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Doctoral Thesis

The Experience of Low Grade and Pituitary Tumours

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Word Count

Section	Main Text	Abstracts, references, Tables and Appendices	Total
Thesis Abstract	285	N/A	285
Literature Review	8000	3884	11884
Research Paper	7903	4097	12000
Critical Review	4271	776	5047
Ethics Section	5333	3910	9243
Total	25792	12667	38459

Thesis Abstract

Low grade brain tumours make up approximately 45% of all brain tumour diagnoses each year in the UK, of which 10% are pituitary tumours. People with low grade and pituitary tumours can experience a wide range of physical, psychological and cognitive difficulties. Studies have reported mixed results in regard to the extent and cause of psychological and cognitive difficulties. However, qualitative research has highlighted the need for a greater understanding of the experience of low grade and pituitary tumours, in order to provide best care and support.

In section one, studies with information regarding the psychological and emotional wellbeing of people with primary low grade brain tumours were systematically reviewed. A total of 14 papers were identified, and a meta-synthesis approach was utilised. The results highlighted significant psychological and emotional turmoil for people with a primary low grade brain tumour. Results demonstrated that the low grade morphology of a brain tumour does not diminish the overall distress in comparison with high grade tumours, though the focus on mortality was less constant. Findings demonstrated the need for significant psychological support for people with a low grade brain tumour, and further potential research was discussed.

Section two explored the experiences of people with a history of pituitary tumour in regard to cognitive difficulties and neuropsychological testing. Individual interviews were conducted, and analysed using Interpretative Phenomenological Analysis. Results revealed cognitive functioning as an underlying source of distress during pituitary tumour care and showed how neuropsychological testing can be beneficial. Clinical implications and potential future research were discussed.

Section three was used to reflect on a variety of issues which arose during the research process, and to reflect on the results and implications of the research study.

Declaration

This thesis reports on research undertaken between August 2014 and May 2015 and is submitted in partial fulfilment of the Lancaster University Doctorate in Clinical Psychology. The work presented is the author's own work except where due reference is made. This work has not been submitted for the award of any higher degree elsewhere.

Benjamin Daniel Dawson

Signature:

Date:

Acknowledgements

Firstly, I would like to thank all those who participated in this research project. It was a privilege to be given a window into your lives and a humbling experience to explore your journeys with you. I hope what I have done with your stories makes you feel your time was well spent. I would like to thank my academic supervisor Ste Weatherhead for his support, direction and most of all his honesty in working with me not just on this project, but for the last three years. I am by no means the easiest student, but I hope I have been a worthwhile one in the end. Next I would like to thank my field supervisor Gemma Wall for her unending patience, for her support in starting and finishing this project and for helping me to build a true passion for neuropsychology.

Lastly I must thank all my family and friends. In particular, my Nan, Pat. I can only say that without your tireless proof reading, unwavering confidence in my ability and tenacity in splitting my infinitives, I would not have survived this process. To my mum and dad, I will say that you have made me who I am. Your faith, guidance, tolerance and love will never be forgotten and whoever I have helped, or may help in future, you are responsible. One final thank you must go to someone I cannot thank in person, who taught me to stand up for others, to be proud of your family and never to back down when protecting someone. To my Auntie Elsie.

Contents

Section One: Literature review

An Examination of the Psychological and Emotional Experience of Having a Primary Low Grade Brain Tumour – A Meta-Synthesis of Qualitative Research

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Abstract

The purpose of this qualitative meta-synthesis was to explore the psychological and emotional experience of having a primary low grade or benign brain tumour. Electronic databases were systematically searched according to specified inclusion and exclusion criteria. A total of 14 qualitative papers were included for final review, using an adapted meta-synthesis approach based on guidance from Noblit and Hare (1988). Relevant themes and interpretations were extracted from the selected papers, and used to generate six final themes which represented the entire data set. These were: emotional states; interaction with health care professionals; change and coming to terms; re-evaluating; the importance of reassurance, support, and hope; and looking back vs. looking forward. The findings highlight the significant psychological and emotional turmoil experienced by people with a primary low grade brain tumour, and identify potential areas for professional involvement. Findings, strengths, limitations, clinical implications and areas for future research are discussed.

Keywords: brain tumour, meta-synthesis, review, low grade, benign, qualitative

An Examination of the Psychological and Emotional Experience of Having a Primary Low Grade Brain Tumour – A Meta-Synthesis of Qualitative Research

Introduction

In the United Kingdom brain tumours make up approximately 3% of cancer diagnoses, with a prevalence rate of 15 out of every 100,000 in the general population, split evenly across men and women (Cancer Research UK, 2011). Primary brain tumours are those tumours which begin within the brain, and are not the result of metastases from other forms of bodily tumour. Low grade tumours are those tumours which do not present as malignant, meaning they are unlikely to grow rapidly or spread to other areas. There is however a risk of malignant transformation in this type of tumour, meaning the tumour can begin as low grade but become high grade. Primary low grade brain tumours (PLGBT) make up approximately 45% of all brain tumours diagnosed each year (Cancer Research UK, 2011).

Within brain tumour research, psychological status and wellbeing is commonly assessed as part of a wider concept of quality of life (QoL). At present no single gold standard QoL assessment exists to assess people with a brain tumour (Pace, Villani , Zucchella & Maschio, 2012) and psychological difficulties form only one part of QoL studies (e.g. Johnson, Woodburn & Vance, 2003; Van der Klaauw et al., 2008; Page, Hammersley, Burke & Wass, 1997; Tooze, Gittoes, Jones & Toogood, 2009). The experience of having a brain tumour brings duality in "the trauma and uncertain prognosis associated with cancer diagnosis [and] the direct neurological effects of the tumour" (Ownsworth, Hawkes, Steginga, Walker & Shum, 2009, p. 1038). Brain tumour patients experience a direct threat to their life, but also to their personality (Adelbratt & Strang, 2000). Quantitative studies have

demonstrated a number of fundamental issues when considering the psychological wellbeing of adults with a primary brain tumour (both malignant and low grade). Issues such as anxiety and depression have a negative impact on QoL (Flowers, 2000; Heimans & Taphoorn, 2002; Khan & Amatya; 2013; Ownsworth, Hawkes, Steginga, Walker & Shum, 2009; Tooze, Gittoest, Jones & Toogood, 2009; Tsay, Chang, Yates, Lin & Liang, 2012;Vargo, 2011) and self-report measures have found anxiety and depression have a substantial impact on confidence, independent living ability and participation in social and family activities (Khan & Amatya, 2013) which can further impact psychological wellbeing.

A number of systematic reviews have been conducted to investigate areas of brain tumour experience. Huang, Wartella, Kreutzer, Broaddus & Lyckholm (2001) reviewed quantitative literature regarding functional outcomes and quality of life in patients with a brain tumour, and found significant changes in quality of life over the course of brain tumour experience. Sterckx et al. (2013) analysed sixteen qualitative papers relating to the impact of high grade glioma on everyday life for people with a brain tumour and their carers. They reported on areas such as supportive care and information needs, the financial implications, the change in roles and the process of diagnosis. Underpinning a number of their findings were emotional concepts such as shock, anxiety, depression and anger. Moore et al. (2013) reported on the palliative and supportive care needs of high grade glioma patients and their carers. They combined psychological needs with social, and found issues such as maintaining hope, the importance of relationships and struggling with cognitive impairments to be paramount. These reviews demonstrate several issues, firstly that the psychological and emotional consequences of PLGBT are pivotal in the broad experience of having a brain tumour, that despite this they are often regarded as secondary to more social or

practical issues, particularly in larger reviews, and lastly that focus has tended to be on high grade, malignant tumour types. This focus may be because there is an assumption that the experience of people with high grade tumours will be worse than those with low grade, due to the increased chance of death. Additionally these reviews tend to focus on one tumour type, reducing generalisability to other tumour types.

As demonstrated, when included as part of larger whole (along with social and physical issues) the exploration of psychological wellbeing can become overshadowed. More detail on the psychological difficulties facing people with a brain tumour can be found in the idiographic qualitative studies of brain tumour experience. Some studies do attempt to focus on a singular psychological issue facing people with a brain tumour, for example studies of anxiety (e.g. Jagadeesh & Bernstein, 2014), however psychological difficulties are also often part of a wider exploration of experience, such as the experience of symptoms (e.g. Molassiotis et al., 2010). As yet no review has drawn together the psychological and emotional elements of these qualitative studies to assess the commonalities in the psychological experience of having a PLGBT.

The practice of meta-synthesis in qualitative research aims to draw together larger numbers of qualitative studies, and evaluating their commonalities to produce a larger data pool, which can be viewed as more robust than any one study alone. However, qualitative data must be considered using criteria other than generalisability, with focus on individual experience, with the possibility, but not certainty, that issues arising may affect the wider population. Meta-synthesis involves the re-interpretation of qualitative data to produce a novel set of findings (Pope, Mays & Popay, 2007) with the hope that these combined findings provide a more in depth and better understanding of the sensitive issues often addressed by qualitative

research (Boland, Cherry & Dickson, 2014). As argued, emotional wellbeing in people with a brain tumour constitutes both an area with a number of isolated qualitative studies and an area which receives limited research focus compared to other issues. This makes it a good candidate for the use of a meta-synthesis approach. Whilst every person with a low grade brain tumour may have a different experience, and experiences may differ across tumour type, understanding any commonalities in experience can help clinicians to be more prepared and subsequently make more informed choices regarding care. Consequently, the current review will utilise a qualitative meta-synthesis approach (Noblit and Hare, 1988) to draw together qualitative evidence regarding the psychological and emotional experience of having a PLGBT, within the scope of the inclusion and exclusion criteria established below. This review aims to highlight those difficulties and concerns common across people with a PLGBT, and to identify areas for potential support.

Method

Search strategy

Identification of papers for this review was conducted through a computerised search of four academic databases, these included: PubMed (incorporating MEDLINE and additional life science sources), PSYCINFO, CINAHL and Academic Search Complete. The search was limited to peer-reviewed journals published in English, and was conducted between November to December 2014. When using the PubMed database, an additional filter of human research was used to exclude any studies done with animals. Search term thesauri were consulted using an initial search term set, to ensure full and appropriate search terms were used, this resulted in additional terms such as neoplasm (more commonly used in the USA). Brain tumour search terms were based on the inclusion of all known tumour types. There are over 130

morphologies of brain tumour (Louis, Ohgaki, Weistler, Cavenee, 2007), which necessitated an extensive list of search terms. Some specific types of brain tumour have names which are partially shared with others, for example multiple forms of Glioma, this meant search terms could be reduced to include only the necessary words which would identify multiple tumour types. The full list of search terms can be found in Appendix 1-B.

The search terms used were deliberately broad, and it was recognised this would result in a number of papers which were unsuitable for review here, such as those focussing on malignant tumour types. However in the interests of ensuring all relevant papers were included, broad search terms were necessary. All search terms were applied to each database consulted. The searches were done as a free text search, once the exploration of search terms had been completed using thesauri, as outlined above. Databases such as PubMed and Academic Search Complete also have an automatic mapping search tool, which allows the users search terms to be automatically expanded out to include available associated terms, this option was utilised to ensure maximum article inclusion.

All abstracts were then examined, and those that potentially met the inclusion criteria were examined in greater detail. A manual search of the reference lists of papers identified was also conducted, to identify other articles that may have met the inclusion criteria. Table 1 outlines the specific inclusion and exclusion criteria used to determine whether a paper was to be included in this review, along with a rationale for each criterion.

Insert Table 1 here

Search results

The search yielded 1957 results which were all examined by title and abstract. Twelve papers met the criteria for final inclusion, and an additional 2 were added from a manual search of reference lists within papers. Therefore a total of 14 papers were included for review. The numbers of papers found, examined and included or excluded at each stage can be found in the flow diagram in Appendix 1-A, along with further detail of how inclusion and exclusion criteria were applied at each stage.

The majority of papers excluded were removed on the basis of the inclusion criteria alone, primarily being quantitative, not being focussed on PLGBT or having any aspect of psychological wellbeing. A small number of papers were excluded based on the exclusion criteria, for example being too specific and only tangentially related to the subject. For example, one paper was excluded as it focussed solely on the impact of religious beliefs on brain tumour experience. Whilst this contained elements of psychological thinking, it would not have aided in answering wider questions about common psychological experience.

Characteristics of the included studies

A summary of the main characteristics of each study are presented in **Table 2.** Individual research questions varied between papers, however all included studies aimed in some way to explore qualitatively some aspect of the experience of having a primary brain tumour. The majority of studies (11/14) used individual semi-structured interviews, three used a combination of individual interviews and focus groups and one study used recordings of existing group therapy sessions.

Only one paper exclusively examined on psychological experience (Jagadeesh & Bernstein, 2014), whilst the rest focussed on broader issues but included themes which incorporated psychological experience (Cavers, et al., 2012; Cavers, et al.,

2013; Cornwell, Dicks, Fleming, Haines & Olson, 2012; Edvardsson & Ahlstrom, 2005; Edvardsson, Pahlson & Ahlstrom, 2006; Fox & Lantz, 1998; Gurel, Bruening, Rhodes & Lomax, 2014; Hayhurst, Mendelsohn & Bernstein, 2010; Janda, Eakin, Bailey, Walker & Troy, 2005; Leavitt, Lamb & Voss, 1996; Molassiotis et al., 2010; Ownsworth, Chambers, Hawkes, Walker & Shum, 2010; Simpson, Heath & Wall, 2014).

Thirteen studies used mixed male and female samples, with one study not reporting their sex statistics (Fox & Lantz, 1998) and participant ages ranged from 18-82 years. Some studies included information from families and carers as well as people with a brain tumour, wherever possible data exclusively from people with tumours themselves were extracted. Studies were conducted in the UK, Australia, Sweden, USA and Canada, and ethnicity was only sporadically reported.

Studies utilised a variety of qualitative methodologies, four utilised grounded theory, four used content analysis, three used thematic analysis, one used narrative and two referred to general qualitative phenomenological principles. Choice of methodology was also used to help make a determination about the epistemological stance of each paper (Bannister, Bunn, Burman & Daniels, 2011, p. 10; Willig, 2013, p. 52) as this was not directly cited in any paper. As this is the first meta-synthesis in this subject area, a range of methods and epistemological stances were included, however they all shared an inductive approach to their qualitative research.

Insert Table 2 here

Quality assessment

All of the selected studies were subjected to a quality appraisal using the Critical Appraisal Skills Programme tool (CASP, 2013). This tool aids in the systematic appraisal of quality in qualitative papers, covering 10 areas such as appropriate design and methodology, ethical considerations and appropriate analysis. The quality appraisal was undertaken by the main researcher alone, as was the decision whether to exclude any papers. Exclusion decisions were made based on whether a study appeared to have a higher number of reporting flaws than the collective, and whether the removal of a study would be of detriment to the final synthesis.

Walsh & Downe (2006, p109) note that without quality appraisal a meta-synthesis can be flawed. Walsh & Downe recognise the idea of appraising qualitative research for specific quality is contestable based on the variety of epistemological stances adopted by qualitative research, which may reject the traditional idea of quality in research, which is based in reliability and validity. However, they cite Murphy et al. (1998) in saying that practical concerns such as whether research should be funded, mean at least an attempt to approximate some kind of wider truth is necessary.

No study was excluded as a result of the appraisal conducted, as quality was determined to be generally good across all included papers. There were a small number of consistent reporting quality gaps across papers, for example papers failing to justify their research design or discuss the relationship between researcher and participant. Table 3 presents a summary of the findings from the quality appraisal process.

Insert Table 3 here

Meta-synthesis process

The meta-synthesis process used the style established by Noblit and Hare (1988, p. 26-29) to proceed through the following steps: (1) Identifying the subject area; (2) searching and selection of relevant studies; (3) reading the studies; (4) determining how the studies are related; (5) translating the studies into one another; (6) synthesising the translations; (7) expressing the synthesis. This approach relies on the synthesis of the interpretations made in studies, rather than the synthesis of raw data (Doyle, 2003). The approach by Noblit and Hare is categorised as a meta-ethnographic approach, and as such they suggest the use of only 3-5 papers (Noblit & Hare, 1988). This review looked to adapt this approach by utilising an increased number of papers, whilst maintaining the approach of synthesising interpretative data.

Table 4 gives an overview of the main psychological wellbeing findings extracted from each of the included studies. Table 5 demonstrates the synthesis of individual study themes into final meta-themes. The interpretative data extracted from the studies was limited to information surrounding psychological experience. This meant that for a number of papers, only a selection of themes from their overall collection were utilised in the synthesis. Where possible only data regarding the low grade participants in mixed population studies was extracted. Where this data was fully integrated, an assumption was made that the themes represented issues which were prevalent in both populations and therefore relevant to this meta-synthesis.

Insert Table 4 here

Insert Table 5 here

Reflexive Statement[1]

I attempted to remain reflexive whilst conducting this literature review, in part this meant ensuring I was aware of my own thoughts, feelings and perspectives and how these could influence my data analysis. My experience of working with people with a low grade brain tumour was that they do not always receive similar levels of support as people with high grade tumours. I recognised a motivation to help improve services in this areas and subsequently I needed to be cautious of over-interpreting results to this end.

As with my research paper I adopted a realist social constructionist (Elder-Vass, 2012) epistemology which integrated both my view that the individual participants were communicating their own constructed meaning and that their experiences would be influenced by wider social structures which required acknowledgement.

Results

The meta-synthesis process resulted in six themes relating to both the direct psychological impact of having a PLGBT and those factors which influence it. These themes were: emotional states; interaction with health care professionals; change and coming to terms; re-evaluating; the importance of reassurance, support and hope; and looking back vs. looking forward. Noblit & Hare (1998) suggest using the titles from the study themes to form the titles for the meta-synthesis themes. This was done where possible, and where the original themes did not reflect the newly constructed meta-synthesis theme, a new theme title was created. Four of the six final themes used titles from the original studies (emotional states; interaction with health care

[1] This section is written in the first person to ensure clarity

professionals; re-evaluating; and the importance of reassurance, support, and hope). Figure 1 gives a diagrammatic overview of the meta-synthesis themes and how they relate to one another.

Insert Figure 1 here

Emotional states

Ten of the fourteen studies contributed to this theme, which was the largest in both numbers of studies contributing and total number of constituent themes. This highlights the importance of the impact that having a PLGBT has on emotional state. The theme encapsulates the direct discussion of emotional wellbeing as an issue in itself, rather than as a consequence of other factors (as discussed in later themes). The theme overall demonstrated the significant influence emotional state can have on the thoughts, feelings and behaviour of people with a PLGBT. The emotional state of participants across studies affected the choices they made in relation to their care, relationships and attempts to move forward in their lives. Studies discussed a plethora of emotions, most commonly difficulties with anxiety, anger and depression (Cavers et al., 2013; Edvardsson & Ahlstrom, 2005; Gurel, Bruening, Rhodes & Lomax, 2014; Hayhurst, Mendleson & Bernstein, 2010; Leavitt, Lamb & Voss, 1996; Molassiotis et al., 2010; Ownsworth, Chambers, Hawkes, Walker & Shum, 2010 and Simpson, Heath & Wall, 2014), but also with compound psychological constructs such as devastation (Hayhurst et al., 2010), control (Gurel et al., 2014; Molassiotis et al., 2010; Simpson et al., 2014) and shame (Edvardsson & Ahlstrom, 2005; Edvardsson et al., 2006).

Emotional distress and volatility permeated every stage of the psychological journey through experiencing a PLGBT. Study participants described how overwhelming the sense of emotion could be (Hayhurst et al., 2010) but also how difficult it can be to express emotion (Edvardsson & Ahlstrom, 2005), sometimes leading to further feelings of isolation and helplessness, even from professionals: "the doctor stops talking if I cry" (Leavitt et al., 1996, p. 1250). Fox & Lantz (1998) described how the stigma of mind-body illness can result in people hiding their feelings: "You feel so alone. You want to talk about it, but no one can see that you have it" (Fox & Lantz, 1998, p. 247)

The emotional impact of the tumour diagnosis was unexpected for some: "to tell you the truth, I think, once you've had it removed, you maybe think the worst is over" (Simpson et al., 2014, p. 168) and some described a sense of bewilderment at the complexity of their situation (Gurel et al., 2014). Participants described a feeling of being out of control: "I can't do anything about it" (Molassiotis et al., 2010, p. 413) and this leading to a sense of desperation as they searched for answers and understanding (Simpson et al., 2014), sometimes concluding in feelings of relief or acceptance, despite bad news (Gurel et al., 2014; Hayhurst et al., 2010)

The emotional difficulties described in this theme were both the result of and the cause of a number of the difficulties and experiences described in later themes. It became evident throughout this meta-synthesis that emotion underpinned all aspects of psychological wellbeing. Figure 1 demonstrates how the emotional state of the participants influenced and was influenced by all other themes.

Interaction with health care professionals

This theme emerged from a commonality in the ways the studies discussed the way relationships and interactions with health care professionals (HCP) can impact on

emotional wellbeing during the various stages of having a PLGBT. The idea of having knowledgeable and accessible professionals was prominent in this theme, and often mediated the fluctuations in a person's mood: "My most important resource is my endocrinologist...He has helped me through some very difficult times" (Gurel et al., 2014, p. 59). Relationships with HCPs were seen as the foundation of trust and confidence in medical care (Gurel et al., 2014), able to reduce anxiety (Hayhurst et al., 2010) and able to influence the emotional impact of brain tumour discovery and diagnosis: "It didn't seem like a big deal; there was no concern or crisis expressed by the doctors. So I did everything in a relaxed way, I was pretty happy about it." (Jagadeesh & Bernstein, 2013, p. 378). Trust was not only needed in the HCP's abilities, but also required from the HCP towards the patient (Edvardsson, Pahlson & Ahlstrom, 2006).

Alongside the discussion of the importance of this relationship with HCPs was the discussion of how difficult it can be to establish these positive relationships and the negative impact that this can have on the emotional and psychological state: "Five years it took begging people to look at me...this condition can drive someone mad, but it does not help with some of the medical professional's attitude" (Gurel et al., p. 56). Frustration in dealing with 'medical diplomats' who do not listen was evident (Fox & Lantz, 1998) and studies discussed how people can be left feeling abandoned (Edvardsson et al., 2006) and even "orphaned" (Gurel et al., 2014, p. 58) when they are unable to establish a good relationship with their HCP: "What makes me almost the angriest is that they did not take more notice. When a patient comes back time and time again complaining of the same thing, you don't just tell them to take an aspirin and go home" (Edvardsson et al., 2006, p. 419). Additionally the level of information given, or not given, by professionals played an important role in the levels of anxiety,

uncertainty and "negative forecasting": "When you're left to your own devices it's only human nature to come up with the wrong conclusions" (Cavers et al., 2013, p.1302).

Overall, this theme highlights the importance of a positive relationship between brain tumour patient and HCP, and demonstrates how this relationship can have a positive or negative impact on psychological wellbeing. Figure 1 highlights how this theme in particular fed into the importance of reassurance, support and hope, and how these themes together then influenced the wider emotional state and patterns of thinking.

The importance of reassurance, support, and hope

Six papers contributed to this theme, which encapsulated the needs of people with PLGBT to feel supported and possessed of hope for the future. Support and hope were drawn from a variety of sources, but most prominently from HCPs and family members.

In addition to those functions detailed in the above theme, HCPs performed an important role in providing reassurance, support and, crucially, hope, to people with PLGBT. People with a low grade tumour can be less likely to have the same immediate concerns about death as people with high grade tumours, making them more likely to hold on to increased hopes for a recovery: "So I just hope it doesn't start growing again" (Cavers et al., 2013, p. 1302). When HCPs do not focus on providing reassurance and emotional support, hope and positive adjustment were more difficult to achieve (Cavers et al., 2013) and this can increase the emotional turmoil experienced: "It felt like a roller coaster. There's a fear factor, a large quantity of unknown; it's like being in the middle of a mental desert and there's a sandstorm and you don't know what to do" (Jagadeesh & Bernstein, 2014).

When people are unable to find the support they needed in HCPs they may attempt to seek support independently, with this gap often being filled by family members: "...I got in touch with the community health people to see if they did have somebody that could come a couple of times a week...but they don't do short term so unless I'd looked up in the paper and got somebody private...but my family said no, they'd handle it so that's what they've done" (Cornwell et al., 2012, p. 2601). Family support covered a broad range of input, including support with managing uncertainty and anxiety, attempts to return to pre-diagnosis roles and responsibilities and overcoming stigma and discrimination (Janda, Eakin, Bailey, Walker & Troy (2005). However, family input also led people with a tumour to worry about the burden on their family member carers (Janda et al., 2005, Ownsworth, Chambers, Hawkes, Walker & Shum, 2010) and to consider their new positions in the family: "I had the classic, 'You can go back to work in a couple of months, everything will be fine'. No, the wife's the main breadwinner and she's got this disabled husband on her hands" (Ownsworth et al., 2010, p.128). In these scenarios it was all the more important that people with tumour felt supported and were able to reach out to family, HCPs and other sources, in order to maintain hope: "I managed to speak to a young lady who had just had a debulking done and she was my inspiration that everything's going to be fine" (Ownsworth et al., 2010, p. 129)

Wherever hope comes from it was a vital thread throughout this theme, and one which acted as a positive coping strategy for people with PLGBT, providing drive and motivation to live on: "Whatever happens, I'm going to live to the age of 80. I've made up my mind" (Edvardsson & Ahlstrom, 2005, p. 733)

Reassurance, support and hope were first sought from the interactions with healthcare professionals and then from wider sources such as family, as demonstrated

in Figure 1. The satisfaction with the levels of reassurance, support and hope received then went on to influence the emotional state and the ways of thinking about participants' circumstances. Likewise the emotional state and current ways of thinking (e.g. current grief over past life or stage of coming to terms) influenced how people viewed their interactions, support and subsequent hope.

