.81	13.07 (6.6)	5.27 (5.2)	4.16***	1.29
MQOL-								
Existential	6.33 (1.9)	7.00 (1.9)	-1.77	.35	6.00 (1.9)	7.48 (1.5)	-2.40*	.85
Total	6.45 (1.8)	7.18 (1.9)	-2.01	.39	6.60 (1.6)	7.75 (1.4)	-2.34*	.76
DASS-								
Depression	13.25 (10.6)	8.50 (8.9)	2.66*	.48	13.50 (10.7)	7.50 (8.8)	1.56	.61
Anxiety	10.96 (9.2)	8.00 (7.9)	1.81	.34	8.83 (7.5)	7.00 (11.1)	0.67	.19
Stress	18.92 (10.8)	14.33 (8.9)	2.23*	.46	15.83 (7.8)	10.91 (10.7)	1.20	.51

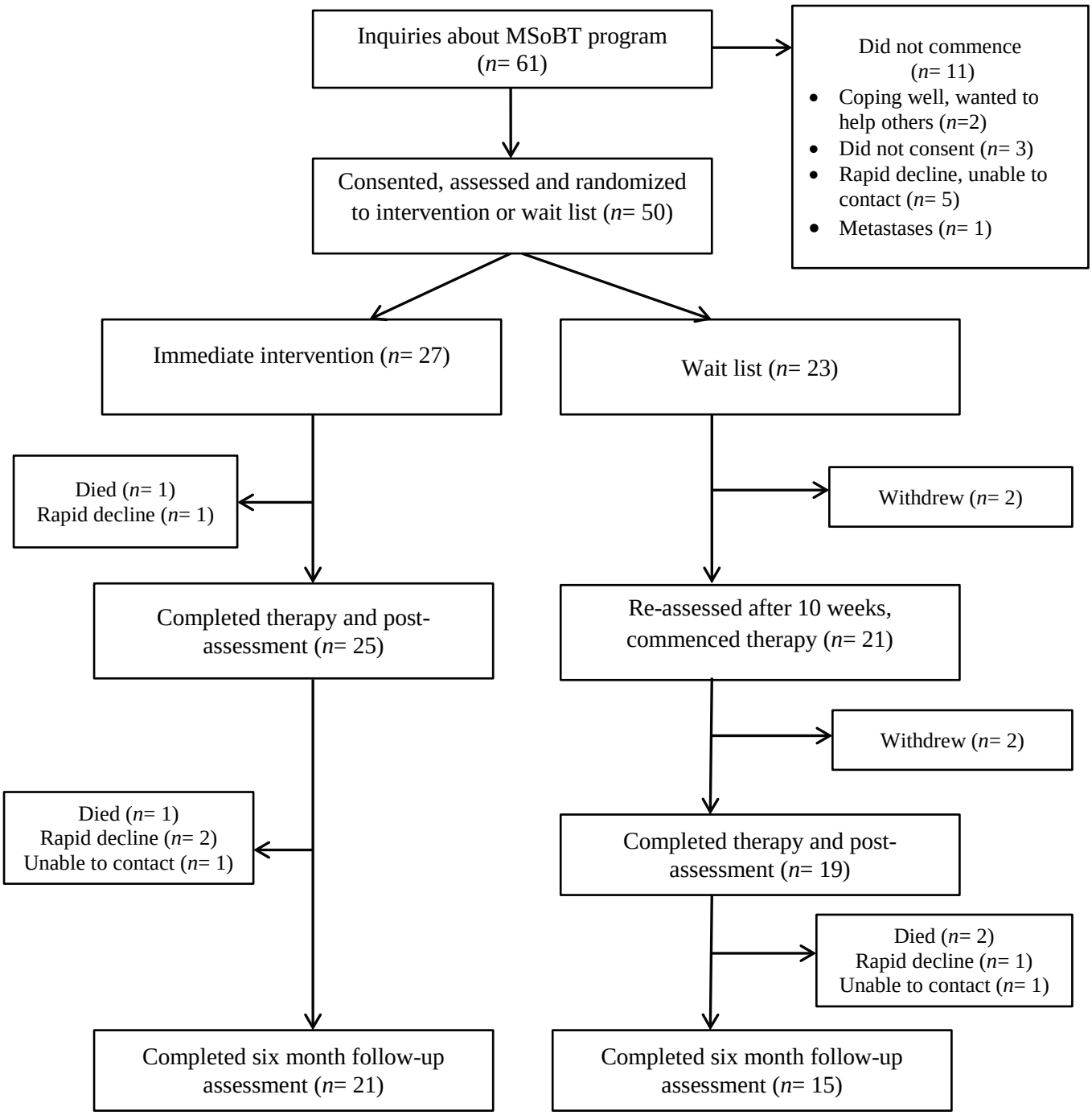

Figure 1: Participant flow diagram