Change and coming to terms

Change, and adjustment to change, was discussed in seven of the papers. Change was evident in multiple areas of a person's life including practical, social, relational and occupational, all of which resulted in frequent change in psychological and emotional wellbeing (Edvaardsson, Pahlson & Ahlstrom, 2006).

Changes to roles within family life and the emotional difficulties this brings were particularly emotive in discussions. People with a tumour found themselves increasingly unable to care for themselves or others (Leavitt, lamb & Voss (1996) and often were left with feelings of being a burden to others. These feelings were dealt with by either finding ways to increase independent activities, such as part time work (Molassiotis et al., 2010) or by masking emotional and physical difficulties: "Learn to be guarded over your emotions and your tiredness and everything like that (.) erm (.) so you feel loathed to actually speak out about how you are feeling" (Simpson et al., 2014, p.170)

In addition to influence from external change factors, psychological change was also stimulated by internal thought processes such as shifts in priorities and perspectives (Cornwell, Dicks, Fleming, Haines & Olson, 2012). The studies demonstrated an increasingly fluid and turbulent nature within the ongoing psychological wellbeing of people with a PLGBT. In reality, these internal and

external change processes are likely to be interrelated and to have significant effect on one another.

Lastly, participants in the studies described the process of coming to terms with all of the changes present in their lives. For some this was a difficult process, and involved emotional distress and feeling of isolation, while others struggled to find purpose in their lives: "...I don't feel like I've got any purpose. I don't know where I'm going. I want to work but...Yeah I sort of feel quite lost really and am drifting every day." (Cornwell et al., 2012, p. 2605). Some participants described finally coming to terms as both acceptance and using change to help coping. For example, by finding new ways to think about work or recreational activities: "So maybe I won't be 100% OK in my left side, but it doesn't matter. Life goes on. Things are the way they are, there's no point getting hung up about it" (Edvaardsson & Ahlstrom, 2005, p. 733)

Looking back vs. looking forward

This theme utilised themes from six papers, and comprised two distinct but connected elements of the psychological processes involved in adjusting to life during and after PLGBT. The idea of looking back to life before the tumour symptoms and diagnosis and comparing that to life now are common themes in the data. This is partnered by those times when a person looks forward towards the future, including positive attempts to make life progress and more anxious worry about things to come.

Fox & Lantz (1998) referred to the "invasive disease of the self" (p.247), which demonstrates the extent to which people with a tumour can negatively evaluate the changes to their sense of self. Reflection and comparison to the past can create a sense of having lost the past self: "I think I remember who I used to be, but the further it gets away the harder it gets..." (Fox & Lantz, 1998, p. 247). This reflection on the

past can be triggered by the slow realisation over time that difficulties are permanent (Leavitt et al., 1996).

In the early stages of tumour experience, participants discuss a "fighting spirit" (Molassiotis et al., 2010, p. 414) when looking forward, but over time this is lost, and replaced by a loss of hope regarding continuing progress and grief over what has been lost .

When people look back on their experiences there can be a process of hypothesising over what could have been if circumstances had been different, sometimes leading to attributions of blame: "He refused to order any blood tests. Now if he had ordered them then, it would have been a very small tumour at that stage...there is a lot of anger at that" (Ownsworth et al., 2010, p. 130)

Whilst some focus on the past in this way, others look forward to the future with both anxiety and positivity, depending on the person and the circumstances. It may also be that this is a staged process where looking back is a step towards being able to look forward. Some people express a fear of the future (Simpson et al., 2014) and an uncertainty about what will come next for them, leading them to question what the whole process will mean for them (Ownsworth et al., 2010).

For some, looking to the future continues to hold a hope for full recovery: "I would just like to feel me again, and not have these stupid emotions...I just want to feel normal again, back to the normal me." (Simpson et al., 2014, p. 172). For others this is more of a recognition that they will need to learn to cope with their difficulties (Leavitt et al., 1998). This recognition of the need to adjust leads some to make practical adjustments in order to support their own psychological wellbeing. For example, by recognising that some tasks and responsibilities are now beyond them, a

person can begin to establish new goals which are achievable and give a sense of positive attainment (Edvardsson & Ahlstrom, 2005).

Lastly, within this theme there was an examination of how people perceived their quality of life in comparison to the past, and how it would be going forward. Two main points came from this, firstly that for some this was felt as a loss of past quality of life, but a recognition of the importance in "living life to the fullest" (Fox & Lantz, 1998, p. 248) going forward. Others felt that their quality of life had not been impaired to any significant degree by their tumour, but this then became a focus of anxiety for them. For example the fear that intervention (such as surgery) would cause neurological deficits where previously none existed: "If it affects my quality of life then it [surgery] is not worth it...if something does come we'll deal with it then" (Hayhurst et al., 2011, p. 259)

Re-evaluating

This theme was formed from those times when study participants were able to experience the situations, difficulties and psychological changes described in the themes above and come to re-evaluate their situation with some positive reflection points. This usually represented a late stage of thought processes from participants in studies, and the ability to find positives was not easy or even achievable for some.

Edvardsson & Ahlstrom (2005) described this type of positive reflection as a process of re-evaluation which acts as a coping mechanism for people with a tumour, for example participants reported feeling positive about losing weight, or even focussed on ways they were special and unique, such as their tumour being unusual (Edvardsson et al., 2006). Additionally study participants sometimes felt fortunate for having accessed healthcare, or having their condition discovered: "Once they got these images, it scarcely took more than a week. Then I got word that I had to get

moving. It happened very quickly then, and that was good!" (Edvardsson et al., 2006, p. 419).

Lastly, there was a tendency to come to place more value on the ordinary aspects of their lives, and on life itself: "So it's a changing person if you like, so every time I go out for a walk I think oh I'm here, you know, even the simplest things in life you think this is great" (Molassiotis et al., 2010, p.413). A sense of gratitude for still being alive (Edvardsson & Ahlstrom, 2005) was an important factor in helping people to improve their psychological wellbeing, and conversely an increased level of psychological wellbeing overall was linked to a more positive outlook on life (Molassiotis et al., 2010).

The three themes of: looking back vs. looking forward, change and coming to terms and re-evaluating form a triad of thinking processes which occur for people with a PLGBT, each influencing the others. Collectively these processes then go on to influence the emotional state of the person and perceptions of situations such as HCP interactions and support. Conversely, these thinking process are also influenced by these other factors. This interaction is demonstrated in Figure 1.

Discussion

This meta-synthesis drew together qualitative findings regarding the psychological experience of people with a primary low grade brain tumour. Whilst the majority of the papers used had a broader scope than this, such as overall quality of life, the meta-synthesis process allowed for the extraction of only that data which was relevant to psychological and emotional experiences. The review aimed to elucidate information regarding the psychological experience of having a PLGBT and to highlight areas for potential support, and it has achieved this.

The results regarding the emotions involved in the experience of PLGBT share a number of similar results found in qualitative and quantitative research into high grade brain tumour (Huang et al., 2001; Moore et al., 2013; Sterckx et al., 2013), suggesting that any assumption of low grade tumour experience being less emotionally and psychologically taxing than high grade may be flawed. Experiences are characterised by strong emotions of anxiety, depression, shock and difficulties adjusting. The synthesis demonstrated a particularly strong tendency for fluctuation in emotion for people with PLGBT, particularly between fears and anxieties for the future and attempts to reclaim a normal life. This variable pattern is perhaps more prominently seen here than in high grade research, perhaps due to difference between potential for death because of the tumour, as opposed to a certainty in most high grade cases.

The suggestion that having a tumour can be an "invasive disease of the self" (Fox & Lantz, 1998, p. 247) may suggest that for some, the person they are when they receive a diagnosis may be very different to the person they are later in the experience. Identity theory is a useful vehicle for considering these issues, for example the humanist approach to self-concept, which includes self image, self esteem and the ideal self (Rogers, 1959). In this model, all three aspects of the self are potentially affected when the core self, in psychological and neurological domains, is changed via PLGBT experience. This area of identity has also been more extensively considered in traumatic brain injury research (Carroll & Coetzer, 2011) and other neurological conditions, and this may be useful in helping to draw comparisons with identity change in future research and in considering service model changes. When drawn together, the information regarding identity change presented here suggests a cycle of change which may result in significant changes across psychological,

personality, lifestyle and behaviour domains. Full exploration of this cycle or model for change is beyond the scope of this review; however further exploration may be beneficial in a future project.

Identity change and psychological and emotional changes associated with PLGBT are part of the recovery process commonly seen in neuropsychological practice. Neuropsychological recovery theory allows clinicians to help people begin to process their experiences and move towards some form of recovery. For example the Y-shaped process model of rehabilitation (Wilson, Gracey, Evans & Bateman, 2009) aims to help people with neuropsychological presentation reduce the discrepancy between the past self and the current self, thus helping the person to adapt to the reality of their current situation. The synthesis here provides strong indication that this form of identity linked rehabilitation model and subsequent intervention are key in the continuing psychological wellbeing of people with PLGBT.

The capacity PLGBT patients to experience significant change over time in provides both a point of caution and of hope. By helping people to manage the negative changes carefully, and by promoting positive change and adjustment, we can help to prevent declines in psychological wellbeing and promote positive focus on the future.

Strengths and limitations

This synthesis is the first to draw together available qualitative research regarding people with a primary low grade brain tumour. As such it has a particular strength in being novel and potentially useful for clinical practice (as discussed later). The exploratory nature of this kind of synthesis provides a valuable contribution to the understanding of brain tumour experience. National guidelines clearly outline the psychological needs of people being treated for a primary brain tumour, but place

much of the emphasis for psychological care on support services and neuropsychological services (National Institute for Health and Care Excellence, 2006). This synthesis provides psychological knowledge and understanding which can be applied to help broaden the medical understanding of low grade brain tumours as a health condition. In this way a more holistic understanding of people with a brain tumour can be gained by all professionals, and used to work positively with people's psychological difficulties.

The specific methodological flaws discussed in the quality appraisal section of this review, whilst not enough to justify the removal of any papers, may have influenced the overall quality of this review. For example, Yardley (2000) explains that consideration of the relationship between researcher and participant is an important part of methodological quality and research ethics. Since this was present in only four of the papers used, assessing the overall quality was made more difficult and thus the final results cannot reflect these issues. However, it is important to recognise that the methodological quality reported for these papers is only a reflection of reporting quality, not necessarily actual flaws in the methods or ethics of the studies.

This synthesis may have been limited by the search terms used, in that when attempting to start from a position of examining all available qualitative research and then applying inclusion and exclusion criteria, it is possible that some studies are not captured. Broad search terms were used here to attempt to capture as much qualitative research relating to PLGBT as possible, however it is difficult to say with certainty that all available information was captured, both in regards to variations of qualitative methodology used and PLGBT morphology.

When considering psychological and emotional wellbeing it is also important to consider the authorship and intended focus of the papers utilised in this synthesis. Papers conducted by non-psychological/psychiatric professionals, could be argued as lacking expertise to conduct research in this area. Additionally where papers had a wider focus than just the psychological impact of PLGBT (which was the majority), it is questionable as to whether their research design, intent and thus questioning, would have led to the most accurate and comprehensive responses for addressing the synthesis question. Despite this possible limitation, studies utilised do represent at least some aspect of experience for people with a PLGBT and findings are representative of the available information.

Lastly, the studies included here spanned a large time period, with the earliest paper published in 1996 and the latest in 2014, with the majority of the papers (9/14) from the last five years. The experience of people with a PLGBT from 19 years ago to the present day may be significantly different, particularly given current advances in treatment protocols (Capatina et al., 2013). This may mean that the results from studies published prior to the last few years may not be fully representative of current experience, and therefore could have skewed results. However, given the emotive nature of brain tumour diagnosis and treatment, the potential for psychological and emotional difficulties remains pertinent, regardless of advances in treatment. It is possible that as treatment and outcomes change, there will be concurrent changes in the way that emotional and psychological issues are experienced and discussed, and this is worthy of attention. Additionally, the evolutionary and sometimes revolutionary nature of medical intervention may cause both positive and negative psychological phenomena for people with brain tumour. The hope for new and better treatments and support could be seen as a source of anxiety as people wait for help

which may never come, or as a source of hope as they look towards an uncertain future and complex recovery process.

Clinical implications and recommendations

This research highlights the need for attention to be paid to the psychological wellbeing of people with a PLGBT. Results stress the importance of the psychological and emotional process of change, adjustment and coping to all aspects of a person's life and the need for psychological support occurs in all areas, meaning that it is the responsibility of all professionals, from the point of first contact with services, to be able to provide some level of psychological support. The most positive psychological experiences were drawn from experiences where medical staff were able to provide engaged psychological care and understanding during the early stages of diagnosis and treatment, rather than exclusively focussing on physical health needs. This suggests that it may be helpful for those in clinical practice to more fully explore what kinds of psychological support needs their patients have and how these could be best met by services. The process of audit and departmental research could be very helpful in establishing these needs. Based on this it may be that there are implementable changes that could be made (e.g. providing clearer information at different stages). It could also result in some areas of psychological support which require more specialist input from psychology and neuropsychology professionals. This could be achieved in a number of ways, for example clinical psychologists and neuropsychologists could facilitate training and education sessions for other professions around the importance of psychological care in this population and provide consultation for more complex cases of psychological need.

These results also suggest a need for flexibility in the approach taken to the treatment, psychological care and support of people with a PLGBT. People will likely

be subject to a range of emotions towards their treatment and care at different points during their experience. This means that professionals will need to be willing to explore options and reasons for choices carefully and sensitively. The changes in personality and therefore life choices discussed above mean clinicians will need to be able to adapt to their patients' changing needs. This need for flexibility may be particularly important when considering the needs of people with PLGBT against those with high grade tumours. The results have shown that people with PLGBT may be subject to a more fluctuating set of emotions and thought processes, and this may require clinicians to be sensitive to subtle changes in psychological support needs. By doing this clinicians can help people with PLGBT to recognise the patterns in their own psychological wellbeing and behaviour and therefore help them to be more prepared. Patient need here could be reasonably easily investigated by services and may be open to small but important changes which utilise existing models of support. For example some organisations operate a buddy system, whereby PLGBT patients are paired with someone else in a similar situation. With some increased focus on the psychological change process, patients could learn to recognise warning signs which require further input. For more complex input, clinical psychology and neuropsychology services may be ideally placed to utilise formulation based approaches to help both professionals and patients to understand these dynamic needs. MDT case formulation and joint work may be an ideal vehicle for establishing a shared and comprehensive understanding of the individual.

People with a PLGBT may require significant support to try to find the ongoing positive aspects to their lives, and even to tumour diagnosis and treatment. This again needs to be the responsibility of all professionals, but perhaps more significantly a point for consideration for psychological services. This synthesis

demonstrated that, in time, people can often find positive elements of their lives to motivate them, and that sometimes even relatively small positives, can help to improve psychological wellbeing.

Lastly, it may be useful to take the information produced from this synthesis and use it to construct, or adapt existing, information leaflets for people with PLGBT. This would be particularly helpful in preparing people with a recent diagnosis of PLGBT in regards to what psychological and emotional difficulties they might experience, and help to validate experiences and encourage discussion from people with PLGBT.

Recommendations for future research

A number of areas for potential future research have been highlighted by both the results of this synthesis and from its possible limitations. The relatively low number of studies focussed solely on the experience of PLGBT and the questions raised regarding paper authorship in this area, suggest the need for more general qualitative research in this area, particularly studies which focus exclusively on psychological wellbeing. The synthesis highlights the myriad of emotional and psychological difficulties faced by people with PLGBT, and these warrant clear and targeted research. Additionally, if this type of research begins to emerge, it would be useful to conduct a further synthesis which utilises only recent research with PLGBT, and potentially only research focussed on the psychological experience. In this way a potentially purer synthesis could be conducted. Lastly results here suggest it would be promising to research an interactional model of change and identity within PLGBT, with consideration of the themes and issues arising from this synthesis.

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Table 1 - Inclusion and Exclusion Criteria

Inclusion Criteria	Rationale
1. Must utilise qualitative methodology as the main approach to research	The purpose of this review is to systematically examine qualitative literature, therefore only papers utilising a qualitative methodology will be included.
2. Must have conducted research with adults with a low grade brain tumour	This review is concerned with examining literature for adults with a low grade brain tumour. The studies must include the direct experience of the adult with a tumour (not just relatives or carers, nor child studies).
3. Must discuss, at least in part, the topic of psychological wellbeing or the emotional impact of having a brain tumour	This review is concerned with the emotional effects of being a person with a brain tumour. Therefore papers must include these issues.
4. Published in a peer reviewed journal	This allowed for a basic level of quality assurance within the papers.
5. Published in English.	No resource was available for the translation of papers not published in English.
Exclusion Criteria	**Rationale**
1. Papers that focus on an single event such as a particular episode of treatment or surgery	As the review is interested in the broad psychological and emotional consequences of having a brain tumour, research that focuses on a specific event, particularly those that could produce extraordinary levels of emotion may skew results.
2. Papers that are only loosely or tangentially related to the topic	Some papers could be loosely defined as relating to psychological wellbeing, such as issues of spirituality. However if these have been examined in isolation from the broader experience, they may confuse results.
3. Papers that examined mixed types of cancer or brain metastases	This review is concerned only with the specific issues related to people with a brain tumour. Any studies which include cancer in other locations, or cancer originating elsewhere may confuse results.

Table 2 – Characteristics of papers included in the meta-synthesis

Study No	Authors, date & country of origin	Recruitment method and location	Sample size & participant details	Aim	Data collection method &timing	Data Analysis	Epistemology
1	Cavers, Hacking, Erridge, Morris, Kendall & Murray (2013) UK	Purposive sample recruited through neuro-surgical centre	26 Participants 14 men, 12 women 21-76 years Range of tumour types	To explore patients and families emotional experience of illness, information and support needs and their impact on adjustment.	Series participant guided interviews 80 Interviews over immediate, 1 month, 2 month and 6 month intervals.	Grounded theory	Realist
2	Cavers, Hacking, Erridge, Kendall, Morris & Murray (2012) UK	Purposive sample recruited through neuro-surgical centre	26 Participants 14 men, 12 women 21-76 years Range of tumour types	To explore the trajectories of physical, social, psychological and existential wellbeing during brain tumour progression.	Series participant guided interviews 80 Interviews over immediate, 1 month, 2 month and 6 month intervals.	Grounded theory	Realist
3	Cornwell, Dicks, Fleming, Haines & Olson (2012) Australia	Purposive and convenience sampling from brain tumour clinic	9 Participants 6 men, 3 women 36-70 years Non Malignant brain tumour	To understand the early post-discharge support services and care requirements of individuals with brain tumour.	Semi-structured interviews at 2 weeks and 3 months post surgery.	Content analysis	Realist
4	Edvardsson & Ahlstrom (2005) Sweden	Convenience Sample recruited through a regional cancer register	39 Participants 27 men, 12 women 21-79 years Low grade glioma	To describe perceived illness related problems and coping strategies in adults with low grade glioma	Single Semi-structured interview of 1-2 hours.	Content analysis	Realist

5	Edvardsson, Pahlson & Ahlstrom (2006) Sweden	Convenience Sample recruited through a regional oncology centre	27 Participants 18 men, 9 women 23-79 years Low grade glioma	To describe adults' experience of falling ill and being diagnosed with low grade glioma	Semi-structured interviews	Content analysis	Realist
6	Fox & Lantz (1998) USA	Convenience sample from neuro-oncology clinic	23 Participants 30-70 years Varied tumour types	To explore brain tumour patients' experience of quality of life	Individual and group semi-structured interviews	Thematic analysis	
7	Gurel, Bruening, Rhodes & Lomax (2014) USA	Online and advertisement recruitment across various sites	19 Participants 7 men, 12 women Mean age 41 Acromegaly resulting from pituitary tumour	To understand the impact of acromegaly on patients' lives from their own perspectives	Individual and group interviews	Qualitative categorisation of responses	
8	Hayhurst, Mendelsohn & Bernstein (2010) Canada	Convenience sample recruited from authors client list	24 Participants 21-82 years Low Grade Glioma	To explore the impact of low grade glioma	Semi-structured interviews	Grounded theory	Realist
9	Jagadeesh & Bernstein (2013) Canada	Convenience sample based on authors patients	32 participants 18-76 years 8 men, 24 women Incidental tumour	To better understand patients' experience of incidental brain tumour findings	Semi-structured interviews	Thematic analysis	

10	Janda, Eakin, Bailey, Walker & Troy (2005) Australia	Convenience sample from local brain tumour support service	36 participants 11 men, 25 women 27-83 years Various tumour types	To explore the experience of support services of patients with a brain tumour	Focus groups and structured interviews	Modified, structured thematic analysis	
11	Leavitt, Lamb & Voss (1996) USA	Convenience sample of existing support group	78 participants 36 men, 42 women Various tumour types	To describe the experiences and needs of brain tumour patients as established in support groups	Analysis of existing recording of support groups over 6 months	Grounded theory	Realist
12	Molassiotis, Wilson, Brunton, Chaudhary, Gattamaneni & McBain (2010) UK	Convenience sample from specialist oncology centre	9 participants (with decrease over time) 33-73 years 7 men, 2 women Mixed tumour types	To understand the symptom experience and impact of symptoms in daily life of brain tumour patients	Semi-structured interviews	Content/ framework analysis	Realist
13	Ownsworth, Chambers, Hawkes, Walker & Shum (2010) Australia	Purposive sample from neuro-surgical practice	18 participants 10 men, 8 women 28-71 years Mixed tumour types	To investigate the personal and social process of adjustment in brain tumour patients	Semi-structured interviews	Open and selective coding following by synthesis of data.	
14	Simpson, Heath & Wall (2014) UK	Convenience sample recruited through local health care professional	8 participants 5 men, 3 women 38-69 years Pituitary tumour	To explore the illness narratives of people with a pituitary tumour	Narrative, open interviews	Narrative analysis	

Table 3 – Appraisal of included studies using the Critical Appraisal Skills programme tool (CASP, 2013)

No	Authors	Clear Aims	Qualitative methodology appropriate	Appropriate research design	Appropriate recruitment strategy	Appropriate data collection	Relationship between researcher and participants considered	Ethical issues considered	Rigorous data analysis	Clear statement of findings	Value of research
1	Cavers, Hacking, Erridge, Morris, Kendall & Murray (2013)	**Y**	**Y**	**C**	**Y**	**C**	**Y**	**C**	**Y**	**Y**	**Y**
2	Cavers, Hacking, Erridge, Kendall, Morris & Murray (2012)	**Y**	**Y**	**C**	**Y**	**Y**	**N**	**C**	**Y**	**Y**	**C**
3	Cornwell, Dicks, Fleming, Haines & Olson (2012)	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
4	Edvardsson & Ahlstrom (2005)	**Y**	**Y**	**C**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**

5	Edvardsson, Pahlson & Ahlstrom (2006)	**Y**	**Y**	**C**	**Y**	**Y**	**C**	**Y**	**Y**	**Y**	**Y**
6	Fox & Lantz (1998)	**Y**	**Y**	**C**	**Y**	**Y**	**N**	**C**	**Y**	**Y**	**Y**
7	Gurel, Bruening, Rhodes & Lomax (2014)	**Y**	**Y**	**C**	**Y**	**Y**	**N**	**Y**	**N**	**Y**	**Y**
8	Hayhurst, Mendelsohn & Bernstein (2010)	**Y**	**Y**	**C**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**
9	Jagadeesh & Bernstein (2013)	**Y**	**Y**	**C**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**
10	Janda, Eakin, Bailey, Walker & Troy (2005)	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**
11	Leavitt, Lamb & Voss (1996)	**Y**	**Y**	**C**	**Y**	**Y**	**N**	**C**	**Y**	**Y**	**Y**

12	Molassiotis, Wilson, Brunton, Chaudhary, Gattamaneni & McBain (2010)	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
13	Ownsworth, Chambers, Hawkes, Walker & Shum (2010)	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**
14	Simpson, Heath & Wall (2014)	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**

Y = Yes
N= No
C = Can't tell

Table 4 – Summary of study findings included in the Meta-Synthesis

No	Authors	Main Findings
1	Cavers, Hacking, Erridge, Morris, Kendall & Murray (2013)	Theme 1: Distress anxiety and worry Theme 2: Variations and timing of information preferences Theme 2: The importance of reassurance, support and hope
2	Cavers, Hacking, Erridge, Kendall, Morris & Murray (2012)	Theme 1: Dynamic psychological trajectory Theme 2: Dynamic existential trajectory
3	Cornwell, Dicks, Fleming, Haines & Olson (2012)	Theme 1: Unmet support needs Theme 2: Role changes Theme 3: Relationship changes Theme 4: Coming to terms with the reality of brain tumour Theme 5: Changes in priorities and perspectives
4	Edvardsson & Ahlstrom (2005)	Theme 1: Memory & cognition Theme 2: Emotional states Theme 3: Refraining from and avoiding Theme 4: Re-evaluating Theme 5: Expressing emotions and thoughts Theme 6: Struggling Theme 7: Maintaining hope Theme 8: Accepting
5	Edvardsson, Pahlson & Ahlstrom (2006)	Theme 1: Rapid illness onset Theme 2: Prolonged illness onset Theme 3: Negative healthcare situations Theme 4: Positive healthcare situations Theme 5: Negative life-situations consequences Theme 6: Positive life-situation consequences

6	Fox & Lantz (1998)	Theme 1: The stigma of mind-body illness Theme 2: An invasive disease of the self Theme 3: Dealing with the medical diplomats Theme 4: Quality of life: No substitute for living
7	Gurel, Bruening, Rhodes & Lomax (2014)	Theme 1: Path to diagnosis Theme 2: Impact of diagnosis Theme 3: Taking back control / patient empowerment Theme 4: Interaction with HCP's
8	Hayhurst, Mendelsohn & Bernstein (2010)	Theme 1: Initial devastation followed by acceptance and low anxiety Theme 2: Absence of symptoms mitigates anxiety concerning progression Theme 3: Anxiety is reduced by trust in the physician Theme 4: Quality of life is not affected by the diagnosis, as fear of morbidity from intervention is greater than fear of uncertainty
9	Jagadeesh & Bernstein (2013)	Theme 1: A patient's emotional status over the incidental finding is largely dependent on how they were informed of the news Theme 2: Breaking worrisome news is best done in person… but if a patient has a good relationship with their doctor then telephone communication is acceptable Theme 3: Waiting for neurosurgical consultation is a stressful time without adequate support
10	Janda, Eakin, Bailey, Walker & Troy (2005)	Theme 1: Need for support, but unable to name exactly what kind of support Theme 2: Need for information and coping with uncertainty Theme 3: Need for support to return to pre-treatment responsibilities or prepare for long-term care Theme 4: Need for support to overcome stigma/discrimination
11	Leavitt, Lamb & Voss (1996)	Theme 1: The long haul Theme 2: Family life changes Theme 3: Telling the story

12	Molassiotis, Wilson, Brunton, Chaudhary, Gattamaneni & McBain (2010)	Theme 1: Neurocognitive symptoms Theme 2: Social restrictions Theme 3: Renewed perspective in life as a result of heightened awareness of mortality Theme 4:Fatalism Theme 5: Social contacts Theme 6: expectations
13	Ownsworth, Chambers, Hawkes, Walker & Shum (2010)	Theme 1: What is going on here? Theme 2: What does this mean for me Theme 3: How things will be vs how things actually were Theme 4: What could have been? Theme 5: What does the future hold?
14	Simpson, Heath & Wall (2014)	Theme 1: Symptoms and diagnosis Theme 2: Treatment, hospitalisation and radiotherapy Theme 3: Recovery and the impact of the tumour Theme 4: Coping with a pituitary tumour Theme 5: On-going symptoms and the future

Table 5 – Meta-synthesis themes and constituent original study themes

Author	Emotional States	Re-evaluating	Interaction with health care professionals	Change and Coming to Terms	The importance of reassurance, support and hope	Looking Back vs. Looking Forward
Cavers, Hacking, Erridge, Morris, Kendall & Murray (2013)	Distress anxiety and worry		Variations and timing of information preferences		The importance of reassurance, support and hope	
Cavers, Hacking, Erridge, Kendall, Morris & Murray (2012)	Dynamic psychological trajectory (sub theme 1: anxiety and stress during diagnosis. Sub theme 2: Anxiety lessening through treatment period. Sub theme 3: Anxiety about life expectancy and loss of control, uncertainty)			Dynamic psychological trajectory Dynamic existential trajectory		
Cornwell, Dicks, Fleming,				Coming to terms with the reality of brain tumour	Unmet support needs	

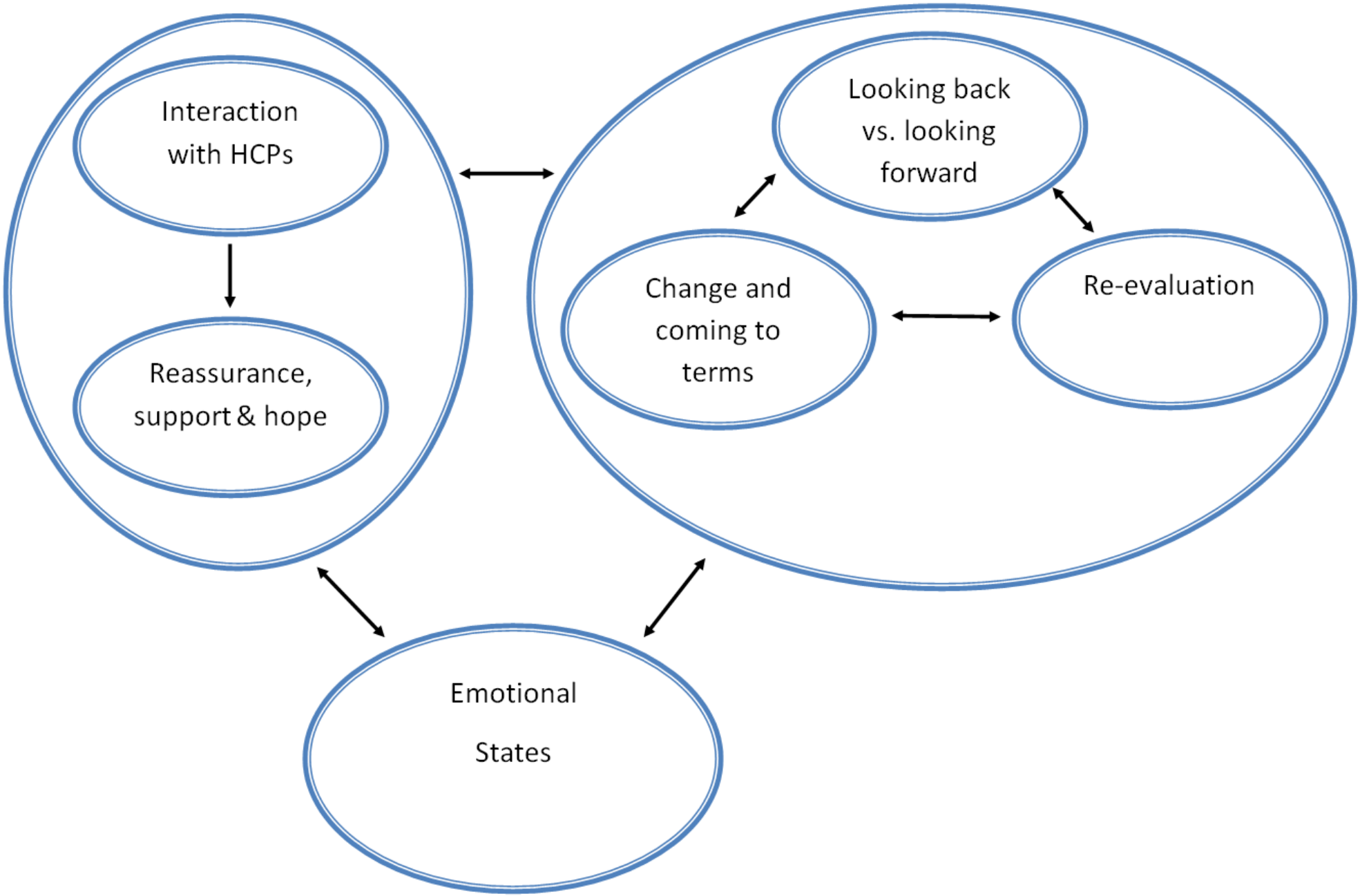
Haines & Olson (2012)				Role changes Relationship changes Changes in priorities and perspectives		
Edvardsson & Ahlstrom (2005)	Memory & cognition Emotional states Expressing emotions and thoughts	Re-evaluating		Accepting	Maintaining hope	Refraining from and avoiding Struggling
Edvardsson, Pahlson & Ahlstrom (2006)	Rapid illness onset Prolonged illness onset	Positive healthcare situations Positive life-situation consequences	Negative healthcare situations	Negative life-situations consequences		
Fox & Lantz (1998)	The stigma of mind-body illness		Dealing with the medical diplomats			An invasive disease of the self Quality of life: No substitute for living

Gurel, Bruening, Rhodes & Lomax (2014)	Path to diagnosis Impact of diagnosis Taking back control / patient empowerment	Interaction with HCP's		
Hayhurst, Mendelsohn & Bernstein (2010)	Initial devastation followed by acceptance and low anxiety	Anxiety is reduced by trust in the physician Absence of symptoms mitigates anxiety concerning progression		Quality of life is not affected by the diagnosis, as fear of morbidity from intervention is greater than fear of uncertainty
Jagadeesh & Bernstein (2013)		A patient's emotional status over the incidental finding is largely dependent on how they were informed of the news Breaking worrisome news is best done in person… but if a patient has a good relationship with their doctor then telephone communication is acceptable	Waiting for neurosurgical consultation is a stressful time without adequate support	

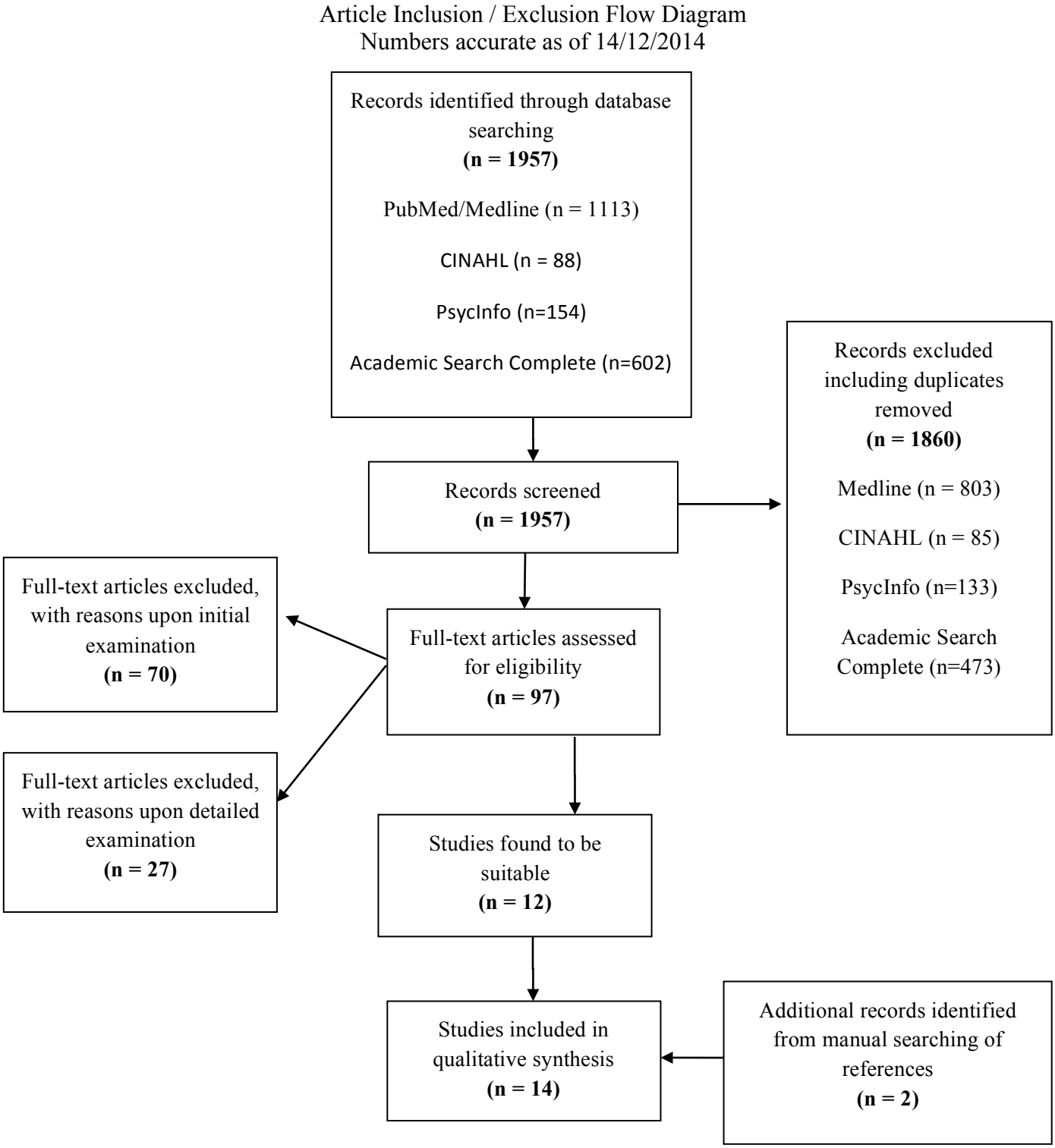
Janda, Eakin, Bailey, Walker & Troy (2005)				Need for support, but unable to name exactly what kind of support Need for support to overcome stigma/discrimination Need for information and coping with uncertainty Need for support to return to pre-treatment responsibilities or prepare for long-term care	
Leavitt, Lamb & Voss (1996)	Telling the story		Family life changes		The long haul
Molassiotis, Wilson, Brunton, Chaudhary, Gattamaneni & McBain (2010)	Neurocognitive symptoms Social restrictions Fatalism	Renewed perspective in life as a result of heightened awareness of mortality	Social contacts		expectations

Ownsworth, Chambers, Hawkes, Walker & Shum (2010)	What is going on here?			How things will be vs how things actually were	What does this mean for me What could have been? What does the future hold?
Simpson, Heath & Wall (2014)	Symptoms and diagnosis Treatment, hospitalisation and radiotherapy Recovery and the impact of the tumour		Coping with a pituitary tumour		On-going symptoms and the future

Figure 1 – Map of meta-synthesis themes and interactions



Appendix 1-A – Search Flow Diagram and Inclusion / Exclusion Detail



The initial screen (removing 1860 studies) was conducted using the inclusion criteria and subsequent removals were a combination of the inclusion and exclusion criteria. During the initial screen the vast majority of papers were removed as they were not qualitative studies and a small number were removed as they were focussed solely on work with children. The peer review and English language

inclusion criteria were already in place as part of the search criteria for each database. Following this an initial sift of 97 full text articles was done to assess for suitability, the majority of those excluded here met exclusion criteria of either focussed on a single treatment event such as surgery or being studies of brain metastases. Detailed examination of full text articles led to a number of exclusions based on the paper either not meeting the inclusion criteria of discussing psychological or emotional impact (for example being entirely based on the financial impact) or being only tangentially related (for example being focussed only on spirituality). Those considered loosely or tangentially related were considered in detail, to see if part of their findings could be included (as was done with some articles which include mixed social and psychological elements), however in a small number of cases this was not possible and thus the articles were excluded.

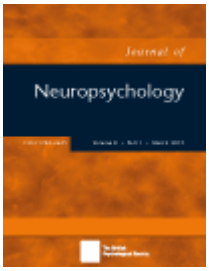
Appendix 1-B – Full Search Terms

The search terms used for a final free text search were as follows:

qualitative OR "focus group" OR "IPA" OR "interpretative phenomenological analysis" OR "grounded theory" OR narrative OR "discourse analysis" OR "thematic analysis" OR "content analysis" OR Ethnograph OR Phenomenolog* OR Hermeneutic AND brain tumour OR pituitary OR brain cancer OR brain neoplasm OR intracranial neoplasm OR Acoustic neuroma OR Adenoma OR Astrocytoma OR Chondroma OR Chondrosarcoma OR Chordoma OR Craniopharyngioma OR Ependymoma OR Esthesioneuroblastoma OR Glioma OR Ependymoma OR Glioblastoma OR Hemangiopericytoma OR Meningioma OR Neurofibroma OR neuroblastoma OR Oligodendroglioma OR Osteoma OR Pituitary tumor OR "Rathke's cleft cyst" OR Rhabdomyosarcoma OR "Skull base tumour" OR "vestibular schwannoma"*

Appendix 1-C – Author guidelines for chosen publication journal

Journal of Neuropsychology



Edited By: Stephen Jackson

Impact Factor: 3.818

ISI Journal Citation Reports © Ranking: 2013: 7/83 (Psychology Experimental); 14/74 (Psychology)

Online ISSN: 1748-6653

Author Guidelines

The Journal of Neuropsychology publishes theory-driven patient studies. The central brief is to learn more from patients with brain dysfunctions to gain a better understanding of brain-behaviour relationships and to help future patients. Important developments in neuropsychology will follow from a multidisciplinary approach embracing neighbouring fields such as developmental psychology, neurology, psychiatry, physiology, endocrinology, pharmacology and imaging science. The journal publishes group and case studies addressing fundamental issues concerning the cognitive architecture of the brain. In addition, the journal includes theory-driven studies regarding the epidemiology of specific deficits, new assessment tools, and the evaluation of treatment regimes.

The journal is committed to a fast and efficient turn-around of papers, aiming to complete reviewing in under 90 days. Submissions are processed via a web-based system and reviewers are required to complete their referee report within 28 days.

Papers will be evaluated by the Editorial Board and referees in terms of scientific merit, readability, and interest to a general readership.

1. Quality Control

The content, format, quality and ambition of the JNP as a major outlet for theory-driven neuropsychological studies is under constant review by the Consulting Editors:

• Kenneth M. Heilman (University of Florida College of Medicine, Gainesville, USA)

• Donald T. Stuss (Rotman Research Institute, Baycrest, University of Toronto, Canada)

• Giuseppe Vallar (University of Milan-Bicocca, Italy)

• Elizabeth Warrington (National Hospital for Neurology and Neurosurgery, London, UK)

2. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

3. Paper formats and length

Research papers are full-length reports of original scientific investigations. Papers should normally be no more than 6000 words excluding abstract (maximum 250 words) and references. Multiple citations for a single point are usually duplicative and authors are urged to cite the best reference. The Editor retains discretion to publish longer papers.

Theoretical or review articles are full-length reviews of, or opinion statements regarding, the literature in a specific scientific area. They need not be exhaustive but should give an interpretation of the state of research in a given field. They should normally be no more than 4000 words excluding abstract (maximum is 250 words) and references. The number of references should not exceed 40-45. Multiple citations for a single point are usually duplicative and authors are urged to cite the best reference. The Editor retains discretion to publish longer papers.

Brief communications are short reports of original research or case reports. They contain no more than 1500 words excluding abstract (maximum is 80 words), references, a total of up to three tables or figures, and no more than 10 references.

Fast-track papers are timely and relevant reports that, to the discretion of the Editor, are included in the issue following acceptance. Authors may ask that their submitted manuscripts are considered for fast-track.

Commentaries and rejoinders are short reactions to publications in JNP followed by an invited rejoinder from the original authors.

Special issues may be proposed to the Editor. The proposal should include a short description of the topic and a number of (possible) contributors. The same quality criteria apply as for other submissions.

4. Submission and reviewing

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5. Manuscript requirements

• Contributions must be typed in double spacing with wide margins. All sheets must be numbered.

• Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. A template can be downloaded here.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript with their approximate locations indicated in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi.

• All articles should be preceded by an Abstract (see point 3 for guidelines), giving a concise statement of the intention, results or conclusions of the article.

• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide DOI numbers where possible for journal articles.

• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

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At the editors' discretion, colour figures can be provided for use in the journal. Good quality photographs will be considered for inclusion where they add substantially to the argument, to a maximum of three per article. These can be supplied electronically as TIF files scanned to at least 300dpi. If they are not printed in colour, then they can be reproduced in colour online and black and white in print.

9. Pre-submission English-language editing

Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English. A list of independent suppliers of editing services can be found at http://authorservices.wiley.com/bauthor/english_language.asp. All services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication.

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final corrections have been incorporated. Because they are in final form, no changes can be made after online publication. The nature of Early View articles means that they do not yet have volume, issue or page numbers, so they cannot be cited in the traditional way. They are cited using their Digital Object Identifier (DOI) with no volume and issue or pagination information. E.g., Jones, A.B. (2010). Human rights Issues. *Human Rights Journal*. Advance online publication. doi:10.1111/j.1467-9299.2010.00300.x

Further information about the process of peer review and production can be found in this document. What happens to my paper?

Section Two: Research Paper

How do People with a Pituitary Tumour Experience Cognitive Difficulties and Neuropsychological Testing?

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How do People with a Pituitary Tumour Experience Cognitive Difficulties and Neuropsychological Testing?

Abstract

Pituitary tumours make up around 10% of brain tumour diagnoses in the UK. The condition itself alongside treatment can have a significant impact, including on cognitive function and psychological wellbeing, often resulting in an impaired quality of life for the individual and their family / social networks. Cognitive function makes up only part of most quality of life research, and the experience of neuropsychological testing for these difficulties is particularly under-researched. This study examines qualitatively the experience of people with a history of pituitary tumour, focussing on cognitive difficulties and subsequent neuropsychological testing. Seven semi-structured interviews were conducted and analysed using Interpretative Phenomenological Analysis. Six final themes emerged: (1) My brain just is not working; (2) Invisible but debilitating; (3) I thought I would be cured, more support and understanding are needed; (4) Neuropsychological testing is hard but important; (5) Life will never be the same; (6) Learning to cope. These are examined in relation to existing literature and clinical implications, limitations, and directions for future research are discussed.

Keywords: pituitary, tumour, cognitive, neuropsychology, interpretative phenomenological analysis

EXPERIENCES OF PEOPLE WITH A PITUITARY TUMOUR

Introduction

Approximately 16,000 people are diagnosed with a brain tumour each year in the UK (Brain Tumour Research, 2015), pituitary tumours making up approximately 10% of diagnoses (Macmillan, 2015). The majority of pituitary tumours are benign adenomas, commonly comprising prolactinoma, Cushing's disease, acromegaly and non-functioning pituitary tumours (Fernandez, Karavitaki, & Wass, 2010).

Pituitary tumour diagnosis has an estimated prevalence rate of 75-100 per 100,000 in the general population (Daly et al, 2006; Gruppetta, Merciecca & Vassallo, 2013 & Fernandez, et al., 2010). A systematic review by Ezzat et al. (2004), utilising autopsy and incidental discovery statistics, estimated an overall prevalence of 16.7% (16,700 per 100,000). This difference in statistics may represent the under-diagnosis of pituitary tumours or a lack of people with more minor symptoms seeking support

One of the distinctive features of pituitary tumours, compared to other types of brain tumour, is production of excess hormones and disruption to ordinary hormone production and regulation in the brain[1]. This can lead to many potential physical, psychological and cognitive effects (See Appendix 2-A), particularly problems with memory and executive function (Peace, Orme, Padayatty, Godfrey & Belchetz, 1998; Tooze, Gittoes, Jones & Toogood, 2009). The location of larger pituitary tumours near the base of the skull can create pressure on nerve and artery function in the brain, increasing the likelihood of surgical complications (Nakase et al., 1994; Liu et al., 2011). The proximity of the pituitary gland to the optic chiasm can result in problems with vision (Freda, 2011; Tanemura et al., 2012). All these factors can impact on the quality of life (QoL) of patients[2].

---

[1] Prolactinoma affects prolactin (a hormone linked to sexual and reproductive functions)
Cushing's Disease affects cortisol (a hormone linked to stress, metabolism and immune responses)
Acromegaly affects human growth hormone (a hormone linked to cell production and growth)

[2] Patient in used in this paper to reflect both the common medical environment around pituitary tumour and the chosen language use of participants during interviews.

QoL measures used in pituitary tumour either pre-treatment or in groups not requiring treatment, have found decreased QoL levels in areas such as physical functioning, bodily pain, vitality, anxiety, depression and social functioning (Johnson, Woodburn & Vance, 2003; van der Klaauw, Biermasz, Hoftijzer, Pereira & Romijin, 2008; Page, Hammersley, Burke & Wass, 1997; Tooze et al., 2009), suggesting that with or without treatment intervention, people with a pituitary tumour are at significant risk of a decreased QoL.

Several studies have evidenced that both surgical (Milian, Honegger, Gerlach & Psaras, 2013; Tanemura et al., 2012) and radiological (Page et al., 1997; Dyer et al., 2014) interventions can have a significant negative impact on QoL, worsening those potentially affected areas described above. Reductions in QoL may have a relatively short recovery period of one to six months (Milian, Honegger, Gerlach & Psaras, 2013; Tanemura et al., 2012) and a recent study by Capatina et al. (2013) suggested current treatment protocols can offer normal levels of QoL following intervention. Capatina et al. suggest that advancing surgical techniques and post-operative hormone replacement therapies offer a previously unachievable QoL for patients. However, their study examined only patients with non-functioning adenoma; further research would be needed to examine if current practices lead to similar improvements across all pituitary tumour types. Treatment developments potentially mean that experiences described in quantitative and qualitative studies more than a few years old, may not be representative of current experience. More up to date research is needed in order to elucidate current patient experience.

One aspect of QoL that has received significant attention is cognitive function following intervention (e.g. Brummelman et al., 2011; Noad, Narayanan, Howlett, Lincoln & Page, 2004; Tooze et al 2009). Surgery and radiotherapy have both been investigated for their effect on cognitive function. Evidence suggests that surgery can have a significant impact, particularly in areas of memory, attention, concentration and possibly executive function

(Guinan, Lowy, Stanhope, Lewis & Kopelman, 1998; Peace et al., 1997; Peace et al., 1998). Evidence for radiotherapy is more complex, some studies finding that radiotherapy (both alone and when paired with surgery) has no appreciable impact on cognitive function (Brummelman et al., 2011; Brummelman et al., 2012; Peace et al., 1998; Van Beek et al., 2007). Other sources have found significant cognitive impairment as a result of radiotherapy (McCord et al., 1997; Guinan et al., 1998; Noad, et al., 2004).

Much research surrounding patients with a pituitary tumour has utilised quantitative methodology, and may overlook contextual and experiential detail. A small number of qualitative studies of experience have been conducted, and all show common themes: loss, changes to self-identity, lack of control, long, difficult journeys to diagnosis, lack of trust in health care professionals and shock at various stages (such as needing surgery) (Gurel, Bruening, Rhodes & Lomax, 2014; Morris & Jackson, 2007; Simpson, Heath & Wall, 2014).

These themes could apply to many types of brain tumour, however some of the specifics within them form the overall distinctive pattern of pituitary tumour experiences. For example, the consistent discussion of how difficult it is to get a diagnosis (Gurel et al., 2014; Morris & Jackson, 2007; Simpson et al., 2014), and the idea that once a pituitary tumour has been removed and hormones stabilised, patients will have no further difficulties (Morris & Jackson, 2007). Additionally, the notion that if difficulties are raised, they will be seen as transient by healthcare professionals and thus patients learn to say nothing (Gurel et al., 2014).

Some qualitative results included experiences of cognitive difficulties, particularly in regard to subsequent personal and interpersonal difficulties. For example, the idea that inhibition was impaired, leading to more childlike, socially inappropriate behaviour (Simpson et al., 2014). However, none of the papers examined neuropsychological services' involvement with pituitary care. The notion of shock around emerging difficulties,

particularly psychological and cognitive difficulties, is prevalent. Participants report few expectations of these difficulties (by them or their healthcare professionals) (Morris & Jackson, 2007; Simpson et al., 2014) which can lead to a lack of support and communication (Gurel et al., 2014; Morris & Jackson, 2007)

Regardless of cause, level of impact or statistical prevalence, the quantitative and qualitative evidence above demonstrates that cognitive function is a key issue in the experience of pituitary tumour. The core functions of neuropsychological assessment are to aid diagnosis and treatment planning by providing measurement of cognitive function and assessment of complex cognitive difficulties (Lezak, Howison, Bigler & Tranel, 2012, pp 4-5), yet patients' experience is not discussed in any paper examined above.

Neuropsychological testing in pituitary tumour uses various standardised tests to measure cognitive functions, covering global functioning, and specific areas at risk as a result of pituitary tumour and subsequent intervention (e.g. memory and executive functioning). These tests can be used as measures of pre- and post-operative ability, or used only in post-operative circumstances where there is concern. Usage is largely down to the protocols of individual departments, and resources available.

Little information is available regarding the experience of people undergoing neuropsychological testing, in pituitary tumour or other types of brain tumour research. An unpublished thesis by Owen (2012) highlighted that people with a traumatic brain injury often gained significant insight into their own cognitive difficulties as a result of neuropsychological assessment; participants were divided between those who were aware of difficulties and those unaware, but both groups found testing an informative process in regard to their care and wellbeing. Bennett-Levy, Klein-Boonschate, Batchelor, McCarter & Walton (1994) explored the experiences of patients who had undergone neuropsychological testing after a variety of acquired brain injuries, participants gave qualitative statements, but those

statements were subsequently coded into quantitative data. Of their participants, 91% found the experience of neuropsychological assessment a positive or neutral one. Some found the process tiring and frustrating, and overall perception of testing was linked to how useful the feedback of results was. Thirty two percent of participants reported having received no feedback. Westervelt, Brown, Tremont, Javorsky & Stern (2007) approached 349 patients with mixed neurological diagnoses and 218 significant others with open ended questionnaires about neuropsychological testing, with a 37% return. They collated qualitative responses and examined these for trends. Results showed a positive reaction to the assessment experience, but a more negative reaction to practical issues such as the room they were assessed in. However, the study did not anonymise surveys, potentially leading to some bias amongst responses.

The paucity of literature regarding neuropsychological testing experience in people with a brain tumour, and limited but complex findings from related neurological fields, means that exploring the individual experiences of patients may be helpful in developing neuropsychological services further. The demonstration of some of the distinct aspects of pituitary tumour patients (e.g. prevalence, hormonal impact, expectations) in the above sections highlights how their experience could be different to other forms of tumour and neurological condition. This suggests that exploring neuropsychological testing experience and cognitive difficulties in this population may be of value in designing and targeting specialist services, and better understanding the lived experience of patients and their interaction with services.

The Present Study

The present study sought to examine gaps in research related to the qualitative experiences of people with pituitary tumours, with particular emphasis on the cognitive difficulties and neuropsychological testing. Both areas currently display paucities of research

compared with the body of quantitative evidence for overall QoL and treatment options for people with a pituitary tumour. By examining these areas using individual interviews, it was hoped a better understanding of lived and shared experience could be gained.

Methodology

Design

This study used a qualitative design employing Interpretative Phenomenological Analysis (IPA) methods (Smith, 1996) to explore the experience of cognitive decline and neuropsychological assessment in people with a pituitary tumour. IPA was used to explore how patients understand and make sense of their experiences of cognitive difficulties and neuropsychological testing.

Ethical Considerations

Ethical Approval was sought through the Integrated Research Application System and granted by a local Research and Ethics Committee. The study was approved and insured by Lancaster University. Full documentation regarding ethical approval can be found in the ethics section.

Participants and Recruitment

Participants were recruited according to specific inclusion and exclusion criteria. Inclusion criteria were the experience of a pituitary tumour and the experience of formal neuropsychological testing. Initially it was hoped to have only participants who had undergone testing in the last 12 months, however this was not possible due to recruitment numbers. The only exclusion criterion was a significant communication difficulty that would compromise understanding and participation. Participants were recruited from a National Health Service (NHS) site, local and national charitable organisations and via social media. Pituitary tumour may represent a small sample of people involved in the various organisations used to recruit. In order to provide the best possible anonymity for participants,

information about which organisations were approached, recruited from and in what numbers, will not be presented here. A process diagram for recruitment can be found in Figure 1. All participants gave fully informed consent, and were given pseudonyms and anonymised during the study.

Insert Figure 1 Here

An important part of IPA research involves finding homogeneity in the sample of participants (Smith, Flowers & Larkin, 2009). Homogeneity requires finding participants who have shared similar experiences, for whom the research question will be meaningful (Smith, et al., 2009), sometimes this will involve sharing demographics, but not always. Here, given pituitary tumour prevalence rates, demographic homogeneity was not appropriate and shared experience more important.

Specific demographic information is not presented here to protect anonymity. However, participants were Caucasian and between the ages of 18 and 65, and included men and women. All participants had adult onset pituitary tumours, but subsequent medical complications varied across participants.

Data Collection

All data was collected using semi-structured interviews, arranged in accordance with participants' wishes. Where the researcher went to the home of a participant, this was done in accordance with the Lancaster University lone working policy (Lancaster University, 2007).

Interviews followed the interview schedule (see ethics section), designed to allow participants to explore freely any issues relating to cognitive difficulties associated with their tumour, followed by their experiences of neuropsychological assessment. The schedule was devised after examination of relevant literature and consultation with the academic and field supervisors. The schedule was not used in an exact order, and some items were not asked

explicitly as the participant covered the information in other answers. Some of the discussion was expected to be not relevant to the issues of cognitive difficulties and neuropsychological testing; however discussion of wider issues may have led to more specific discussion of these areas.

Interviews lasted between 40 and 90 minutes, averaging 65 minutes. Each interview was completed in one session, at the request of participants. Interviews were digitally recorded and transcribed verbatim within two weeks of the interview date.

Data Analysis

IPA was used to analyse all interview data. IPA is a flexible methodology, allowing the researcher a degree of freedom in adapting the style of analysis (Cronin & Lowes, in press; Smith, 1996; Smith et al., 2009) to suit circumstance and personal preference. For this research each transcript was examined individually, and then all superordinate themes from all transcripts were brought together to form final themes. This ensured that all participants' data was equally weighted, and reduced the possibility of preconceived ideas of themes effecting data extraction. The process followed a path from initial reading of the data to examination of final, cross-participant themes. A summary of the steps involved can be found in Box 1 (please see Appendix 2-B for an example of a coded transcript).

Box 1. – Based on process outlined by Smith et al. (2009, p. 82-106)

Step 1 – Immersion in initial data – The researcher reads and re-reads a transcript until they feel familiar with the data. The researcher also listens to the audio recording alongside reading the transcript at least once, in order to ensure the participant and their interpretations remains at the forefront of the researcher's thought process.

Step 2 – Initial Notations – The researcher begins to note initial thoughts, ideas and points of interest directly on to a transcript as they read. No restrictions are placed on what can be noted. Notes will encompass descriptive comments (highlighting the actual detail of what was said), linguistic comments (examining specific language use) and conceptual comments (more interrogative, reflective ideas about the data).

Step 3 – Emergent Themes – The researcher uses the notations made and their knowledge of the data to begin to group together comments, reducing the volume of information whilst maintaining complexity.

Step 4 – Bringing together emergent themes – The researcher begins to draw together emergent themes to form clusters of related themes, which are finalised into the major emergent themes for a participant's data.

Step 5 – Exploring themes across participants – After the above 4 steps have been conducted for each data set, the researcher can begin to create super-ordinate themes for the entire data set.

Ensuring Methodological Rigour[3]

I adopted a reflexive approach to this research, and acknowledge that my own perspective was likely to influence my interpretation of data (Elliott, Fischer and Rennie (1999). This is in line with IPA's double hermeneutic involvement concept, whereby the

[3] This section is written in the first person to ensure accuracy in understanding for the reader

researcher is actively engaged in interpreting and understanding the participant as they try to make sense of their own experiences (Smith, et al., 2009 pp. 3). By recognising this, I hoped to improve transparency and rigour. I reflected throughout on my own influences and ideas about practice and research in this area and with this population. This helped to inform my decisions at each stage and allowed me to recognise issues I could take to my academic and field supervisors for discussion.

I involved my academic supervisor in the early stages of this process, in an attempt to ensure quality and robustness in my work. My use of verbatim quotations in the results section helps to demonstrate transparency in theme development, and a full paper trail (Yardley, 2008, p. 243) is available showing the journey from raw data to final themes.

I adopted a realist social constructionist (Elder-Vass, 2012) epistemology, and this related closely to the IPA epistemology which is traditionally based in both social constructionism and critical realism. I believed that each participant would construct their own meaning in relation to the topics they discussed, and wished to help them explore this. However, I also appreciated the influence of the outside world and wider (e.g. social) structures on experience.

Results

The interpretative phenomenological analysis generated six final themes: (1) My brain just is not working; (2) Invisible but debilitating; (3) I thought I would be cured, more understanding and support are needed; (4) Neuropsychological testing is hard but important; (5) Life will never be the same; (6) Learning to cope.

A summary of each final theme resulting from the analytic process and its constituent superordinate themes is represented in Table 1.

Insert Table 1 Here

Figure 2 represents a diagrammatic map view of how the final themes interact, discussed further during the results and discussion section.

Insert Figure 2 Here

Theme 1: My brain just is not working

> ...it's just too much, annoying, frustrating, quite crushing to be honest, it's just too much information, it's just not going through … everything just stops (TP4)

This theme was universally contributed to by participants and included: a sense that the brain is not working the way it should; the direct descriptions of cognitive difficulties experienced; the impact on mood; and how both cognitive problems and mood resulted in a cycle of difficulty.

Participants had noticed their cognitive difficulties in daily living: "I leave my shopping bag on the till...bring the teapot up to my mouth...and burn my lips" (TP5). Participants reported attempting tasks which previously would have presented no difficulty, but were unable to complete them: "I couldn't put these shelves up, it was a real battle" (TP2).

A wide range of cognitive problems was reported; most commonly issues with memory, attention, concentration and executive functions such as problem solving, inhibition and mood regulation. Participants found these difficulties hard to manage and restrictive in their daily lives: "Normally [at work] there would be...lots of activity...functionality... processing... and...just nada" (TP7). Often the descriptions of specific cognitive functions and the understanding of these was drawn from neuropsychological sessions, whilst prior to this they only knew that something was not functioning correctly in their brain: "My brain just is not working" (TP3).

Mood was included in this theme because participants responded with mood-based difficulties when asked about cognitive difficulties. Mood was seen as both a direct cognitive

issue and as intricately linked to the experience of cognitive difficulties, particularly the ability to regulate mood, resulting in "mood swings" (TP4) which prevent clear thinking: "I'm just not thinking straight, nothing's working" (TP4).

Participants described anxiety, depression and general mood difficulties as a result of their cognitive problems. They could not enjoy relaxation activities:

"I can't watch the television...I can't really concentrate on reading a book" (TP1).

The frustration and upset in being unable to complete tasks, activities and routines was very difficult.

> … what's it like to live with it, depressing... I went through the oh I'm fine … and then it just hit rock bottom ... took a long time to get used to the fact that I needed psychiatric help ... but now … the anxiety ... that's the thing that I'm dealing with every day (TP6)

Cognitive problems and mood also produced a cycle of stress and cognitive decline which participants found hard to manage. One participant described this as a "self defeating cycle" (TP3), where struggling to complete a task or utilise memory would cause stress, and then stress would cause further cognitive difficulty:

> ... as a result … [struggling with task] I'll get very stressed ...the stress of the memory not working or the fear that what might happen... causes you more stress, which causes you... more inability to remember things (TP3)

The experience of cognitive difficulty and the resultant cycle of stress were linked in later discussion to the neuropsychological testing process. Participants noted that neuropsychological testing results helped them to understand their own cognitive processes; they were more able to understand how their brain now functioned, rather than seeing only the lack of function.

> Its one of the most important documents that I have for helping me understand (TP7)

Theme 2: Invisible but debilitating

> I could see it happening, but people … it's invisible to them. They just see 'well your working fine' but they don't see what it's like inside. (TP7)

This theme described how the types of cognitive problems described above are often invisible to others, but impact on nearly all areas of life. Participants explained that they do not always want to have to explain how and why they have difficulty and why they live as they do. However, participants felt that if they did not explain, others would negatively judge them.

> I don't necessarily want to tell every person that I meet ... but you can see them sort of thinking okay, so why don't you work....we're socially conditioned to want respect from our peers … and you want to be accepted (TP1)

Participants expressed that the impact on them is "debilitating" (TP3). They described significant changes to their daily life, ability to work, social contact, self worth, motivation and ability to move forward with their lives.

> ...the implications of what can happen or what's going to happen in the future, the memory loss seems to be getting worse... you're thinking have you got Alzheimer's or some other degenerative brain disease (TP3)

Lastly, some participants explained how hard they work to ensure that others do not see them as having difficulties: "...in many respects tried to hide the difficulties" (TP2), or in need of help. For some this was about maintaining their sense of independence, or feeling other people could not understand, or because they could not tolerate receiving sympathy from others: "It's horrible when people do that sad face, "oh you've got a brain tumour, oh and they didn't be able to cut it all out [sic]" (TP6)

Theme 3: I thought I would be cured, more understanding and support are needed

> I thought any kind of difficulty I was having functioning was just the recovery process and eventually... it became clear...that it was a permanent situation (TP5)

This theme encapsulated three closely linked threads of conversation. First, participants were unprepared for the cognitive difficulties they experienced: "...it was all new to me this cognitive dysfunction, I wasn't expecting it" (TP5). Second, participants wished that professionals knew more about these difficulties: "the doctor's actually said to me well we don't know, so I had to look things up for myself" (TP1). Lastly, the struggle in convincing professionals of their difficulties and accessing support: "you're constantly being put down, as if they're not hearing what you are saying" (TP7). These three aspects were also influenced by the neuropsychological testing experience. Participants were able to use neuropsychological test results and subsequent understanding as a form of support and as a way to validate their experiences to date.

All participants said they did not know of the potential for cognitive problems. One participant did state that they had been told radiotherapy could cause some cognitive deterioration, but had not been given the same warning about surgery, which had caused difficulty for them. Participants had different opinions on why this information was not given. For some there was a belief that their doctor did not themselves know enough to be able to help: "my doctor didn't really understand" (TP7) Others felt that information is deliberately withheld. Sometimes these issues were later discussed with their neuropsychologist and whilst this did not always give concrete answers, it did provide an outlet for the emotion. One participant was invited to talk to people awaiting surgery for their tumour, but was later excluded as they had wanted to advise people of the potential cognitive problems.

> they asked me would you consider talking to these people … and I was going yeah I'll tell them all about it...they was trying to be positive and I was going "yeah but.." and when I did the 'yeah but' they then said no we don't want you to attend (TP4)

The shared experiences of participants were a sense of shock and depression when their cognitive difficulties began to emerge, particularly those following surgery. Participants attached all of their hope to the idea of being cured following surgery, an idea reinforced by professionals. To then experience cognitive difficulties left them unprepared, and less able to cope with the challenges facing them.

> ...he said, 'this will be a cure … this treatment will be a cure'. So to me a cure meant I'm not left with any residual problems, I did actually say to him...it would have been so helpful ...to have prepared me for this (TP7)

A number of participants said that their doctor tied all difficulties into hormonal imbalances, so that if hormones are balanced, there should be no remaining problems. This was not their experience, and caused further distress.

> The medical doctors would always say… you've had the tumour removed, you're having all the hormone treatment so you should be fine now, but you don't actually feel like that yourself, you feel that there's lots of things that you can't do (TP2)

Trying to convince professionals of the existence of cognitive difficulties was challenging for a number of participants. They would report difficulties, but would be dismissed or not listened to: "at best they can sympathise and at worst they can sit there looking bewildered and dismissive" (TP5). This process was draining and emotionally challenging. Participants discussed the worry that people thought they were making their difficulties up, and the stress of fighting for support: "Because I was so fed up of 'she reports' … as though 'we don't believe her'." (TP7). As discussed later, this process was then often

linked to the later feelings of relief when accessing neuropsychological services, which by their nature, are there to recognise and provide support for cognitive difficulties.

The combination of lack of understanding, lack of belief in the reports of the participants and lack of resources led to a common description by participants that there is little to no support available for them.

> I didn't get any support ... it's like... you're a body that needs to be fixed physically ...and that's all they concentrate on … and other than that you're on your own (TP1)

This lack of support covered physical, psychological and life management domains, and was a significant source of distress and disappointment for participants.

> I used to go to … a meeting of the [charity support group] ... whoever you talk to there, they've all got basically the same problems … that group's now gone...that's a shame ... They also provided support for wives, girlfriends … but now there there's been no assistance whatsoever. (TP2)

Participants expressed a strong desire to access any kind of support that might be available to them: "there definitely does need to be some sort of support...I thought I was dying" (TP4). Sometimes neuropsychological input (discussed below) was given as a notable source of support, but this was short term and its removal caused distress and anxiety.

> I do feel a bit let down now that I'm cut off from all of that [neuropsychology services]... it would be very nice if I could have some kind of catch up, follow up...I sometimes think that the statement 'there's nothing more we can do'...shouldn't lead to being completely cut off from ever being able to talk to someone about it again (TP5)

Theme 4: Neuropsychological testing is hard but important

> This is worth its weight in gold, it meant so much to me. It helped me think 'I am not going mad'...I can't say enough...for my neuropsychological assessment (TP7)

This theme contained participants' experience of the neuropsychological testing process, including accessing neuropsychological services, being tested and the use and utility of results. A number of participants described how difficult it was to gain access to a neuropsychologist: "...via the endocrinologist and that was a reluctant referral more or less I don't want to deal with this anymore let them deal with you." (TP5). In some cases the participant had had to drive forward the referral, sometimes having to seek out their local team themselves as the professionals around them had no knowledge of neuropsychological services: "I came back and said look ...I need to see a neuropsychologist, so there's a very good team at..." (TP7). These struggles were exacerbated by the difficulty in convincing professionals that their cognitive difficulties existed.

After participants had accessed neuropsychological services, their experiences were fairly similar, describing a difficult, tiring and energy consuming process, but one which ultimately felt worthwhile and provided a measure of understanding around their cognitive difficulties.

> She made me feel there's a light at the end of the tunnel where before there wasn't, you know we've found something out, we've actually found that the brain is damaged (TP4)

Participants explained that results helped to validate their own thoughts and feelings, as their belief about their cognitive difficulties was finally confirmed. Neuropsychological results can also be used to defend themselves when discussing their difficulties with other people, including professionals: "Neuropsychological reports...are quite powerful...they don't get questioned really so they are of a big use in that way" (TP5)

Neuropsychological services were also described as useful in helping to develop practical strategies for managing neuropsychological difficulty (described further in the

learning to cope theme), however, for some the testing process felt useful at the time, but they found it difficult to make use of the results in any meaningful long term way.

> I did feel that I benefitted from going in and having the testing but... it certainly didn't make an impact on changing my life long term...other than I had a better leg to stand on when I was arguing ... "I'm not mad I've had psychological testing" (TP1)

Lastly, some felt that neuropsychological testing did not recognise all difficulties. This was due to two main issues: firstly that the tests sometimes report that participants are within the normal range of abilities, but they feel this is still deterioration from their previous abilities: "I didn't perform particularly well but the results came back yes you know I'm the norm, before the operation I was better than the norm" (TP2). Secondly, the intermittent cognitive problems experienced mean a single testing event may not capture the peaks and troughs of cognitive function.

> I don't think that really it was able to really show what cognitive difficulties a pituitary person would have because...I wasn't necessarily feeling stressed or upset or any of those things (TP1)

Theme 5: Life will never be the same

> ...you are going to give up, because you're tired and your brain doesn't work and you sit at home and think, ok this is my life then. (TP7)

This theme was contributed to by all participants, stressing the important role it played in the overall experience. For many the journey through diagnosis, treatment, and life since was characterised by initial devastation and fear, but continued hope for a full cognitive recovery. This theme represents the realisation from participants that their cognitive function, and by extension their lives, will never fully return to the way they were: "it just gradually dawned on me that nothing ever got better, I think that was a slow shock if you like, it was 'this is not getting better is it' " (TP5)

Constant comparison to the old self was present, and grief for what had been lost, both in terms of lost functioning and abilities, and loss of a potential future.

> … as a child I think I sort of had this … fairly normal idea, I'm going to get married by the time I'm 25 and I'm going to have four children and you know, family life…My life has been so vastly different from that fantasy…there's this thought of … 'why am I here now?', 'what is my purpose in life?'… I'm not working, I can't have children, you know, I'm not doing … the normal functions of human life. (TP1)

Participants described emotional turmoil when trying to come to terms with life changes. This was often expressed as a rejection of their difficulties, and a determination to get back to their lives and previous functioning: "I was so determined I just said look even if I just come back [to work] for a little while to prove that I can do it" (TP6)

The notion of getting back to work was prevalent, with participants attaching a lot of their self worth to this. When this proved impossible, it led to feelings of uselessness and low self esteem. Work became the focus of anxiety, as even if participants still wanted to work, they became too concerned about their abilities to attempt it: "I was supposed to go for a job interview...I just don't have the confidence in my ability... so I withdrew" (TP7)

For most there was an eventual sense of resignation and acceptance of their difficulties: "there's nothing we can do about it ... just a matter of trying to have a lifestyle to fit...and accept it" (TP3). This created low mood, anxiety about the future, but also relief as they moved away from the fight to get back to 'normal'.

> So I'm a little oddity sitting there, trying not to be difficult, trying to just accept it, accepting is a …[laughs] an important thing. So we've sort of been on a weird journey where I kept thinking I can recover and get back to it and I think...I've sort of given up. (TP7)

Theme 6: Learning to cope

> The way I cope with it … just live life on a day to day basis…I can go a long time now without trying to think about it … because there is no point (TP1)

This final theme encapsulated the ways in which participants were learning to manage their cognitive difficulties, and the more positive outlook on the future. Whilst many feel that their lives will never be the same, this theme did show hope for managing ongoing difficulties and potentially continuing to recover cognitive function. The eventual acceptance of difficulties was discussed, but also the ongoing desire to improve and recover. As discussed above, neuropsychological testing played a key role in this coping process and participants were able to utilise test results and the expertise of their neuropsychologist to help them begin to adjust to the changes in their life in a more positive way. However, for most neuropsychological results and interactions came quite late to their coping process and so other methods were sought over time.

Participants discussed practical ways that they found to cope, such as managing their lack of energy: "… if I worked through lunch ... leave an hour early, that gave me enough time to recharge and go in the next day" (TP7)

The psychological coping process involved a variety of strategies, often involving family and friends as sources of support and motivation: "I had to get back home then, with the kids...back round the family for support..." (TP4). Participants described learning to find the positives in their situation, such as thinking how much worse things could have been, and moving away from locating blame.

> ... because the operation had done such good in saving my sight I certainly couldn't look upon it as something that shouldn't have been done, I don't think the surgeon made any mistakes at all (TP5).

Participants found comfort and positive experiences in finding new ways to use their time, such as in new activities and hobbies, but also returning to old activities which in the

early stages of their difficulties, had been lost to them, something which participants said was encouraged by their neuropsychologist as a way to reengage with their previous life activities.

> My main hobby before the operation … was model engineering … after the operation I wasn't safe near any of the equipment...last year I decided to have another go...and I'm finding that yes I can now use it safely so things do progress … (TP2)

Being a "functional person" (TP7) and being useful were key factors for participants, despite most being unable to work they had begun to find ways that they could contribute, and this was key in helping them to move forward. Participants described involvement with groups and networks, and even participating in this research, as a way they could contribute to a better understanding of pituitary tumours, and this helped them to cope.

> ...if I can ever say anything or do anything to help publicise it... they'd [a charity organisation] like me to do a blog or article on multi-morbidity so … I'm beginning to inform others and help where I can … it helps to get it out of my system a little bit as well, just to vocalize it really (TP5)

Often, methods of coping began to emerge following participants involvement with neuropsychological services. Sometimes this was because neuropsychologists were able to provide direct coping strategies and sometimes this was because neuropsychological involvement providing a new understanding and a fresh sense of hope and motivation for participants.

Discussion

This study is the first to examine qualitatively the specific experiences of cognitive difficulties and neuropsychological testing in people with a pituitary tumour. As such its findings represent a first, exploratory examination of these experiences, and how they impact on the wellbeing and life experience of this population. Findings here echo the psychological and emotional turbulence associated with having any form of brain tumour (Ownsworth,

Chambers, Hawkes, Walker & Shum, 2010; Sterckx et al., 2013; Huang, Wartella, Kreutzer, Boraddus & Lyckholm, 2001), but highlight cognitive difficulties as a particularly pervasive source of difficulty.

The findings demonstrated an array of life changing cognitive difficulties participants experienced. In keeping with known triggers (Guinan et al., 1998; Peace et al., 1997; Peace et al., 1998), participants connected cognitive problems to the tumour, surgical and radiological interventions and hormonal dysregulation. Additionally, results here suggest cognitive difficulties can vary significantly based on stress levels and psychological wellbeing. Participants highlighted this as a flaw in neuropsychological testing, as they are not always stressed or in distress when being tested. Alternatively, clinical psychologists and neuropsychologists may not be communicating their understanding of deficit variability to patients following assessment.

Shock around diagnosis and arising difficulties is a common experience in the diagnostic journey for people with a pituitary tumour (Morris & Jackson, 2007; Simpson et al., 2014), results here continue this into the post treatment phase and demonstrate participants' experience of being entirely unprepared for cognitive difficulties. Participants felt inadequately informed, and this led to two key issues: shock, distress, and inability to cope with difficulties, and a lack of trust and faith in professionals. Given the importance of the doctor patient relationship in both wellbeing (Kelley, Kraft-Todd, Schapira, Kossowsky & Riess, 2014) and treatment adherence (Moore et al., 2004), maintaining trust needs to be more carefully considered. Clear potential for cognitive difficulties in previous research and findings here, is at odds with the lack of preparation given to participants, suggesting either a lack of knowledge and understanding in professionals or a deliberate withholding of information. This raises issues of the ability to give informed consent when unaware of all potential consequences.

Participants had undergone substantial change throughout their journey, and the experience of change was (within these findings) closely linked to their experience of cognitive difficulties. Participants' eventual acceptance of never fully recovering led to a process of coping and making the best of their lives as they are. This is in keeping with how neuropsychology recovery theory considers the integration of the past and present self as key in psychological recovery e.g. The Y-Shaped Model (Wilson, Gracey, Evans & Bateman, 2009) (as discussed in the literature review section). Findings here therefore highlight the value of applying neuropsychology theory and rehabilitation to recovery work conducted with people with a pituitary tumour.

The type and level of changes described by participants here mirror the types of experiences described in the process of Grief. Kubler-Ross (1969) proposed that during loss and grief, people will move through five stages: denial, anger, bargaining, depression and acceptance. Whilst not considered fully representative of grief experience, this model does help to demonstrate the ways people within this study experienced the loss of their past cognitive functioning. A full mapping of these concepts can be found in the critical appraisal section of this thesis, however, participants here demonstrated all of the above named stages of grief during their experiences, but were both transient in their stage of grief and capable of expressing multiple forms of grief concurrently. For example participants were both angry with professionals and bargained by wondering 'what if'. Tying together both the grief and change processes described above is a theory of transformational grief, whereby those who experience significant loss (traditionally bereavement, but here a loss of self) are fundamentally a different person following their experience, than they were before. This is perhaps even more prominent for those with neurological difficulty, who experience not only a psychological change, but a neuroanatomical one as well. By better understanding the

fundamental changes and subsequent sense of loss experienced by people with a pituitary tumour, services can better support and intervene when necessary.

Whilst important, cognitive difficulties form only one part of QoL (e.g. Johnson et al., 2003; Van Der Klaauw et al., 2008; Page et al., 1997; Tooze et al., 2009), but results here would suggest a broad impact on other areas of life. The reported focus of professionals on physical (particularly hormonal) symptoms does not reflect the spectrum of support and care needs described by participants. This dichotomy led to increasing amounts of distress and difficulty as participants fought to be believed. This draining experience should also be considered as a potential factor in subsequent performance during neuropsychological testing. By the time participants reach neuropsychological services, their tolerance, trust in professionals and general energy levels may lead to sub-optimal performance on measures of functioning, thus leading to some of the negative narratives seen in these results.

Findings reinforced the value of neuropsychological input (Owen, 2012) and supported the idea that the experience can be a positive one (Bennett-Levy et al., 1994; Westervelt et al., 2007). Additionally, the perceived utility of neuropsychological testing was related to the ability of the patient to use results as leverage for support, and as a defence when others questioned their cognitive abilities. Findings also demonstrated neuropsychological testing as a support to self-worth, as participants felt validated and vindicated when receiving results, even results which were hard to hear. Possibly the perceived value of neuropsychological testing may relate to how difficult participants found it to access. By having to fight hard for a service, people may over emphasise the importance of their contact to justify the fight itself. It may be important that neuropsychological services do not inadvertently support the status quo because the people seen are both relieved to be seen and positive about their outcome with the service. The discussion of being ‘cut off’ from neuropsychological services following assessment and intervention also raises the question of

whether current structures for neuropsychological input are adequately meeting needs. The variability in functioning and the perceived lack of support generally may suggest a need for change in the standard assessment, formulation, intervention, discharge approach.

When examined collectively the results of this study form an interactive network of experiences which have a profound effect on the lives of the people described within this research. Figure 2 demonstrates the way each final theme interacted and influenced other themes (and therefore other parts of participants' lives). The themes born of direct experiences (My brain just is not working, Invisible but debilitating, and I thought I would be cured, more understanding, support and hope are needed) fed into the core existential theme (Life will never be the same again) which was fundamentally about change and adjustment. This adjustment in turn concluded with participants finding ways to progress their lives (Learning to cope). Finally the issue of neuropsychological testing (Neuropsychological testing is hard but important) served to aid in understanding cognitive function changes, acceptance of the finality of cognitive changes and in finding ways to adjust and cope. This interactional understanding of the experiences of cognitive function and associated testing (specifically how these experiences underpin wider life experience) represents the unique contribution this research makes to the understanding of pituitary tumour experience.

Clinical Implications

The nature of most pituitary tumours, being both low grade and located away from areas of the brain primarily associated with cognitive function (as opposed to hormone production) may lead professionals to erroneously assume cognitive difficulties will be unlikely. This research has demonstrated the need for support with cognitive difficulties, and this will initially need to come from medical professionals involved in care (GPs, specialist doctors, specialist nurses) as these will have the earliest and greatest number of interactions through diagnosis and treatment. To better understand the needs of this population, it would

be necessary for services to begin to scrutinise current practices and investigate what type of psychological service may be most useful for people with a pituitary tumour. The level of cognitive difficulties and their impact demonstrated in this study, may mean neuropsychological services should be more closely involved. This may mean ensuring services are available, well publicised and well understood (by both professionals and patients). This could be done by establishing standard neuropsychological referral pathways when people with a pituitary tumour enter medical services. Additionally neuropsychologists could become more involved in the wider multi disciplinary work. However, a more basic psychological understanding and on going support structure from wider professionals may be sufficient for some people with pituitary tumour. By being more attuned to these needs to begin, with professionals could better assess the long-term needs of patients.

The need for greater understanding of cognitive difficulties has been strongly presented in this research. All professionals involved need to have basic knowledge regarding the potential cognitive consequences, and patients need to be made aware of potential difficulties so they can be prepared. Preparation will help to reduce negative psychological consequences, reduce future contacts with services and help in the long-term psychological and practical adjustment process. It is the responsibility of all professionals to ensure they are providing the best care for both physical and mental health; however neuropsychologists may be well placed to increase understanding of cognitive problems in other professionals, through earlier involvement in care, and through consultation and training. This may represent continuing involvement, or short term educational work which would then be disseminated more widely as professionals with better psychological knowledge, then go on to train others in their own discipline.

Findings here suggest cognitive problems affect all areas of life, including physical and psychological wellbeing. Despite clear national guidance (National Institute for Health

and Care Excellence, 2006) indicating psychological wellbeing should be an important consideration for all professionals, participants here described a broad lack of such support. Future service developments should focus on more integration of psychological wellbeing into the QoL as assessed by professionals working with these patients.

Neuropsychological services represented an important supportive factor within findings but were not perfect. Neuropsychological services may be limited in their ability to remain involved with long term care due to funding or other considerations however patients need to be aware of the ability to re-engage with services if they experience continuing cognitive decline or mental health difficulties. Common service models of discharge following intervention may be better replaced by open-ended care packages. This could involve the use of patient for life policies, as are seen in endocrine services, or annual review policies seen in services such as epilepsy.

Neuropsychological services need to be cautious of variability in cognitive problems experienced by each person, particularly based on stress levels, and formulations and reporting mechanisms should clearly note this. Additionally the experience of being reported as within normal ranges may not appreciate the way subtle deficits, or moderate deficits in previously high functioning people can be hard to detect but can have a profound impact on quality of life. Additionally, neuropsychology services should carefully examine their own interactions and outcome measures in light of the idea that patients may have had a lengthy and difficult battle to access their service. Helping patients to be realistic about their expectations from neuropsychological services and actively promoting neuropsychology to wider professionals (thus streamlining referrals) would be helpful steps.

Limitations and future research

Whilst useful, findings need to be considered alongside potential limitations. The findings presented here represent only the shared experiences of a small group of people who

were all Caucasian and from England (despite wider recruitment). While findings may resonate with anyone with a pituitary tumour, they should not be interpreted as representative of everyone's experience. It is also possible this study only captured the experiences of people with negative experiences of care and wellbeing, with those who had experienced negative interactions with health care professionals potentially most inclined to volunteer. The lack of contribution from family and carers may also represent a significant missing piece of information.

The range of time since diagnosis and treatment was varied, making it possible the experiences described by some participants do not accurately represent the most up to date treatment and management protocols.

This research and its findings provide valuable information to the pituitary tumour knowledge base, however there remains a general paucity of research. More quantitative and qualitative research is needed to establish a clear knowledge base. In particular, the experience of neuropsychological involvement in brain tumour care would benefit from more extensive evaluation. The evaluation of cognitive problems as a result of pituitary tumour and treatment will need continuing study, particularly if claims regarding near normal QoL with current treatment protocols (Capatina et al., 2013) are to be accepted. There would be value in research which evaluates current practice, and knowledge and understanding, of professionals involved in pituitary tumour care regarding cognitive difficulties. The experience expressed by participants here is not a positive one in this regard, and further research could establish either the reasons for this, or if this is not representative of wider experience.

Conclusion

This research has highlighted the important role cognitive difficulties play in the experience of pituitary tumour. For those with cognitive difficulties, the activities of daily

living, along with psychological and emotional wellbeing can be significantly impaired. The need for clear, accurate and honest information from professionals is paramount, and neuropsychological services are ideally placed to support patients alongside other professionals. Clinical psychology, neuropsychology, medical and wider services need to work together to promote a better understanding of the role of cognitive difficulties in pituitary tumour experience.

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Table 1 – Final themes and constituent superordinate themes

Participant / Theme	My brain just is not working	Invisible but debilitating	Neuropsychological testing is hard but important	I thought I would be cured, more understanding and support are needed	Learning to cope	Life will never be the same
TP1	Direct cognitive impact	Invisible condition Cognitive problems affect all areas of life	Neuropsychological tests are important but potentially damaging	Searching for understanding No support	Coping	Grief for past, fear for future
TP2	Feeling useless The direct cognitive impact	It affects everything but I hide it	Testing is hard but gives hope	Medics need to understand cognitive problems better	Finding ways to cope	Life will never be the same
TP3	Self defeating cycle of stress and cognitive problems Cognition and mood	Debilitating in all areas of life		Searching for answers and belief Lack of support		Unable to cope Life will never be normal again

TP4	The cognitive impact Mood swings Everything just stops	It changes you and your life	Neuropsychological results can be hard to hear but are important	Cognitive problems were a surprise Lack of support		
TP5	My brain just doesn't work Cognitive problems	The invisible condition	Neuropsychological testing gives proof but isn't perfect Neuropsychology can be hard to access and results are not always used well	I thought I would be cured Doctors are not prepared for cognitive problems Relationship with professionals matters More awareness is needed	Learning to cope	My life has permanently changed
TP6	Direct cognitive impact	I must not let others see		Need for better understanding of cognitive problems Need for support	Finding coping strategies Striving to get back to normal	Loss of past, loss of future

TP7	My brain just isn't working The cognitive impact	Testing is draining but worth it	They won't listen The fight to prove difficulties Not enough support	Recovery	Resignation The old me

Figure 1 – Recruitment Process

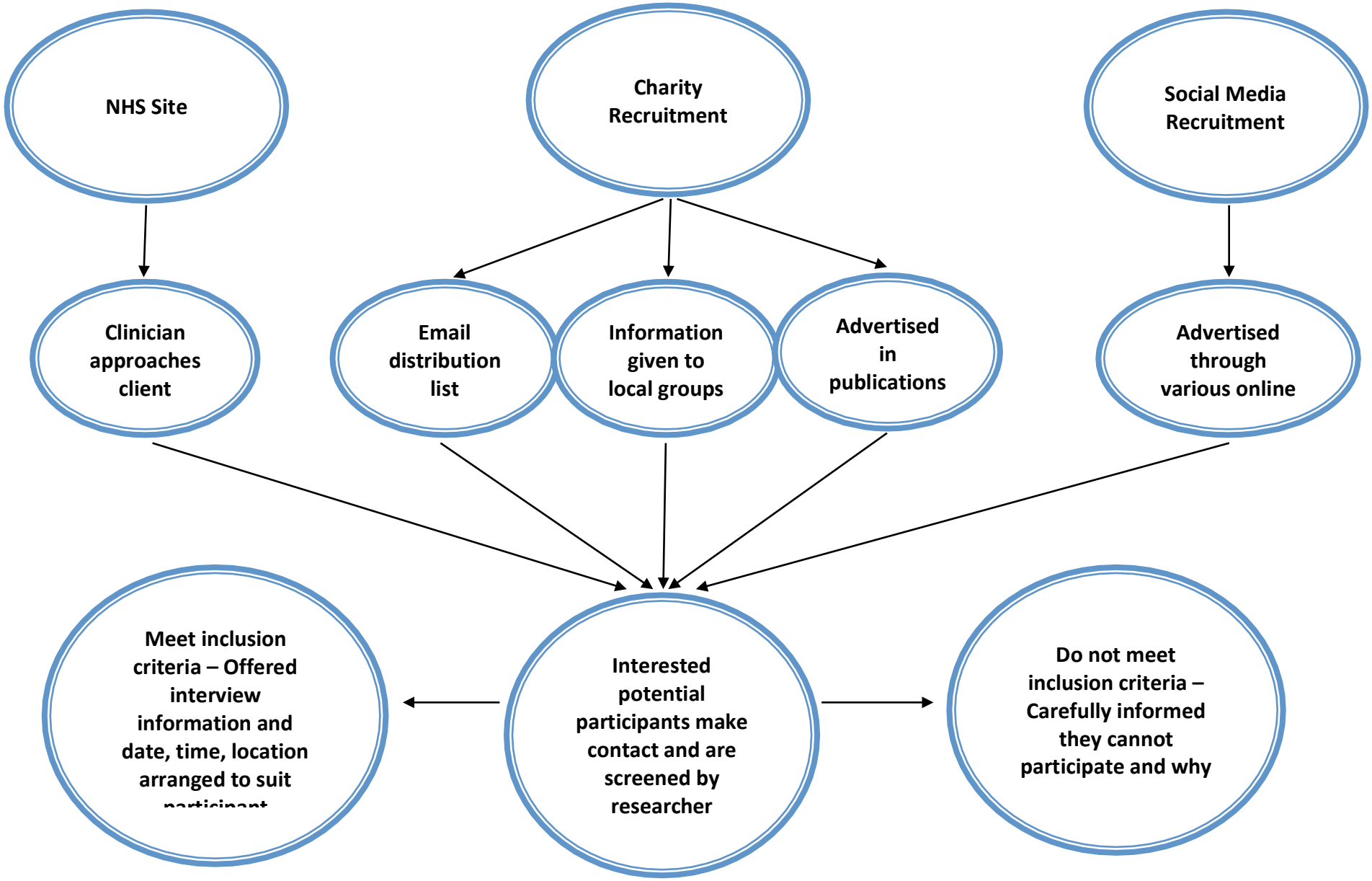
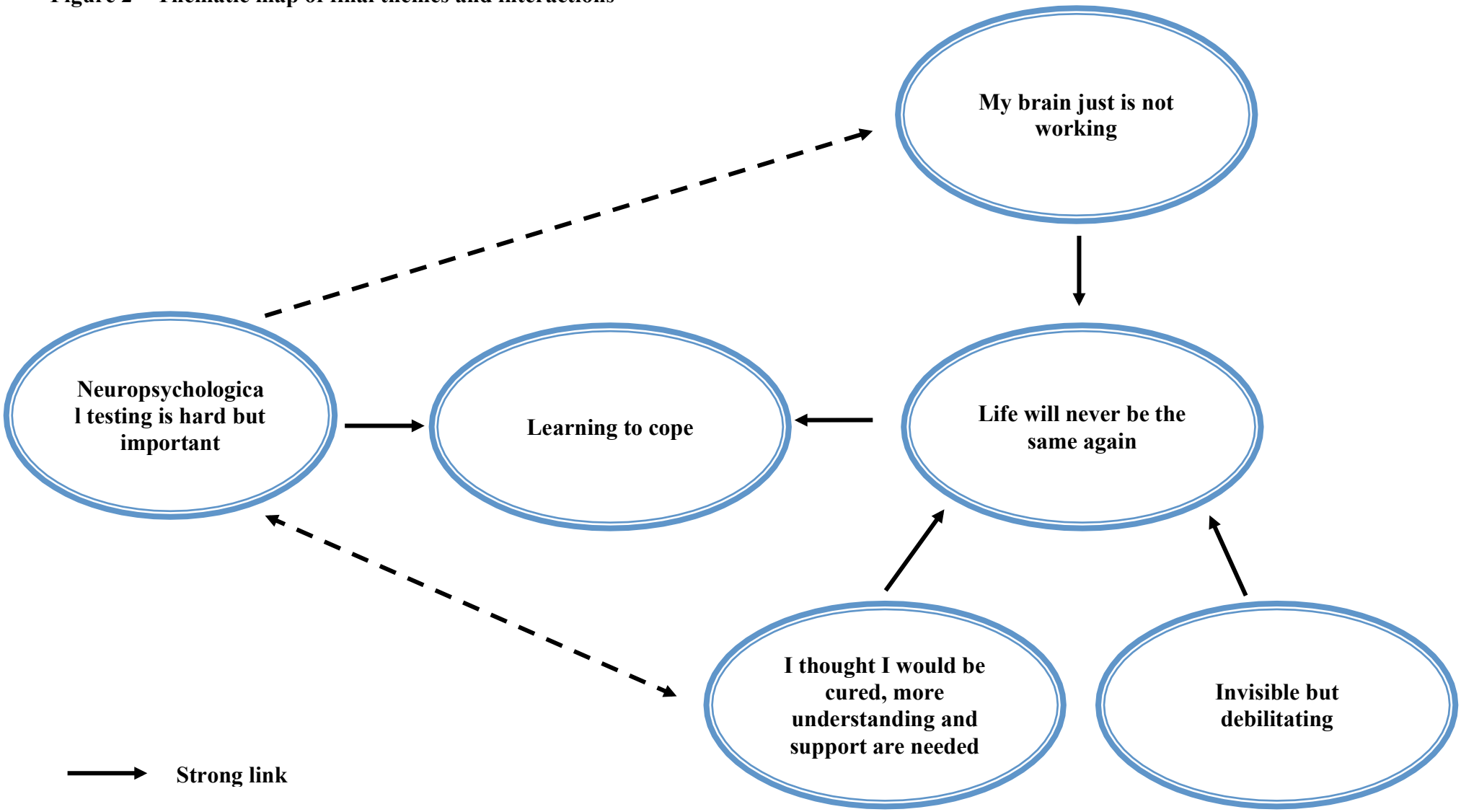


Figure 2 – Thematic map of final themes and interactions



Appendix 2-A – Extended list of physical and psychological difficulties associated with varieties of pituitary tumour.

This list was drawn from the Pituitary Foundation website:

http://www.pituitary.org.uk/information/pituitary-conditions/

Physical	Psychological / Cognitive
• Appetite and weight variations • behaviourial changes, depression and mood swings, occasionally psychological problems can be severe • Carpal Tunnel Syndrome • Changes in blood cholesterol concentrations • Coarsening of facial features • Constipation • Decrease in bone density, increase in rate of fracture in middle age and beyond • Decrease in lean body muscle • Decrease in sex drive • Decrease in strength and stamina, reduction in exercise capacity • Diabetes mellitus • Diabetes Insipidus • Discharge from breasts • Disturbed sleep patterns	• Anxiety • Depression • Behavioural changes • Introversion • Inability to concentrate • Feelings of social isolation • Memory problems

• Dry skin • Enlarged hands and feet • Excessive sweating and oily skin • Tiredness • Decreased energy • Headaches • Impotence • Blood pressure problems • Increase in hair growth on the face and body • Sensitivity to cold or heat • Loss of normal menstrual function • Pale appearance • Reduced body hair • Fertility problems • Sleep apnoea • Slow growth • Tendency to bruise easily • Susceptibility to infections • Vision disturbance • Weight gain	

Appendix 2-B – Example of annotated transcript with emergent themes

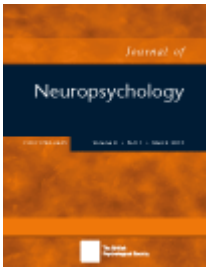
Research Question:		**Participant:** TP5
Annotations: Descriptive *Linguistic* Conceptual	**Transcript**	**Emerging Themes**
Co-morbid health problems Fatigue – mental and physical Short term memory loss Lots of life changes all at once Brain blanking Confusion Getting irritable as a result of cog problems Recognition of the importance of surgery – and yet? Invisible condition Have to persuade people to understand What I say vs blood tests Need to have faith that people believe you	So can you tell me about any cognitive difficulties you've experienced from your tumour or from the treatment? Yeah, I've got several, I mean I come under the category of multi morbidity now because there's so many different symptoms that have occurred since my surgery which was in 2005. Chronic fatigue, both mental and physical, instant memory loss so I don't have too much trouble with long term memory but you know literally something I've just done I won't remember that I've done it ten seconds later. I've lost all my afternoons for life because I have to sleep every afternoon, I go off to sleep, it's not a conscious decision, inability to cope with more than a couple of functions at a time, I mean lots of these things are so related that it's almost describing the same thing in more than one way but uh brain blanking when over loaded which happens very easily, confusion, resultant occasional irritability and desperation, depression, bad dreams and really word finding difficulties, it's all kind of, it's all linked and it was very much after the tumour was removed which was a success because it saved my sight, I'd have apparently gone blind had I not had the operation and I think because the tumour had done such damage to the pituitary gland he virtually had to remove all of the pituitary gland as well, the surgeon who was a brilliant surgeon I will say but they can never tell what side effect there'll been and of course I mean I might be jumping head here because this might be for another question but once again because it's invisible it take so much more persuasion to try and get people to understand and you have to, you literally have to just then put your faith in the person that they are going to believe you because all they need to do is say that's rubbish you're blood tests are okay and immediately it sounds like you're making it up so but I was aware of it and I was aware of it as a consequence of the surgery so I'm not saying that the surgery in any way, the surgery was culpable or anything like that but it was just one of those things that	Lots of life changes Memory Brain blanking Invisible condition I have to persuade people I am struggling

Sense of loneliness in words / tone No connection between people with similar pituitary conditions Fatigue is the biggest problems and affects all others Sleep does not refresh Disorientated Early belief that difficulties following surgery were short term *Naturally – use suggests basic expectation of full recovery* Slow realisation of permanent cog damage Difficult relationship with doctors Rude doctors Doctors dismissive of reported difficulties	happened and I believe that there are others out there that have had similar but unfortunately I never get to meet them because they're normally scattered around the country somewhere and you know there's various phone lines and things like that where you can talk to them but I never as yet met anyone face to face with the same problems so because it's invisible I find it very very hard to have to explain to people what's going on. The fatigue is probably the biggest of all the cognitive dysfunctions I think that's pretty mighty, the sleep I have to have in the afternoon isn't the same as the kind of sleep you'd have at night because it doesn't refresh at all it's something that just comes upon me and I wake up and I feel extremely, it's almost like a very bad hangover to be quite honest, very disorientating. So you mentioned in there sort of your experience with surgeons and doctors, talking to them about your cognitive problems With various doctors? Yeah can you talk me through it? Yeah it was a situation that when was in the, when I was going through the first few weeks after surgery naturally I thought any kind of difficulty I was having functioning was just the recovery process and eventually once during as the weeks went by and the months went by it became clear both to me and my wife and my family in general that it was a permanent situation so of course then you just rely so much on the understanding and trust of your doctors and the really that the main contact, the person that I was due to see at that time who had the most say over what was going on and dealt with the blood tests and results of the blood tests what have you was my endocrinologist at the time and he ended up being in the end he was very very rude, very very dismissive, my wife witnessed that as well, it would be very much, as this was the first, my first back up, the first endocrinologist that I had, the first doctor that I would discuss my symptoms with post surgery it was very very damaging to me because at that time I hadn't had anyone else say to me hang on TP5 he's wrong no there is more to what you're saying so everything that he said seemed to kind of belittle	Fatigue I thought I would be cured I slowly realised the cognitive damage was permanent

Difficult doctors damaged trust with professionals Belittle what is reported by patient 'cured' opinion from doctors Doctors not seeing symptoms as problems e.g. fatigue Doctors don't acknowledge that difficulties have come from surgery <u>Doctors taking information and differences for granted and assuming patients know this?</u> Falling out with doctors '*Ad nauseam'* – insulting Doctor becoming defensive when patient is upset Relationship break down Some people are determined not to listen	what I was reporting I ended up going away sometimes even doubting myself thinking well am I exaggerating here but it was very much a case of your bloods are fine so what do you mean, you're cured you should be okay, oh yeah but I've got such and such and there were initially he just look like he wasn't understanding me and eventually he became quite insulting about it basically and I said I have to sleep every afternoon, well just chill out then he said sometimes as if it's all very easy, sometimes he would have the sheer disbelief that anything that I said was to do with the surgery, one day, strangely enough this same person, as I said I'm not mentioning any names at this stage, had a moment where he had, he obviously put on a sensible cap for five minutes because he suddenly said to me one day you do realize that, he said oh are you religious and I said not especially and he said well it must be remembered that replacement hormones that we give you are not the same as God gave you, in other words you will not be able to function as well with these as you would do with the normal hormones and that was probably the one time where he seemed to slip into some kind of empathy with me but it got worse and worse and worse to the extent where we fell out and he was quite insulting saying things like I've gone through this with you ad nauseam and I didn't hear that, my wife picked that up and I eventually said to him have you any idea how difficult it is for me to sit here and have to explain all of this and not be believed and his response was have you any idea what it feels like to have to sit here and listen to this and by that time naturally any relationship if you can call it that had broken down because if someone's determined not to listen to you they're determined not to listen to you I don't think they're ever going to, if they are that cussed I don't think they're ever going to have a moment where they suddenly think oh okay I'll believe you so it was a lost cause so that was my first experience.	Doctors think I am cured but I'm not The doctors will not believe me Doctors becoming defensive Relationship breakdown with professionals

Appendix 2-C – Author guidelines for chosen publication journal

Journal of Neuropsychology



Edited By: Stephen Jackson

Impact Factor: 3.818

ISI Journal Citation Reports © Ranking: 2013: 7/83 (Psychology Experimental); 14/74 (Psychology)

Online ISSN: 1748-6653

Author Guidelines

The Journal of Neuropsychology publishes theory-driven patient studies. The central brief is to learn more from patients with brain dysfunctions to gain a better understanding of brain-behaviour relationships and to help future patients. Important developments in neuropsychology will follow from a multidisciplinary approach embracing neighbouring fields such as developmental psychology, neurology, psychiatry, physiology, endocrinology, pharmacology and imaging science. The journal publishes group and case studies addressing fundamental issues concerning the cognitive architecture of the brain. In addition, the journal includes theory-driven studies regarding the epidemiology of specific deficits, new assessment tools, and the evaluation of treatment regimes.

The journal is committed to a fast and efficient turn-around of papers, aiming to complete reviewing in under 90 days. Submissions are processed via a web-based system and reviewers are required to complete their referee report within 28 days.

Papers will be evaluated by the Editorial Board and referees in terms of scientific merit, readability, and interest to a general readership.

1. Quality Control

The content, format, quality and ambition of the JNP as a major outlet for theory-driven neuropsychological studies is under constant review by the Consulting Editors:

• Kenneth M. Heilman (University of Florida College of Medicine, Gainesville, USA)

• Donald T. Stuss (Rotman Research Institute, Baycrest, University of Toronto, Canada)

• Giuseppe Vallar (University of Milan-Bicocca, Italy)

• Elizabeth Warrington (National Hospital for Neurology and Neurosurgery, London, UK)

2. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

3. Paper formats and length

Research papers are full-length reports of original scientific investigations. Papers should normally be no more than 6000 words excluding abstract (maximum 250 words) and references. Multiple citations for a single point are usually duplicative and authors are urged to cite the best reference. The Editor retains discretion to publish longer papers.

Theoretical or review articles are full-length reviews of, or opinion statements regarding, the literature in a specific scientific area. They need not be exhaustive but should give an interpretation of the state of research in a given field. They should normally be no more than 4000 words excluding abstract (maximum is 250 words) and references. The number of references should not exceed 40-45. Multiple citations for a single point are usually duplicative and authors are urged to cite the best reference. The Editor retains discretion to publish longer papers.

Brief communications are short reports of original research or case reports. They contain no more than 1500 words excluding abstract (maximum is 80 words), references, a total of up to three tables or figures, and no more than 10 references.

Fast-track papers are timely and relevant reports that, to the discretion of the Editor, are included in the issue following acceptance. Authors may ask that their submitted manuscripts are considered for fast-track.

Commentaries and rejoinders are short reactions to publications in JNP followed by an invited rejoinder from the original authors.

Special issues may be proposed to the Editor. The proposal should include a short description of the topic and a number of (possible) contributors. The same quality criteria apply as for other submissions.

4. Submission and reviewing

All manuscripts must be submitted via http://www.editorialmanager.com/jnp/. The Journal operates a policy of anonymous peer review. Before submitting, please read the terms and conditions of submission and the declaration of competing interests.

5. Manuscript requirements

• Contributions must be typed in double spacing with wide margins. All sheets must be numbered.

• Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. A template can be downloaded here.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript with their approximate locations indicated in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi.

• All articles should be preceded by an Abstract (see point 3 for guidelines), giving a concise statement of the intention, results or conclusions of the article.

• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide DOI numbers where possible for journal articles.

• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

• In normal circumstances, effect size should be incorporated.

• Authors are requested to avoid the use of sexist language.

• Authors are responsible for acquiring written permission to publish lengthy quotations, illustrations, etc. for which they do not own copyright.

For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association.

6. Supporting Information

JNP is happy to accept articles with supporting information supplied for online only publication. This may include appendices, supplementary figures, sound files, videoclips etc. These will be posted on Wiley Online Library with the article. The print version will have a note indicating that extra material is available online. Please indicate clearly on submission which material is for online only publication. Please note that extra online only material is published as supplied by the author in the same file format and is not copyedited or typeset. Further information about this service can be found at http://authorservices.wiley.com/bauthor/suppmat.asp.

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8. Colour illustrations

At the editors' discretion, colour figures can be provided for use in the journal. Good quality photographs will be considered for inclusion where they add substantially to the argument, to a maximum of three per article. These can be supplied electronically as TIF files scanned to at least 300dpi. If they are not printed in colour, then they can be reproduced in colour online and black and white in print.

9. Pre-submission English-language editing

Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English. A list of independent suppliers of editing services can be found at http://authorservices.wiley.com/bauthor/english_language.asp. All services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication.

10. OnlineOpen

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12. The Later Stages

The corresponding author will receive an email alert containing a link to a web site. A working e-mail address must therefore be provided for the corresponding author. The proof can be downloaded as a PDF (portable document format) file from this site. Acrobat Reader will be required in order to read this file. This software can be downloaded (free of charge) from the following web site: http://www.adobe.com/products/acrobat/readstep2.html. This will enable the file to be opened, read on screen and annotated direct in the PDF. Corrections can also be supplied by hard copy if preferred. Further instructions will be sent with the proof. Hard copy proofs will be posted if no e-mail address is available. Excessive changes made by the author in the proofs, excluding typesetting errors, will be charged separately.

13. Early View

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final corrections have been incorporated. Because they are in final form, no changes can be made after online publication. The nature of Early View articles means that they do not yet have volume, issue or page numbers, so they cannot be cited in the traditional way. They are cited using their Digital Object Identifier (DOI) with no volume and issue or pagination information. E.g., Jones, A.B. (2010). Human rights Issues. *Human Rights Journal*. Advance online publication. doi:10.1111/j.1467-9299.2010.00300.x

Further information about the process of peer review and production can be found in this document. What happens to my paper?

Section Three: Critical Appraisal

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Critical Appraisal

This critical appraisal of my research will begin by outlining and reflecting on my motivations for this project and some of the issues which arose as I completed the research. I will then give a reflective discussion of the results, strengths, limitations and potential future projects to arise from this research[1].

Development of the Research

Knowing I had an interest in neuropsychology I explored a number of ideas relating to brain tumour, brain surgery, brain injury and degenerative conditions. These were the areas I had most experience in via clinical practice, and those which interested me most. My early ideas were to explore neuropsychological testing experience, as I did not believe there to be much research in this area, and having conducted many psychometric tests I was aware of how complex the experience can be. I approached my field supervisor, whose specialism in brain tumour and pituitary tumour led to discussions of this population and my own experience in this area. In practice we had both noted a difference between the expectations of cognitive problems in pituitary tumour and other types of tumour, and also the significant cognitive problems that people with a pituitary tumour could present with. I had also conducted neuropsychological testing with people with a pituitary tumour and had noted how difficult this process can be, due to factors such as fatigue and stress tolerance. I decided that joining the issue of cognitive difficulties with that of neuropsychological testing would be potentially beneficial, and proceeded to explore relevant literature. I also noted that much of the focus in literature was on physical health (e.g. van der Klaauw et al., 2008) and even those studies exploring cognitive difficulties (e.g. Tooze, Gittoes, Jones & Toogood, 2009) were more concerned with the statistics and locating cause (surgery, radiotherapy or neither), rather than psychological wellbeing and real life impact. Having completed this research I

[1] I have referred within this paper to the practice of neuropsychologists, but this may also refer to clinical psychologists who work in neuropsychological and health settings, or even to wider mental health professionals.

feel that this early feeling was reflected in the experiences of my participants, who struggled as much with a lack of information and understanding as actual cognitive difficulties. As a result I felt there was a significant gap in qualitative research which explored the experiences of people with a pituitary tumour, and even more so a gap around cognitive difficulties and subsequent neuropsychological involvement.

Selection of a Qualitative Approach

Having conducted both quantitative and qualitative studies in the past I felt I had both options open to me when deciding how to conduct this research study. My own preference as a researcher was towards taking a qualitative approach, as I have found that this is where I find the most professional and personal interest. I have found that my interests in research mirror my interests in clinical practice, which is to help others to explore their own understanding of themselves, and through this for me to understand them. This is closely aligned with Interpretative Phenomenological Analysis (IPA) which posits this process as the double hermeneutic involvement, where the researcher is making interpretations about the interpretations of the participant (Smith, Flowers & Larkin, 2009). I felt that for the issue of cognitive difficulty and resulting neuropsychological involvement, my interest lay with exploring the potentially subtle and complex experiences of people with a history of pituitary tumour. I felt that a qualitative approach was the best way to achieve this aim, and IPA in particular seemed to fit with what I wanted to achieve.

Issues Arising During the Research Process

One of the early difficulties in developing this research was establishing a strong proposal for why pituitary tumour was justifiably different enough from other tumour types or other forms of brain injury, to warrant specific exploration of cognitive problems and neuropsychological testing. My academic supervisor expressed reservations about whether this could be achieved and challenged me to find explicit ways in which I could justify this.

For me, the process of trying to find these justifications highlighted a wider issue. There is an increasing amount of pressure for health research itself to be evidence based. In order to conduct a study, researchers are encouraged (as I was) to think not just about whether a study has been done before, but why past research would suggest a need for it, why now is the right time for the research and how any contribution would be both novel and of utility to practitioners.

Whilst I recognise the above factors as important, I also felt that to some extent they restrict research practice, particularly the idea of exploratory research in fields which have little prior work. The potential differences in practice between pituitary tumour and other tumour types was one such area. My clinical experience (and that of my supervisor) suggested that people with a pituitary tumour often do not expect cognitive problems (particularly memory, concentration and executive problems) and this can cause difficulty in their personal lives and ability to work. There is, however, no prior research examining this idea, so finding research based justification for exploring this was difficult. I therefore had to rely on the types of research outlined in my introduction to demonstrate the potential for cognitive difficulties, the ongoing debate about the cause of cognitive problems and the wider qualitative experiences of people with a pituitary tumour. In doing this I was able to justify the components of my study (cognitive problems and neuropsychological testing), whilst recognising that the foundation of this study was exploratory and that only through some non evidence based exploration (e.g. experiences of services) could the current evidence be expanded in a meaningful way.

Having established the project I wished to pursue, I needed to consider the best way to recruit, and felt I wanted to do this as broadly as possible within the scope of my study. I explored the various charities and services which are involved with people with a pituitary tumour and found a community of people who often actively wanted to tell their story in

newsletters and social media groups, but who also seemed to express a sense of isolation and disconnection. As I began to recruit, the majority of people who contacted me were those who had had a pituitary tumour and were experiencing cognitive difficulties, but who had had no involvement with neuropsychological services. These people could not participate in the study I designed, but still shed light on an important feature of this study. My participants had all received neuropsychological input, and whilst this had often been hard won and fought for, it had been a valuable resource. The people contacting me had not received this support, most had no understanding of what neuropsychological services were, and a few said they had just been unable to access neuropsychology. This situation was complex, as my desire for these people to receive neuropsychological support clashed with the ethical restrictions of my study and who could participate. Some discussions with my academic supervisor led me to a specific approach of giving a brief explanation of neuropsychology to those who asked to know more, and providing ways they could explore the availability of these services for themselves (online, through GP, through endocrinology).

I believe the numbers of people with a pituitary tumour who told me they were experiencing cognitive difficulties but had no knowledge of neuropsychological services is perhaps mirrored in existing research, where cognitive problems are discussed, but neuropsychological input is rare. People with a pituitary tumour may well have cognitive difficulties, but support and neuropsychological input is rarely discussed. It is important to me here that I recognise this is not the case for everyone; I have certainly seen within my clinical practice that some services have excellent practices for the referral of people with pituitary tumour and cognitive difficulties. However, positive referral practices have seemed to depend on the approach taken by individual medical and nursing professionals, rather than any fixed referral pathway. Were I designing a further study, or a study whose results could

adjoin those here, I could focus on this issue and explore pituitary tumour services nationally, looking for strengths, weaknesses, commonalities and differences in current practice.

Another issue with recruitment was a markedly poor response rate to a broad recruitment strategy. Whilst I believe firmly that I recruited enough participants to gain interesting and useful results using interpretative phenomenological analysis (IPA), my early hope had been to recruit around 12 participants. I believe a number of factors could have contributed to this problem with recruitment. The first I have already discussed, which is that a large number of people with pituitary tumour and cognitive problems have no knowledge of neuropsychology and are not referred. Some support for cognitive problems may also be being offered by other professionals (including medical and nursing staff and charitable organisations) outside neuropsychology, particularly when problems are relatively minor. Next I would want to consider whether the energy and motivation levels of people with a pituitary tumour led them to consider participation as too difficult. With hindsight I could perhaps have given more reassurance of my ability to tailor the process to participants' needs. I also consider whether for some, their trust in professionals has been so damaged that they had no desire to have further interaction with a health care professional such as myself. Lastly I am aware that my use of only one National Health Service (NHS) site could have limited my participant pool. I did make contact with a number of services, but due to practical constraints, time constraints and being unable to find staff willing to support the project, I was unable to recruit further in the NHS. Two sites did express interest, but raised concern that they were unaware of participants suitable to my recruitment, which further highlights a lack of people coming through some neuropsychological services with pituitary tumour.

For those who did participate there were a number of ethical considerations which are outlined in the ethics section of this thesis, beyond these there were issues which arose as the research was conducted. The difficult ongoing relationships that some participants described

with professionals required me to consider my role. I had to decide between listening and recording only, or helping participants, after the interview, to explore options going forward. Following early interviews, and after discussions with my supervisors, I decided that my primary role was to listen to participants and help them explore these difficulties for themselves, within the context of my research. However, I also ensured that I was able to give participants general information about services that they could talk to (such as patient liaison services) should they express a wish to do so during the interview or afterwards.

There were some practical issues such as the use of medication that raised concerns during the interviews. For example one participant was unsure about potential contraindicated medications that they had recently started. They stated that they were unsure about this and were waiting for the next appointment with their doctor to discuss it, but continuing to take their medication. Again after discussion with my supervisor, I contacted the participant to encourage them to contact their doctor or GP to discuss the issue. This type of issue meant taking an individual approach to participants and being able to respond in a dynamic way to issues that may present.

The energy levels and stress tolerance of participants was an ongoing consideration for me. I needed to be aware of the obvious and subtle signs of fatigue and distress throughout my interviews and to respond to these. For example if a participant seemed to be tiring, I offered a break, or to return at another time. If a participant was in distress I offered a pause in the interview, a break, or further discussion with me about this, depending on what they preferred. No participant chose to end an interview early and distress was rare overall, but I believe these small adaptations and responses helped participants to contribute in the most positive way possible. I also ensured that participants knew they could contact me after the interview if there were things they wished to say or had forgotten to say, though no one

chose to do this. All participants expressed a desire to see the results of the study, which for me demonstrated positive engagement and experience.

The last issue I will consider here is the supervisory relationship with my academic supervisor throughout this process. This relationship was crucial to my research and for the most part was a positive experience, but there were challenges. Given the important nature of the supervisory relationship (Eley & Jennings, 2005), we both agreed that reflection on the challenges here would be valuable. I have already discussed the emphasis my supervisor had placed on forming a project which was distinctive enough to be justifiable. At times I found it difficult to match what I was being asked for with how I felt about conducting this research. It was only in the later stages of the project, as I became more confident with my work and my understanding of the evidence base, that I was able to adequately express how I felt about the exploratory nature of this study and how valuable I felt this could be. After we had come to this understanding, both our positions became clearer to the other. Reflecting on this, I believe this represents the development of independent thought and understanding that can and should happen during a project such as this. My early understanding was drawn largely from my supervisors, and I based my ideas and work on their advice. As I learnt more and became more comfortable with my own understanding, I was able to better form my own interpretations and integrate my supervisors' thoughts with my own, to produce work which I can confidently say is my own.

The issue of expression and clarity was present throughout the supervisory process. An example of this was during the development of the search terms for the literature review. In choosing search terms, I initially used terms which would cover only around 90% of brain tumours. I did this as I had never seen extensive lists of terms which I thought would be required to cover all brain tumour morphologies. When I discussed this with my supervisor he expressed that he felt I was not being honest, and that my more limited list was the result

of trying to reduce the amount of work I needed to do. This conversation left us both frustrated and unfortunately happened just before a holiday period, making further discussion difficult. I felt hurt by the accusation of being dishonest, and my supervisor believed that I was not making appropriate effort. I do not believe that during this conversation either of us expressed our point of view particularly well, though I cannot speak directly for my supervisor. In our next meeting we both felt the need to discuss this issue further, and were able to honestly and clearly discuss our feelings and come to a better understanding. I was able to understand my own position better, to reflect carefully on why my supervisor felt as they did and to consider how I would act on this going forward. For me the biggest development from this was a determination to prove myself capable, and to ensure that my project was as good as I could make it, both for myself and to value the contributions of my participants. This is not to say that I did not want to produce a good project before this, only that I was able to recognise how best to achieve and demonstrate this more widely.

Reflection on Results and Implications

The research study has provided an exploration into the experiences of people with a pituitary tumour who experience cognitive difficulties and subsequently interact with neuropsychological services. Participants here were each at different stages of the change and adjustment process following the exposure of cognitive difficulties as a result of pituitary tumour and treatment. As discussed within the research paper, participants experiences can be likened to a grief reaction and the stages of change and adjustment can be applied to the stages of grief model presented by Kubler-Ross (1969).

The reason for examining these results in comparison to a model of grief is to highlight the profound sense of loss that participants expressed throughout their interviews. People who have lost cognitive function have not just lost practical skills, but their known way of life. For participants here this meant changes in their family and social lives, changes

to their routines and lifestyle, a loss of their ability to work, a loss of independence and importantly a change in and sometimes loss of their sense of self. All of these changes and loss could be linked back to their loss of cognitive function.

Modern criticism has focussed on the over-simplification presented in this model and on the linear, non individual progression of grief presented (Copp, 1998; Corr, 1993). Certainly in this study the grieving process for loss of cognitive function (and thus known lifestyle) was far from linear, and involved both progression and regression between stages and the straddling of multiple stages at once. Despite this, I can see parallels to each of these stages in the experiences of participants in this study, which I have outlined in Box 1.

Box 1 - Participant grief stages based on Kubler-Ross (1969).

Denial - When participants learnt of their cognitive difficulties there was a continuing sense that difficulties were transient and abilities would recover. This belief was often drawn from the lack of discussion of cognitive function during early diagnosis and treatment and the lack of concern from professionals. Eventually the continuing presence of difficulties began to suggest permanence and precipitated a shift in perspective: "as the weeks went by and the months went by it became clear ...that it was a permanent situation so of course then you just rely so much on the understanding and trust of your doctors" (TP5)

Anger – Participants here expressed anger at healthcare professionals for failing to inform them of potential cognitive problems, and for not taking them seriously when they discussed cognitive difficulties

> "I recounted my problems to him [consultant] and he would just come back and I have to say the tones of the letters…it feels a bit like somebody slapped you across the face because they do this thing which is 'TP7 reports, however everything is fine'…you sort of lose the respect...it's as though you're constantly being put down" (TP7)

Additionally there was notable anger around the difficulty in accessing support and services such as neuropsychology.

Bargaining – This is best characterised by participants' use of the speculative 'if only' approach. Participants discussed how, if they had been informed of potential cognitive problems, or had known more about risks, or had been able to access support sooner, things would have turned out differently or at least they would have felt better about how things are

> "...there definitely does need to be some sort of support for people that come out of the operation...[it] needs to be sorted out like asap...because it was horrible... I thought I was dying... there just needs to be more understanding" (TP4)

Depression – Mood difficulties were highly prevalent here. Low mood permeated a variety of experiences, from pre diagnosis to final acceptance. Low mood was changeable, and subject to the influence of external and internal factors such as social situation, support, or current thinking processes: "[reading a letter] his sleep is poor and he is frequently tearful and agreed that he is depressed at the moment which is another factor ...to these collapses" (TP3)

Acceptance – As discussed in both the 'Life will never be the same' the 'Learning to cope' themes, acceptance was an eventual end point for a number of participants. Acceptance was sometimes a positive way to move forward, and sometimes a cause of further low mood as the permanency of their situation became apparent: "I tell the doctors look I've got it, lets get on with it" (TP6)

The emotion that participants attributed to their experience of cognitive difficulties is in stark contrast to the way they described the balance of their care. Much like my exploration of literature, participants experienced a much greater focus from professionals towards physical health over psychological and cognitive wellbeing. The description by

participants of needing to convince some professionals that they were experiencing cognitive difficulties could be concerning, and would warrant further exploration within pituitary services. This could be achieved through audits of current practice and knowledge, through further research into the relationships between pituitary patients and professionals and through the sharing of existing positive practice amongst professionals. As noted in the discussion section of the research report, it is possible that a significant number of people with a history of pituitary tumour either choose not to pursue support, or are unable to, because of barriers currently in place.

The relationship between patients and the professionals involved in their care is important in factors such as wellbeing (Kelley, Kraft-Todd, Schapira, Kossowsky & Riess, 2014) and treatment adherence (Moore et al., 2004). Early relationships with professionals will form the foundation of trust in healthcare services, which will impact on future interactions. This could be considered in the context of attachment theory, which would highlight the importance of early positive interactions in building strong relationships and how these interactions will affect future relationship building (Bowlby, 1973; Silver, 2013). For neuropsychologists the consideration is often of the importance of the therapeutic relationship (Horvath & Symonds, 1991; Lambert & Barley, 2001; Martin, Garske & Davis, 2000), but the ability to establish a positive therapeutic relationship may be coloured by earlier interactions with other professionals. In considering this it may be beneficial to future therapeutic relationships for neuropsychologists to be involved in care during the early stages of diagnosis (providing the client wishes this).

The consistent discussion by participants was that positive relationships with professionals were damaged by a lack of information (and thus preparedness) regarding cognitive difficulties. This poses a broader issue regarding informed consent as part of the treatment process. Informed consent regarding care is a fundamental right of anyone

receiving treatment in UK health services (Department of Health, 2013). If people with a pituitary tumour are not made aware of all of the possible consequences to their diagnosis and treatment, it could be argued that they are not being given enough information to make fully informed decisions. By increasing access to this information through the methods described in the research paper, clinicians can be more fully assured of their clients' comprehensive understanding when making decisions.

Lack of information provision is an issue which, as already discussed, needs further exploration. Without the firsthand accounts of professionals it would be difficult to speculate as to why information regarding cognitive difficulties was not presented to the participants of this study. Additionally, without further information, it would be inappropriate to assume that the experiences of participants here is representative of wider experience.

Reflections on Limitations and Future Research

The issue of diversity in recruitment presented in the research paper poses questions about why only a demographic of Caucasian, England based candidates who all described previous professional occupations was recruited. Given the small numbers involved this could be attributed to chance. However I would also suggest the possibility that at least some participants here were those with the knowledge, experience and confidence to have sought out neuropsychological assessment. Additionally, as mentioned in the research paper, this sample may have constituted those people more likely to have confidence in presenting and discussing their negative experiences with professionals.

One of the early plans for this study was to recruit those whose experience of neuropsychological testing had been within one year of their recruitment. During discussions with supervisors and potential recruitment sites it became clear that the potential participant pool would not support this, and that this restriction would need to be removed. Unfortunately this meant that it became more difficult to use results from this study to

compare directly to the current practices and protocols of pituitary services. However, most participants had fairly recent experience of interacting with a variety of professionals regarding their difficulties, and their discussions regarding cognitive difficulties remained problematic. The results of this study should also provide a context for the discussion of current treatment protocols and quality of life (Capatina et al., 2013). Whilst recent treatment developments may offer increased quality of life and fewer potential cognitive difficulties, it should be remembered that participants here were told the same thing about hormone replacement and were invariably disappointed. Realistic and strongly evidence based information should form the foundation of information provided to people with a pituitary tumour.

Conclusion

Through this critical appraisal I have hoped to present my reflections on a variety of the issues which are pertinent to this research. I have aimed to demonstrate that whilst this research project is not without flaws, the information presented in the results and discussion still represent a novel and useful set of information which can help to expand current understanding of the experience of people with a pituitary tumour. Conducting this research, particularly being given access to participants' stories, has been a privilege for me, and my biggest aim is to ensure that the time, effort and contributions of all involved are given the best chance to make a difference to the lives of people with pituitary tumours.

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Section Four: Ethics

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Doctorate in Clinical Psychology

Division of Health and Medicine, Lancaster University

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Integrated Research Application System (IRAS) Application Form

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Experiences of neuropsychological assessment in pituitary tumour

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
(●) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (•) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

( ) Yes (•) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

( ) Yes (•) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (•) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
This is a thesis project to be submitted in partial fulfilment of the requirement for the Lancaster University Doctorate in Clinical Psychology.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research involving qualitative methods only

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Experiences of neuropsychological assessment in pituitary tumour

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

How do people with a pituitary tumour experience cognitive difficulties and neuropsychological testing?

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Mr	Ben	Dawson
Address	2 Grange Avenue Rossendale Lancashire		
Post Code	BB47SA		
E-mail	b.dawson@lancaster.ac.uk		
Telephone	07530284427		
Fax			

Give details of the educational course or degree for which this research is being undertaken:
Name and level of course/ degree:
Doctorate in Clinical Psychology

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
Address	[redacted]		

	[redacted]
Post Code	[redacted]
E-mail	[redacted]
Telephone	[redacted]
Fax	[redacted]

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Mr Ben Dawson	☑ [redacted]

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- (●) Student
- ( ) Academic supervisor
- ( ) Other

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Mr Benjamin Dawson
Post	Trainee Clinical Psychologist
Qualifications	BSc (Hons) Psychology
Employer	Lancashire Care NHS Foundation Trust
Work Address	Floor C, Furness Building
	Lancaster University
	Lancaster
Post Code	LA1 4YG
Work E-mail	b.dawson@lancaster.ac.uk
* Personal E-mail	bd1pls@hotmail.co.uk
Work Telephone	07530284427
* Personal Telephone/Mobile	07530284427
Fax	01524592401

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title Forename/Initials Surname
	Ms Debbie Knight
Address	Research Support Office

	B58 Bowland Main
	Lancaster University
Post Code	LA14YT
E-mail	ethics@lancaster.ac.uk
Telephone	01524592605
Fax	01524843087

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	N/A
Sponsor's/protocol number:	
Protocol Version:	1
Protocol Date:	
Funder's reference number:	
Project website: N/A	

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

This study will explore the experience of cognitive difficulties and neuropsychological testing in patients with a pituitary tumour. The study will aim to recruit 8-12 participants who will be interviewed individually using semi-structured interviews. The results of this study will be analysed using Interpretative Phenomenological Analysis (IPA)

There will be three types of recruitment: Firstly NHS patients will be recruited via multiple NHS sites. Secondly recruitment will be conducted via contact with the local offices of brain tumour and cancer charities. Lastly the study will also be advertised using social media. Further details of each recruitment method can be found in the later sections of this application.

Findings are intended to inform future practice when performing neuropsychological assessments, and managing the care of people who have experienced cognitive impacts from tumour.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study*

and say how you have addressed them.

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Participants are being asked to discuss and consider experiences which are likely to have been distressing. This has the possibility to cause further distress in participants. The study may also be fatiguing for participants and this could cause physical and emotional discomfort. Additionally some participants may be active patients in the NHS and have concerns about the effect of reporting negative experiences on their future treatment. In considering all of these issues it is a clear that a clear and open explanation of the study itself is required before participants agree. Participants will need to be monitored carefully during the study and given the opportunity to fully debrief afterwards by discussing their involvement with myself, their local clinician (where appropriate) or [redacted]. Participants will also be encouraged to carefully consider their participation and reassured about anonymity and support available. Types of available support are discussed on the information sheet and the chief investigator will be able to signpost to local support services. Informed consent for the study must be realistic and accurate to the potential benefits but also the limitations of the study. Feedback of the study results will also be important to help participants see their participation in a meaningful way.

A6-3. Proportionate review of REC application *The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.*

(●) Yes - proportionate review ( ) No - review by full REC meeting

Further comments (optional):

The research does not appear to meet any of the criteria of having a material ethical issue, therefore a proportionate review is requested.

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [x] Qualitative research
- [ ] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

This study will explore the experience of cognitive difficulties and neuropsychological testing in patients with a pituitary

tumour. These findings are intended to inform future practice when performing such assessments, and managing the care of people who have experienced cognitive impacts from tumour.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

N/A

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Around 8-10% of tumours in the UK are located on the pituitary gland within the brain. Almost all are benign (non-cancerous) adenomas and post-mortem examination has revealed that as many as one in four people may have a pituitary adenoma and be unaware of it. Tumours on the pituitary gland are split into two main types: functioning and non-functioning. The former releases excess endocrine hormones such as prolactin, adrenocorticotropic hormone and growth hormone into the blood stream, where the latter does not produce hormones, but can affect the pituitary gland and adjacent brain areas.

The symptoms for both functioning and non-functioning pituitary tumour can range from mild to severe and impact on the physical, cognitive and emotional wellbeing of patients. Specific cognitive faculties such as memory, executive function as well as mood and personality are commonly affected in pituitary tumour patients.

In addition to direct side effects of the tumour, surgical intervention on the pituitary gland can result in permanent damage to the gland and create a range of side effects including cognitive deficits and hormone deficiency. Radiotherapy as a common treatment for pituitary adenoma may also negatively impact cognitive function and quality of life though the evidence for this is less clear when compared to surgery alone.

The role of clinical neuropsychological services in patients with pituitary tumour includes the assessment and monitoring of cognitive function and providing psychological and rehabilitative support. The main aims of cognitive testing are to provide a functional assessment of cognitive abilities and to aid in the design of rehabilitative programs. There is little research surrounding the experience of neuropsychological testing for patients, particularly in the field of brain tumour. Research in the wider spectrum of brain disorder shows that the experience of neuropsychological testing can be influenced by factors such as expectations and preparation, perceived relevance, length of assessment and differences in practice between neuropsychologists. The most common reasons for patient dissatisfaction with testing are a lack of helpfulness in understanding and managing the brain tumour and a lack of help in reducing associated stress. In traumatic brain injury the experience of neuropsychological testing can provoke feelings of anxiety, confusion, anger and frustration and experience can be mediated by factors such as familiarity with assessor and fatigue. Due to the rate of regrowth, the progressive nature of tumours and the potential for surgical and on-going medical intervention, neuropsychological testing for pituitary tumour patients is often extensive and repeated, including large batteries of recommended tests. Patients with a pituitary tumour have described the diagnostic stage of a pituitary tumour as a struggle (sometimes against health professionals) and out of their control. Some of the specific features of pituitary tumour, such as hormonal dysregulation and low rate of malignancy make the experience of testing in this group potentially distinct from other forms of tumour and other brain disorders. The present study seeks to acknowledge and understand the unique nature of testing experiences in pituitary tumour patients.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

This is a qualitative study which will use semi-structured interviews to collect data. Interviews will last approximately 60 minutes and will be conducted in the most convenient place for the participant. This may include on NHS sites, the participants home or another appropriate local venue. Where requested by the participant, interviews can be conducted over multiple (but shorter) interviews, this will help to minimise possible issues with fatigue.

Recruitment:

Initial contact will be made with research sites (R&D departments, local charities and through social media). Following the identification of early sites, ethical approval will be sought from IRAS. Whilst IRAS is reviewing the project, local R&D departments will receive the same documents for review. Once IRAS have granted approval to the study and associated documents, final documents will be sent to local R&D departments for final approval. Following this documents will be distributed to local sites for them to distribute to potential participants. The following breaks down the process for each of the three recruitment arms:

- NHS Sites: Following confirmation of ethical approval, local clinicians at NHS sites will begin to distribute the

participant information sheet and consent form to potential participants. Potential participants will then be able to contact the chief investigator or their supervisors in order to express their interest in participating. Following this contact the chief investigator will discuss the study with the potential participant and if appropriate, arrange a time for an interview. At the interview the chief investigator will confirm all the details on the consent form and ensure the participant has understood and accepted these.Interviews will then be conducted, please see below the recruitment section for details of the process from here.

- Local Charity Organisations: There are a number of local charities such as [redacted] which have involvement with service users who may be suitable candidates for participation. Discussion with regional coordinators for these charities has suggested that the most appropriate way to recruit these service users is to make contact with local branches of the charities when the study is ready to recruit. The chief investigator will then be able to provide confirmation of ethical approval and request that local charity staff distribute the information sheet and consent form to potential participants. Potential participants will then be able to contact the chief investigator or their supervisors in order to express their interest in participating. Following this contact the chief investigator will discuss the study with the potential participant and if appropriate, arrange a time for an interview. At the interview the chief investigator will confirm all the details on the consent form and ensure the participant has understood and accepted these. Interviews will then be conducted, please see below the recruitment section for detailsof the process from here.

- Social Media / Online Recruitment: Recruitment through social media and online recruitment will involve distributing a simple message regarding the study on social media such as Twitter and Facebook and also on internet forums who may have members who would be possible candidates for participation. For details of the messages to be put out, please see the documents attached to this application. Potential participants will then be able to contact the chief investigator or their supervisors in order to express their interest in participating. Following this contact the chief investigator will discuss the study with the potential participant and if appropriate, arrange a time for an interview. At the interview the chief investigator will confirm all the details on the consent form and ensure the participant has understood and accepted these.Interviews will then be conducted, please see below the recruitment section for details of the process from here.

Interviews:

- In addition to the consent information, participants will be made aware that they can opt to be informed of the study results, by either receiving a copy of the study or having a telephone conversation with the chief investigator following successful submission of the research. Interviews will last approximately 60 minutes and will follow the topic guide (see attached documents). Should participants show any signs of distress during the interviews they will be offered the option of a break or to discontinue the interview. After the interview participants will be reminded that should they wish to seek support or advice there are people available to discuss any issues with them.

Post Interviews:

Following the interviews (which will follow a format as laid out in the documents attached to this application) the audio recordings of interviews will be transcribed by the chief investigator. All recordings and transcriptions will be given a pseudonym and any identifying data removed. Transcribed data will be analysed using interpretative phenomenological analysis. This analysis will be checked with both the field and academic supervisor during the process. The final report will be submitted as partial fulfillment towards the Doctorate in Clinical Psychology at Lancaster University. This process involves additional presentation of the study to academic groups and a viva. The study may also be published. Following successful completion of the study, participants will be contacted (if they requested this).

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [x] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Members of the Lancaster University Public Involvement Network were involved in the design stage of this research. If there are any ongoing issues with the management of the study, it is also possible for these service users to be contacted as appropriate. They aided in developing the initial ideas, recruitment process and methodology. Due to the sensitive nature of the subject matter, it would be inappropriate to involve service users in the undertaking of the research or give them access to the results. An appropriate service user will be contacted to support in the dissemination of the research to wider sources.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [x] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [x] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

•Must have experienced a pituitary tumour
•Must have undergone neuropsychological testing
•Latest completed neuropsychological testing appointment is no more than 12 months from date of interview

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

•During initial consultation if the researcher feels the participant will be unable to communicate enough detail about the complex ideas relevant to this study, this will be discussed with the participant and supervisors and may result in exclusion from the study.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Discussing participation and gaining signed consent	1	0	15 Minutes	Chief Investigator, location as suits the participant
Interview	1	0	1 Hour	Chief Investigator, location as suits the participant
Final Contact (if requested)	1		15-30 Minutes	Via Telephone, or face to face, at location as suits the participant.

A21. How long do you expect each participant to be in the study in total?

Participants will usually only attend one approximately 60 minute interview. This may be adapted into multiple shorter interviews for participants who request or require this. Following interview the participants will have no further contact with the research team unless they make contact to have their information removed. Average participation will therefore last between 1 day to 1-2 weeks.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

These risks and measures taken are discussed as part of section A6-2.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(●) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

Participants are being asked to discuss and consider experiences which are likely to have been distressing. This has the possibility to cause further distress in participants. The study may also be fatiguing for participants and this could cause physical and emotional discomfort. Additionally some participants may be active patients in the NHS and have concerns about the effect of reporting negative experiences on their future treatment. Participants may also disclose information about a clinician which is of concern, this would be discussed with the academic supervisor from Lancaster University and reported via appropriate channels if required. In considering all of these issues it is a clear that a clear and open explanation of the study itself is required before participants agree. Participants will need to be monitored carefully during the study and given the opportunity to fully debrief afterwards by discussing their involvement with myself, their local clinician (where appropriate) or [redacted]. Participants will also be encouraged to carefully consider their participation and reassured about anonymity and support available. Types of available support are discussed on the information sheet. Feedback of the study results will also be important to

help participants see their participation in a meaningful way.

A24. What is the potential for benefit to research participants?

There are no direct benefits to participants. Participants will be informed that their participation could help to gather information which could be used to develop better services for pituitary tumour patients in future.

Participants will be able to claim up to £10 in travel expenses for any travel related to the interviews. Participants will be offered these forms before and after interviews and this is mentioned on the participant information sheet.

A26. What are the potential risks for the researchers themselves? *(if any)*

It is possible that the researcher may be required to conduct interviews at participants homes. If this occurs, the researcher will use Lancaster University's Guidance on Safety in Field Work document to ensure safe practice.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).*

For NHS sites: Clinicians who may have potential patients who meet the inclusion criteria will be asked to provide the information sheet and consent information to their patients.

For local charity recruitment: Local contacts for each relevant charity will be asked to provide the information sheet and consent information to any member they think may meet the inclusion criteria. Or to distribute this information to support groups and other group activities and potential participants can make contact with the chief investigator to discuss.

For Social Media / Online Recruitment: Recruitment messages will be posted on potential sites for recruitment and to social media sites such as Facebook and twitter. Wherever possible the appropriate owner/moderators of the sites will be contacted to request permission before posting for recruitment.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(●) Yes ( ) No

Please give details below:
At local NHS sites clinicians who work with patients that may meet the inclusion criteria will be asked to screen against the inclusion criteria and provide information sheet and consent forms to their service users. At no point will anyone outside the service user's direct care team have access to personal information, unless the potential participants make contact with the chief investigator first and provide this information themselves.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

As detailed above only members of the direct care team will have access to identifying data until the service user makes contact with the research team. Additionally local staff will not be informed which of their service user's have opted to participate in the study.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

○ Yes ◉ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

Please see sections A13 and A27-1 for details of how and where public recruitment will be conducted. A copy of the messages to be advertised is attached to this application.

A29. How and by whom will potential participants first be approached?

The participant information sheet will be distributed as follows:
-In NHS recruitment – Participants will be offered the information sheet and consent form by their clinician when they attend an appointment at the local departments.
-In charity recruitment – The information sheet and consent form will be available online (for people viewing the online advertisement) and this link has been given in documentation, the forms can also be requested in paper copy by contacting the chief investigator. The information sheet and consent form will also be offered by local charity staff as appropriate, such as at local group meetings.
-In social media recruitment – The information sheet and consent form are available to view online and potential participants can contact the chief investigator or another member of the research team. Potential participants can also print off and mail the expression of interest form.
-In all three cases the chief investigator will also offer an additional copy of the information sheet and consent form when making contact with participants and before the start of any interviews. This will help to ensure they have read and understood all aspects of the information.

If the chief investigator is contacted by a potential participant who is unsuitable for the study, as determined by the inclusion and exclusion criteria, the chief investigator will make contact with the participant by their preferred method of communication. The chief investigator will thank the person for their interest in the study and explain that the study can only recruit people who meet the specific criteria for participation. This will done in a polite and respectful manner and the chief investigator will endeavour to ensure that no offence is caused to the potential participant. The chief investigator will also remind the person that if they have any concerns or complaints about the study, the information sheet has contact information which will assist them.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Participants will all receive a written information sheet and consent form and will be asked, at interview, to sign the consent form. The information contained on these forms will be discussed with potential participants, prior to commencing the interview, in order to ensure understanding and informed consent.

The chief investigator will offer a copy of the information sheet and consent form when participants first make contact (this can be emailed or mailed in paper form) and before the start of any interview. The chief investigator will attend each interview with copies of each sheet, to ensure there is a paper copy available for the participant to refer to.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

(●) Yes ( ) No

A31. How long will you allow potential participants to decide whether or not to take part?

Recruitment will be ongoing for a 2-3 month period, participants will be able to decide at any point up to the end of this period whether they wish to participate. There will be no other deadline from the time when they receive the information sheet.

After participating in an interview, participants will have up to 2 weeks to withdraw their information from the study. This has been noted on the information sheet and consent form.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

No participants will be recruited who do not have a level of English language skills of an adequate level to understand verbal explanations and the written information.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

(●) The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

( ) The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

( ) The participant would continue to be included in the study.

( ) Not applicable – informed consent will not be sought from any participants in this research.

( ) Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [ ] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals

- [x] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [ ] Manual files (includes paper or film)
  - [ ] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:
Information relating to all participants will be anonymised and no identification of participants will be possible for anyone except the chief investigator. Digitised versions of the participants signed consent form will be stored securely, but these will not be able to be linked with transcriptions.

Audio recordings of interviews will be done on an encrypted device, provided by Lancaster University, and these files will be transferred to university servers as soon as interviews are complete. All audio recordings will be as free as possible of any identifying information (participants will be reminded to avoid identifying information during discussions) and stored securely, including password protection, on university servers.

Once transcription is complete the audio files will be destroyed. Lancaster University will hold copies of all electronic documents such as transcription files and consent forms for a mandatory period of 10 years, after which they will be destroyed.

The only personal and potentially identifying data will be the consent form signed by the patient. These will stored securely at Lancaster University and will not be traceable to individual data once it has been merged into the main analysis.

All publication of direct quotes will be fully anonymised.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Audio recording will be done on an encrypted device provided by Lancaster University, following interview these files will be transferred directly to the Lancaster University secure servers and password protected. These will then be transcribed and deleted, leaving only the transcription files.

Transcription files and digitised consent forms will be stored on the secure Lancaster University servers for a mandatory period of 10 years, after which they will be destroyed. Paper copies of consent forms will be destroyed after they are digitised.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All participant data will be anonymised and given a pseudonym for the duration of the study and for the purposes of publication. Signed consent forms will be stored confidentially and at no time will any confidential information, gained by the chief investigator, be shared with any member of the research team or local staff members.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

No one outside the potential participant's direct care team will have access to participants personal information prior to the potential participant making contact with the researcher.

At this point only the chief investigator will have access to any personal information. This has been made clear on all participant information.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Audio files will be transcribed on the Lancaster University secure servers and transcription files will be stored securely here. All transcription will be done by the chief investigator alone. Following the interview all data will be anonymised and given pseudonyms. The academic and field supervisors will have access to anonymised data in order to help with some data analysis.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Jane	Simpson
Post	Researcher Director		
Qualifications	DClinPsy		
Work Address	Department of Clinical Psychology		
	Furness Building		
	Lancaster University		
Post Code	LA1 4YW		
Work Email	j.simpson@lancaster.ac.uk		
Work Telephone	01524592858		
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- (●) Less than 3 months
- ( ) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years
- ( ) Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

After the study is complete all files will be transferred to an encrypted memory stick and stored by the Clinical Psychology Doctorate programme at Lancaster University until the end of the mandatory 10 year storage period.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

(●) Yes ( ) No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
Participants will be entitled to up to £10 to cover travel expenses for their participation in research interviews. This amount is determined by the maximum allowance given by the Lancaster University Doctorate in Clinical Psychology programme. There will be no other payments or benefits.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50-1. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
The study will be registered with R&D department of all local services approached and with the IRAS ethics approval system. The study will also be registered with Lancaster University's research department. This is in accordance with policies from all relevant ethics bodies.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☐ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

N/A

A53. Will you inform participants of the results?

(●) Yes ( ) No

Please give details of how you will inform participants or justify if not doing so.
Participants will be given the choice of whether or not they wish to be informed of study results. If they do they will be asked whether they wish to receive a summary report or a have a telephone conversation with the chief investigator following conclusion of the study.

5. Scientific and Statistical Review

A54-1. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [x] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
In accordance with the requirements of the Lancaster Doctorate in Clinical Psychology, the project will be received by the universities research department before the provide indemnity insurance and approval for the project to continue. The project was also approval by the internal research team at Lancaster University Doctorate in Clinical Psychology.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	10
Total international sample size (including UK):	10
Total in European Economic Area:	

Further details:
Approximately 8-12 participants will be recruited.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The sample size is based on a number of sources of information for Interpretative Phenomenological Analysis which give a standard size of 4-6 as appropriate, with more for a doctoral level study. In this way the numbers were doubled for this study.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by

which the data will be evaluated to meet the study objectives.

The data will be analysed using interpretative phenomenological analysis.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co–applicants, protocol co–authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

[redacted]

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Debbie
Family name	Knight
Address	Research Support Office, B58 Bowland Main, Lancaster University
Town/city	Lancaster
Post code	LA1 4YT
Country	UNITED KINGDOM

Telephone	01524592605
Fax	
E-mail	ethics@lancaster.ac.uk

Is the sponsor based outside the UK?
○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☐ Funding secured from one or more funders
☐ External funding application to one or more funders in progress
☑ No application for external funding will be made

What type of research project is this?

◉ Standalone project
○ Project that is part of a programme grant
○ Project that is part of a Centre grant
○ Project that is part of a fellowship/ personal award/ research training award
○ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

[redacted]

Mobile

[redacted] http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/10/2014
Planned end date: 31/05/2015
Total duration:
Years: 0 Months: 7 Days: 31

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 4

Does this trial involve countries outside the EU?
○ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	2
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☑ Independent (private or voluntary sector) organisations	2
☐ Educational establishments	
☐ Independent research units	

☐ Other (give details)

Total UK sites in study: 4

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

Academic and Field supervisors will monitor the conduct of the research.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☐ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

[redacted]

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

(●) Chief Investigator

( ) Sponsor

- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature: .....

Print Name: Ben Dawson

Date: 09/09/2014 *(dd/mm/yyyy)*

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

Signature: .....

Print Name:

Post:

Organisation:

Date: *(dd/mm/yyyy)*

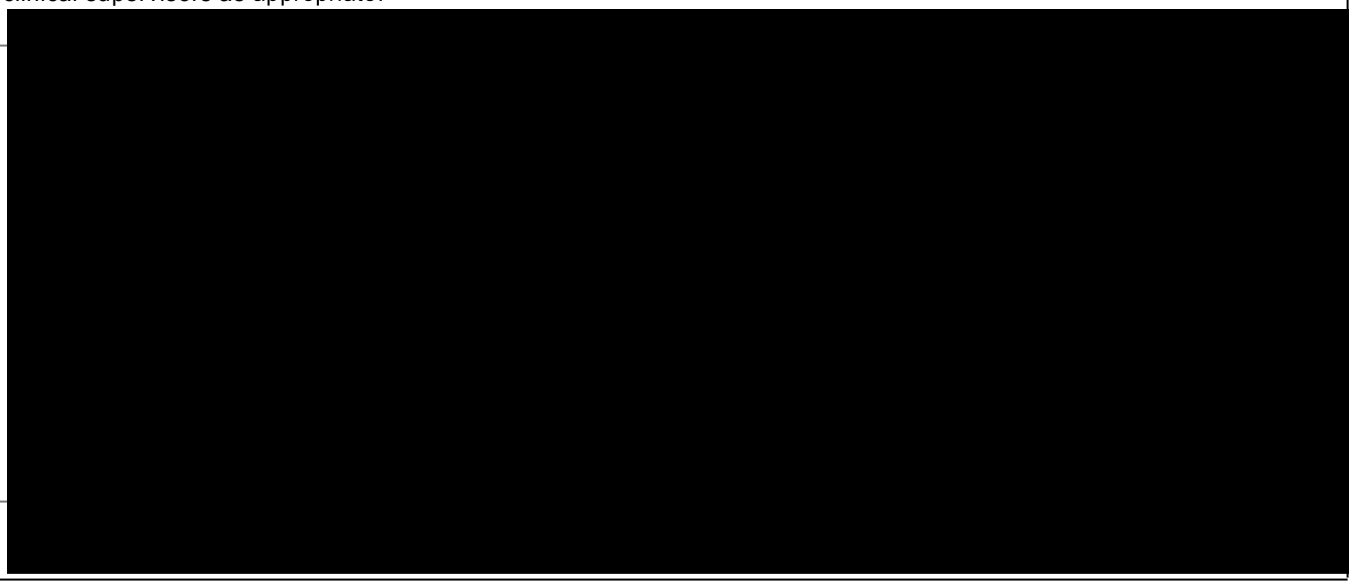
D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.



Research Protocol – Lancaster DClinPsy Service Related Project

Study Title:

How do people with a pituitary tumour experience cognitive difficulties and neuropsychological testing?

Student / Researcher: Ben Dawson (Trainee Clinical Psychologist)

Field Supervisor: [redacted]

Academic Supervisor: [redacted]

Introduction

Around 8-10% of tumours in the UK are located on the pituitary gland within the brain (Cancer research UK, 2014). Almost all are benign (non-cancerous) adenomas and post-mortem examination has revealed that as many as one in four people may have a pituitary adenoma and be unaware of it (American Cancer Society, 2014). Tumours on the pituitary gland are split into two main types: functioning and non-functioning. The former releases excess endocrine hormones such as prolactin, adrenocorticotropic hormone and growth hormone into the blood stream, where the latter does not produce hormones, but can affect the pituitary gland and adjacent brain areas.

The symptoms for both functioning and non-functioning pituitary tumour can range from mild to severe and impact on the physical, cognitive and emotional wellbeing of patients. Specific cognitive faculties such as memory and executive function (Grattan-Smith, Moms, Shores, Batchelor, & Sparks, 1992; Peace et al.,1997) as well as mood (Guinan, Lowy, Stanhope, Lewis, & Kopelman, 1998) and personality(Pereira, Tiemensma, Romijn, & Biermasz, 2012) are commonly affected in pituitary tumour patients.

In addition to direct side effects of the tumour, surgical intervention on the pituitary gland can result in permanent damage to the gland and create a range of side effects including cognitive deficits and hormone deficiency (Taphoorn & Klein, 2004). Radiotherapy as a common treatment for pituitary adenoma may also negatively impact cognitive function and quality of life (Noad, Narayanan, Howlett, Lincoln & Page, 2004) though the evidence for this is less clear when compared to surgery alone (van Beek et al, 2007).

The role of clinical neuropsychological services in patients with pituitary tumour includes the assessment and monitoring of cognitive function and providing psychological and rehabilitative support. The main aims of cognitive testing are to provide a functional assessment of cognitive abilities and to aid in the design of rehabilitative programs (Vakil, 2012).

There is little research surrounding the experience of neuropsychological testing for patients, particularly in the field of brain tumour. Research in the wider spectrum of brain disorder shows that the experience of neuropsychological testing can be influenced by factors such as expectations and preparation, perceived relevance, length of assessment and differences in

practice between neuropsychologists (Bennett-Levy, Klein-Boonschate, Batchelor, McCarter & Walton, 1994).

The most common reasons for patient dissatisfaction with testing are a lack of helpfulness in understanding and managing the brain tumour and a lack of help in reducing associated stress (Westervelt, Brown, Tremont, Javorsky & Stern, 2007). In traumatic brain injury the experience of neuropsychological testing can provoke feelings of anxiety, confusion, anger and frustration and experience can be mediated by factors such as familiarity with assessor and fatigue (Owen, 2012). Due to the rate of regrowth, the progressive nature of tumours and the potential for surgical and on-going medical intervention, neuropsychological testing for pituitary tumour patients is often extensive and repeated, including large batteries of recommended tests (Ferguson, Iverson & Schoenberg, 2011).

Patients with a pituitary tumour have described the diagnostic stage of a pituitary tumour as a struggle (sometimes against health professionals) and out of their control (Simpson, Heath & Wall, 2014). Some of the specific features of pituitary tumour, such as hormonal dysregulation and low rate of malignancy make the experience of testing in this group potentially distinct from other forms of tumour and other brain disorders. The present study seeks to acknowledge and understand the unique nature of testing experiences in pituitary tumour patients.

Research Objectives

This study will explore the experience of cognitive difficulties and neuropsychological testing in patients with a pituitary tumour. These findings are intended to inform future practice when performing such assessments, and managing the care of people who have experienced cognitive impacts from tumour.

Methodology

Design: This is a qualitative study which will use semi-structured interviews to collect data. Interviews will last approximately 60 minutes and will be conducted in the most convenient place for the participant. This may include on NHS sites, the participants home or another appropriate local venue.

Participants: The study will aim to recruit participants who have experienced extensive neuropsychological testing in the last 2 years as a result of a pituitary tumour. Participants will be recruited from multiple NHS sites and through charitable organisations.

Inclusion Criteria:

- Must have experienced a pituitary tumour
- Must have undergone neuropsychological testing
- Latest completed neuropsychological testing appointment is no more than 12 months from date of interview

Exclusion Criteria:

- Must not have communication difficulties which would prevent them from understanding the information sheet and consent form and from participating in complex discussion around their experiences. This will be determined in early discussion with possible participants.

Recruitment Procedure: Initial recruitment will occur using NHS patients from multiple NHS sites. This will be done in liaison with clinicians working with pituitary tumour patients in their respective departments. This will involve initial contact being made with relevant clinicians on site, followed by formal ethical approval from the local R&D department. Following this information sheets (see Appendix 1) will be provided to clinicians. Clinicians will then be able to pass these information sheets on to their patients. This will include active patients and previously discharged patients being contacted by local clinicians. All local R&D sites will have to give formal approval for discharged patients to be contacted Patients will then be able to take the study information and make contact with a member of the research team (likely to be the chief investigator) should they wish to discuss participation. Contact will also be made with local Neuropsychology Special Interest Groups, which bring together regional clinicians who work in the neuropsychology field. If interested these clinicians may then become local collaborators for the research and the above process will be followed for ethical application with R&D departments.

Recruitment will also be conducted via contact with the local offices of brain tumour and cancer charities, to provide information about the study that can be passed on to their members. Members will then be able to contact the research team should they wish to discuss participation.

Recruitment will also be advertised using social media. Where appropriate the chief investigator will contact the owner/moderating team (in the case of online forums) and follow all existing guidelines for research recruitment on broader social media platforms (e.g. Twitter & Facebook). Please see Appendix 3 for a copy of the message which will be used in social media recruitment.
Formal ethical approval will be sought from the NHS Integrated Research Application System (IRAS). IRAS are able to give ethical approval for the recruitment of NHS patients and community based recruitment.

Data Collection Procedure: Once potential participants have made contact, they will be offered the opportunity to discuss further participation in the study and what this will involve. If those who make contact wish to proceed with participation, the chief investigator will then arrange a mutually convenient time and place to conduct interviews. At the beginning of each interview the chief investigator will re-discuss the detail of participation and ask the participant to sign a consent form (see Appendix 2). The interviews will follow the interview schedule available in appendix 4.

Proposed Analysis

The results of this study will be analysed using Interpretative Phenomenological Analysis (IPA). IPA has been chosen for a number of reasons. Firstly there is no predetermined hypothesis to this study and IPA allows a flexible, exploratory approach to examining a research area (Smith, 2008 p.55). IPA is also concerned with detail of human experience but recognises the collection of this data as an interpretative process (Smith, Flowers & Larkin, 2009 p. 32). The chief investigator will be able to use the structure of IPA to reflect on their position when interpreting data and discussing the results. This reflective space is important, as the nature and experience of brain tumours and brain tumour diagnosis are emotive and will be recognise as such in this research.

Sample Size

The sample size chosen for this study is 8-12 participants. The typical sample for an IPA study range from 3 to 6 participants, with larger sample sizes in PhD level research (Smith, Flowers & Larkin, 2009 p. 51). The slightly higher number of participants here reflects the academic level of the research and the desire to find meaningful points of shared experience in this population.

8-12 is also a realistic number of participants to recruit based on the number of potential research sites and recruitment sources. The potential pool of participants at each site varies significantly (particularly in the charitable sector) but NHS and charitable sites should reflect the tumour demographics, in that around 8-10% of their brain tumour population will have a pituitary tumour.

The requirement of IPA to use a homogenous sample will also be met by the study ensuring that all participants have the same specific form of brain tumour (pituitary tumour) and thus will have experienced similar events as a result.

Procedure

Recruitment

Initial contact will be made with research sites (R&D departments, local charities and through social media). Following the identification of early sites, ethical approval will be sought from IRAS. Whilst IRAS is reviewing the project, local R&D departments will receive the same documents for review. Once IRAS have granted approval to the study and associated documents, final documents will be sent to local R&D departments for final approval. Following this documents will be distributed to local sites for them to distribute to potential participants. The following breaks down the process for each of the three recruitment arms:

1. NHS Sites: Following confirmation of ethical approval, local clinicians at NHS sites will begin to distribute the participant information sheet and consent form to potential participants. Potential participants will then be able to contact the chief investigator or their supervisors in order to express their interest in participating. Following this contact the chief investigator will discuss the study with the potential participant and if appropriate, arrange a time for an interview. At the interview the chief investigator will confirm all the details on the consent form and ensure the participant has understood and accepted these. Interviews will then be conducted, please see below the recruitment section for details of the process from here.

2. Local Charity Organisations: There are a number of local charities such as [redacted] which have involvement with service users who may be suitable candidates for participation. Discussion with regional coordinators for these charities has suggested that the most appropriate way to recruit these service users is to make contact with local branches of the charities when the study is ready to recruit. The chief investigator will then be able to provide confirmation of ethical approval and request that local charity staff distribute the information sheet and consent form to potential participants. Potential participants will then be able to contact the chief investigator or their supervisors in order to express their interest in participating. Following this contact the chief investigator will discuss the study with the potential participant and if appropriate, arrange a time for an interview. At the interview the chief investigator will confirm all the details on the consent form and ensure the participant has understood and accepted these. Interviews will then be conducted, please see below the recruitment section for details of the process from here.

3. Social Media / Online Recruitment: Recruitment through social media and online recruitment will involve distributing a simple message regarding the study on social media such

as Twitter and Facebook and also on internet forums who may have members who would be possible candidates for participation. For details of the messages to be put out, please see the documents attached to this application. Potential participants will then be able to contact the chief investigator or their supervisors in order to express their interest in participating. Following this contact the chief investigator will discuss the study with the potential participant and if appropriate, arrange a time for an interview. At the interview the chief investigator will confirm all the details on the consent form and ensure the participant has understood and accepted these. Interviews will then be conducted, please see below the recruitment section for details of the process from here.

Interviews

In addition to the consent information, participants will be made aware that they can opt to be informed of the study results, by either receiving a copy of the study or having a telephone conversation with the chief investigator following successful submission of the research. Interviews will last approximately 60 minutes. Should participants show any signs of distress during the interviews they will be offered the option of a break or to discontinue the interview. After the interview participants will be reminded that should they wish to seek support or advice there are people available to discuss any issues with them.

Post Interview

Following the interviews (which will follow a format as laid out in the documents attached to this application) the audio recordings of interviews will be transcribed by the chief investigator. All recordings and transcriptions will be given a pseudonym and any identifying data removed. Transcribed data will be analysed using interpretative phenomenological analysis. This analysis will be checked with both the field and academic supervisor during the process. The final report will be submitted as partial fulfilment towards the Doctorate in Clinical Psychology at Lancaster University. This process involves additional presentation of the study to academic groups and a viva. The study may also be published. Following successful completion of the study, participants will be contacted (if they requested this).

Practical Issues

An appropriate meeting place will need to be found for each interview. This can be done whilst interviews are being scheduled. These rooms will need to be quiet enough to interview and be at a location where participants feel secure enough to discuss the topic. Some interviews may be conducted on NHS sites and this will be discussed with local R&D departments and made clear on ethical application forms. Some may be at participants homes or local locations, in these cases the chief investigator will follow the lone worker policy set out by Lancaster University. In regards to costs, all photocopying and printing of documents will be done at Lancaster University and therefore the cost will be covered as part of the DClinPsy course. Some minor travel costs (i.e. to participants homes or up to £10 for participants to travel) may be claimed as part of the research, Lastly, as detailed above, all data will be sorted on secure servers at Lancaster University at the earliest opportunity after interview. This is in compliance with data protection policies of the university and local NHS trust.

Ethical Issues

There are some potential ethical issues concerning the participants of this study which have been considered as part of this protocol. Participants are being asked to discuss and consider

experiences which are likely to have been distressing. This has the possibility to cause further distress in participants. The study may also be fatiguing for participants and this could cause physical and emotional discomfort. Additionally some participants may be active patients in the NHS and have concerns about the effect of reporting negative experiences on their future treatment. In considering all of these issues it is a clear that a clear and open explanation of the study itself is required before participants agree. Participants will need to be monitored carefully during the study and given the opportunity to fully debrief afterwards by discussing their involvement with myself, their local clinician (where appropriate) or [redacted]. Participants will also be encouraged to carefully consider their participation and reassured about anonymity and support available. Types of available support are discussed on the information sheet. Informed consent for the study must be realistic and accurate to the potential benefits but also the limitations of the study. Feedback of the study results will also be important to help participants see their participation in a meaningful way.

In addition to these participant-based concerns there are some ethical issues for consideration in the practice of myself as the researcher. Firstly any discussions which prompt concerns about mistreatment of patients will need to be reported to [redacted] for further consideration. All participants will be aware of this process via the information sheet and consent form. There is also a need to protect the anonymity of any staff that may be used as examples during discussion. To ensure this, participants will be asked to try to give alias names to anyone they may discuss in addition during transcription a further randomly selected name will be assigned to anyone mentioned. Interviews may also require me to travel to participants homes or local facilities to conduct interviews, in this case I will adhere to the Lancaster University Lone Worker Policy (See Appendix 5) to ensure my safety.

Timescale

October 2014 – Ethical approval process completed
October/November 2014 – Interviews conducted
October / November 2014 – Interviews transcribed
November / December 2013 – Data analysis
First Draft complete – December 2014 – January 2015
Second Draft complete – January 2015 – February 2015
Final Submission – May 2014.

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Messages for Public Recruitment

Message to be posted on Twitter:

Study looking at experience of people with a pituitary tumour. Please see this website for further details: [redacted] Please RT

Message to be posted on Facebook:

Hi,

My name is Ben Dawson and I am a Trainee Clinical Psychologist at Lancaster University. I'm conducting a research project looking at the experiences of people with a pituitary tumour who have experienced difficulties with cognitive function and have been through neuropsychological testing (such as intelligence tests and other formal tests).

For further information about participating, please read the details on this website:

[redacted]

Thanks,

Ben Dawson.

Message to be posted to Internet forums:

Hi,

My name is Ben Dawson and I am a Trainee Clinical Psychologist at Lancaster University. I'm conducting a research project looking at the experiences of people with a pituitary tumour who have experienced difficulties with cogntivie function and have been through neuropsychological testing (such as intelligence tests and other formal tests).

For further information about participating, please read the details on this website:

[redacted]

Thanks,

Ben Dawson.

Message to be posted on charity websites:

Hi,

My name is Ben Dawson and I am a Trainee Clinical Psychologist at Lancaster University. I'm conducting a research project looking at the experiences of people with a pituitary tumour who have experienced difficulties with cognitive function and have been through neuropsychological testing (such as intelligence tests and other formal tests).

Participating would involve meeting with me for an interview of around an hour at a location convenient to you.

For further information about participating, please read the details on this website:

[redacted]

If you prefer you can contact me at b.dawson@lancaster.ac.uk or by post using the expression of interest form and I will be happy to email or mail you a copy of the information sheet and consent form. By contacting me you are not agreeing to participate and I will not contact you again unless you get back in touch to express your interest in participating.

Thanks,

Ben Dawson.

Participant Information Sheet

How do people with a pituitary tumour experience cognitive difficulties and neuropsychological testing?

My name is Ben Dawson and I am conducting this research as a student of the Doctorate in Clinical Psychology at Lancaster University.

What is the study about?
The purpose of this study is to explore the experiences of patients with a pituitary tumour. I am particularly interested in cognitive difficulties and neuropsychological testing.

Why have I been approached?
You have been approached because you may meet the criteria of having a pituitary tumour, cognitive difficulties and experience of neuropsychological testing.

Do I have to take part?
No, it's completely up to you to decide whether or not you take part but I think your participation can be very valuable and help to make changes to services in future.

What will I be asked to do if I take part?
If you decide you would like to take part, you would be asked to complete an interview of around 1 hour where you will be asked questions about your experiences. These interviews can be at your home, in a local venue or at your hospital, whatever you prefer. If needed this interview can be broken down in to several shorter interviews.

Can I be identified from my data?
All the information you provide is made anonymous after your interview. The data collected for this study will be stored securely and only I will have full access to this data.

- Audio recordings will be encrypted and password protected on a computer, so no one other than me will be able to access them). After they have been transcribed and checked the recordings will be destroyed.
- Your consent form will be stored securely at Lancaster University in a locked cabinet for 10 years, after which it will be destroyed. Your consent form cannot be linked to your data.
- The typed version of your interview will be made anonymous by removing any identifying information, including your name, and will be kept securely in electronic format for 10 years. At the end of this period, they will be destroyed.
- My academic supervisor ([redacted]) will have access to anonymous transcripts to help me analyse the information and my field supervisor ([redacted]) will have access to the data once it has been analysed. You will in no way be identifiable to either of my supervisors.

If something you say during the interview makes me think that you or someone else is at significant risk of harm, I will have to speak to my research supervisor and possibly other services about this. If possible, I will tell you if I have to do this.

What will happen to the results?
The results will be summarised and reported and may be submitted for publication in an academic or professional journal. Anonymous quotations from your interview may be used in the reports or publications from the study.

Are there any risks?

You will be asked to talk about times you have experienced neuropsychological testing and cognitive difficulties, we realise that this could be upsetting and would aim to support you with this. If you experience any distress you can talk to me about this, or any of the contacts at the end of this sheet. I will also be able to signpost you to more support if you feel you need it. Your hospital care will not be affected in any way.

Are there any benefits to taking part?

Although you may find participating interesting, there are no immediate benefits in taking part. After the research has been completed the information may be used to help develop services. If you need to travel to the interview, Lancaster University will pay up to £10 in travel expenses. I can give you the form to claim this either before or after your interview.

Can I withdraw from the study?

You can change your mind about participating at any time before your interview. If you wish to withdraw your interview material after your interview, you can request this up to 2 weeks after your interview and your data will be destroyed. After this your information will have been merged with other data and will not be removable.

Who has reviewed the project?

This study has been reviewed by an NHS Research and Ethics Committee. This is an ethics body that review projects with NHS patients.

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact my project supervisors or me as the main researcher:

Ben Dawson
Trainee Clinical Psychologist
B.dawson@lancaster.ac.uk

I think I want to take part

If you have read all the information and think you want to take part, please look at the Expression of Interest form for details of how to make contact by email or post.

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researchers, you can contact:

Dr Jane Simpson (Research Director)
Tel: 01524 592858
Email:
j.simpson2@lancster.ac.uk
Division of Clinical Psychology
Lancaster University
LA1 4YD

Professor Roger Pickup (Associate Dean for Research)
Tel: 01524 593746
Email: r.pickup@lancaster.ac.uk
Faculty of Health and Medicine
Lancaster University
LA1 4YD

Thank you for taking the time to read this information sheet

Expression of Interest Form

If you have read the information sheet and think that you might want to get some more information or take part in this study, please either contact me on the email address below or send this form back to the address below and I will get in touch with you.

I will contact you to talk more about the study and then I will ask you to confirm that you would like to take part. Then we can arrange a convenient time to meet. I can provide you with electronic or written copies of the information sheet and consent form at any time and these will be available before your interview.

To contact me directly just email me at: **b.dawson@lancaster.ac.uk** or send the below slip with your details to:

Ben Dawson

Clinical Psychology Department

C Floor, Furness Building

Lancaster University

Lancaster

LA1 4YW

I agree to Ben Dawson calling me on the telephone number below to discuss this study, or emailing me on the below email.

My name is _____

Signature:_____

Date:_____

The best telephone number to use is:_____

The best email to contact me with is:_____

Participant Consent Form

Study Title: How do people with a pituitary tumour experience cognitive difficulties and neuropsychological testing?

We are asking if you would be willing take part in a research project aimed at exploring the experiences of patients with a pituitary tumour. The study focuses on experiences of cognitive difficulties and neuropsychological testing.

Before you consent to participating we ask that you read the participant information sheet and mark each box below if you agree. If you have any questions or queries before signing the consent form please contact Ben Dawson, [redacted] (contact details are on the information sheet)

1. I confirm that I have read the information sheet and fully understand what is expected of me within this study ☐
2. I confirm that I have had the opportunity to ask any questions and to have them answered. ☐
3. I understand that my interview will be audio recorded and then made into an anonymised written transcript. ☐
4. I understand that audio recordings will be kept until the research project has been assessed. ☐
5. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐
6. I understand that I have up to two weeks after my interview to ask for my data to be removed from the study.
7. I understand that the information from my interview will be pooled with other participants' responses, anonymised and may be published ☐
8. I consent to information and quotations from my interview being used in reports, conferences and training events. ☐
9. I understand that any information I give will remain strictly confidential and anonymous unless it is thought that there is a risk of harm to myself or others, in which case the main researcher may need to share this information with their research supervisor or other agencies. ☐
10. I consent to Lancaster University keeping my consent form and written transcriptions of the interview for 10 years after the study has finished. ☐
11. I consent to take part in the above study. ☐

Name of Participant: Signature: Date:

Name of Researcher: Signature: Date: ☐

Interview Schedule

Questions about Cognitive Decline

1. Tell me about any cognitive difficulties you have experienced from your tumour or treatment

***Prompts**: What kind of cognitive difficulties did you experience?*
How did your cognitive difficulties affect you?

2. How did you first know you were experiencing cognitive difficulties?

***Prompts**: What alerted you to possible cognitive difficulties?*
Did anyone around you notice difficulties?

3. How did you feel about having cognitive difficulties?

***Prompts**: Did you ever expect some cognitive difficulties?*
Had anyone talked to you about the possibility of difficulties?

Questions about Neuropsychological Assessment

1. Why were you referred for neuropsychological assessment?

***Prompts**: How was the assessment arranged?*
How was the reason for the assessment explained to you?
How did you feel about being referred for assessment?

2. Can you tell me about the assessment you underwent?

***Prompts**: What was the purpose of the assessment?*
How was the assessment explained to you?
How did you feel while you were being assessed?

3. Tell me about the results of the assessment

***Prompts**: What were the main findings?*
What were you told about the results?
How were the results explained to you?
Were the assessment process and the results useful?
How did you feel about the results?

***General Prompts**: Can you tell me a bit more about that? What do you mean by 'X'? How did you feel about that?*

Health Research Authority
NRES Committee East of England - Norfolk
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01 December 2014

Mr Benjamin Dawson
Trainee Clinical Psychologist
Lancashire Care NHS Foundation Trust
Floor C, Furness Building
Lancaster University
Lancaster
LA1 4YG

Dear Mr Dawson

Study title:	**How do people with a pituitary tumour experience cognitive difficulties and neuropsychological testing?**
REC reference:	**14/EE/1255**
IRAS project ID:	**160174**

Thank you for your letter of 27th November 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Lead Reviewer.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Assistant, Tad Jones, NRESCommittee.EastofEngland-Norfolk@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Messages for Public Recruitment]	1	06 November 2014
Copies of advertisement materials for research participants [Messages for Public Recruitment]	2	24 November 2014
IRAS Checklist XML [Checklist_06112014]		06 November 2014
IRAS Checklist XML [Checklist_06112014]		06 November 2014
IRAS Checklist XML [Checklist_26112014]		26 November 2014
Letter from sponsor [Sponsor Letter]	1	21 October 2014
Non-validated questionnaire [Qualitative Interview Schedule]	1	06 November 2014
Other [Expression of Interest Form]	1	24 November 2014
Other [Covering letter for changes following REC]	1	24 November 2014
Participant consent form [Participant Consent Form]	2	24 November 2014
Participant information sheet (PIS) [Participant Information Sheet]	2	24 November 2014
REC Application Form [REC_Form_06112014]		06 November 2014
REC Application Form [REC_Form_26112014]		26 November 2014
Research protocol or project proposal [Thesis Protocol]	4	24 November 2014
Summary CV for Chief Investigator (CI) [Ben Dawson CV]	1	16 October 2014
Summary CV for supervisor (student research) [Academic Supervisor CV]	1	17 October 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received andthe application procedure. If you wish to make your views known please use the feedback formavailable on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/EE/1255	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.Yours

sincerely

Dr Michael SheldonChair

Email:NRESCommittee.EastofEngland-Norfolk@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: [redacted]

Applicant name: Ben Dawson

Supervisor: [redacted] Department: DHR

21 October 2014

Dear Ben [redacted]

Re: How do people with a pituitary tumour experience cognitive difficulties and neuropsychological testing?

The University of Lancaster undertakes to perform the role of sponsor in the matter of the work described in the accompanying grant application. The sponsor as we understand it assumes responsibility for monitoring and enforcement of research governance. As principal investigator you will confirm that the institution's obligations are met by ensuring that, before the research commences and during the full term of the grant, all the necessary legal and regulatory requirements in order to conduct the research are met, and all the necessary licenses and approvals have been obtained. The Institution has in place formal procedures for managing the process for obtaining any necessary or appropriate ethical approval for this grant. Full ethical approval must be in place before the research commences and should be reviewed at all relevant times during the grant.

Yours sincerely,

Fiona Aiken,
University Secretary,
Chair, University Research Ethics Committee.

Cc Sarah Taylor, Secretary, UREC.

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