

**EXPLORING FACTORS ASSOCIATED WITH STRAIN IN CARERS OF PATIENTS
WITH TRAUMATIC BRAIN INJURY**

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Abstract

This study explored what factors are associated with strain in 48 carers of patients with traumatic brain injury (TBI). This was a cross-sectional cohort study of patients who were admitted to a Neurosurgical Unit with TBI over a period of nine years and followed up between five and 14 years post-injury. Their carers were assessed via postal survey for levels of strain using the Caregiver Strain Index (CSI) and asked for their perception of the patients' disabilities using the family form of the Neurobehavioral Functioning Inventory (NFI). Elevated levels of strain were found in 42% of carers. Using logistic regression, outcome as rated by the patients' GP on the Glasgow Outcome Scale (GOS) and all subscales of the NFI (except Somatic) contributed to explain 41 - 57% of the variance in strain, and predicted group membership correctly in 72.9% of cases. No individual variable contributed significantly to the explained variance in the model. The model was not significantly improved after removing outliers. Findings suggest that a number of factors combine to result in feelings of strain and illustrates the difficulty for clinicians to predict when strain may occur. The clinical implications of the study are discussed.

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First of all may I express my gratitude for the help and support provided by my research supervisor, Dr Patrick Vesey, and all of the DClinPsy research tutors, who provided indispensable time and advice. I would also like to thank Dr Paddy Yeoman for his enthusiasm for the research and for allowing me access to his valuable database, without which such research could not have been conducted. Finally, I would like to thank my husband for his patience and for making numerous cups of tea!

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Statement of Contribution

The project was designed by the author (NB), along with guidance from Dr Patrick Vesey and the DClinPsy Research Tutors, who were able to suggest what measures were available and how the study could be practically carried out, as well as supporting the running of the study. The application for ethical review and the literature review were all carried out by the author.

The sample of patients came from a database constructed by Dr Paddy Yeoman. This database had been started for audit purposes on the Neurosurgical Unit at Queens Medical Centre, Nottingham. It contained demographic data and information about the patients' head injuries. Recruitment of patients and carers to this study was undertaken by the author, based on this database.

Collection of data from carers, scoring the questionnaires, data entry and analysis were all undertaken by the author.

Introduction

After active rehabilitation, the responsibility of caring for patients following traumatic brain injury (TBI) usually falls to parents or spouses of the injured person [1]. Family members who provide care for their injured relatives will be referred to as 'carers' for the purposes of this study. The impact of caring on families is an important area for research, as it is 'frequently under-estimated' [2]. As is well documented, carers experience significant strain [3], and this can have effects on a carer's physical health, emotional distress and likelihood of depression [1, 4-6].

It is important to identify what factors are associated with strain in carers, as it may then be possible to identify those at risk of strain and inform interventions and support services for carers. The terms stress, distress, strain and burden are typically used interchangeably and are ill-defined in the literature [7], which means that a reliable estimate for the prevalence of strain in carers is difficult to identify. All of these terms will be referred to in this section and defined whenever possible.

In an attempt to define and measure strain, Connolly and O'Dowd [8] examined the association of carers' levels of strain and stress with five categories of disability following head injury: motor, cognitive, behavioural, perceptual, speech and language. The authors defined carer strain and stress in two different ways using Pearlin, Mullan, Semple and Skaff's [9] model. Here, stress is the challenge presented by the patients' difficulties, which can impact on a carers' self-esteem and sense of mastery, whereas strain is how this affects the carers' roles and activities outside of the caregiving situation. These experiences can go on to result in depression and other ill health. Strain and stress were measured using the Caregiver Strain Index (CSI) [3] and Perceived Stress Scale [10], respectively. Carers were also asked to rate the patients' disabilities using a Likert scale with items taken from the General Health and History Questionnaire (GHHQ) [11]. A range of injury severity, from mild to severe, was eligible for inclusion to this study, although it was not reported what the proportions in the recruited sample were.

The authors found that cognitive and motor difficulties had a moderate to strong correlation with scores on the CSI. Behavioural difficulties also had a moderate association with strain, and showed the strongest association with stress. The categories of disability were found to be more closely related to strain than stress. However, the results may not be generalisable to the whole population of carers for patients with TBI, as half of the sample was recruited from Headway Ireland, with the other half coming from a rehabilitation hospital. As some of these relatives had joined a head injury association, they may have had more support and have more ingenuity in ways of coping than those who have not. The authors accepted this as a limitation of their study.

In two studies by Kreutzer, Gervasio and Camplair [5, 12], 62 carers of outpatients with TBI were assessed for psychological distress and family functioning. Carers were interviewed whilst patients were attending a standard neuropsychological appointment. Around half of the carers showed high levels of distress on the Brief Symptom Inventory (BSI) [13], with a third experiencing significant anxiety, and a quarter depression. Family functioning (measured by the Family Assessment Device, FAD [14]) was found to be unhealthier than that in non-patient and medical patient norms, although better than for families of psychiatric patients.

In the latter study [12] the authors also reported data collected about the patients' neurobehavioural problems (rated by the carer on the GHQ), measures of injury severity (including the Glasgow Coma Scale [15]), neuropsychological tests and relationship of the carer to the patient (i.e. spouse or parent). Using a regression analysis, the authors found that the carers' perceptions of the patients' neurobehavioural problems were the best predictors for all subscales of the BSI. Neuropsychological test scores (particularly verbal skills) were also predictive of carer distress. Relationship of carer to the patient (i.e. parent or spouse) only predicted the Depression subscale, and injury severity failed to predict any score from the BSI. The variables were less able to predict family functioning from the FAD. Of the neurobehavioural difficulties measured, behavioural problems were found to be important with regards to carers' distress. These results suggest that carers' perceptions of patients' difficulties are linked with the carers' experiences of distress, for example anxiety and depression, and to a lesser extent the patients' objective abilities on the neuropsychological tests.

Many studies have attempted to define what factors may lead to strain or distress in carers of patients with TBI, with mixed results. A number of studies have concluded that factors other than the patient's physical disabilities (such as personality change, behavioural or emotional changes in the patient) have the most impact on carers' well-being [4, 16-19]. Other research has concluded that aspects about the carer themselves may be linked to well-being, such as their gender (females are more likely to experience distress than males [20]), their relationship to the patient (spouses reporting more distress than parents [5]) or the amount of time spent caring for the patient (with longer periods of caring associated with more unmet needs [21]). There have also been inconclusive results regarding the relationship between carer experience and injury severity, which has been measured in a number of ways, such as post traumatic amnesia and Glasgow Coma Score. Severity has been shown to mediate the relationship between burden and the consequences of TBI [18], although some studies have not found any association [1].

These mixed findings are likely to be a product of the inconsistent terms used to describe strain in these studies, which may be measuring different experiences for the carer. This would be likely if the model by Pearlin and colleagues [9] were followed. There is also inconsistency in these studies regarding length of time since injury, with some studies being up to 12 months post injury [4] and others being more longitudinal [19]. Many studies also employ stringent inclusion criteria regarding injury severity, with only the most severe head injuries being selected [16-17]. Finally, samples are often recruited from very different sources (e.g. hospital admissions, rehabilitation programmes or head injury associations), which may influence their results. All of these factors combine to produce a confused picture of carer strain and may limit the generalisability of those findings to the whole population of carers of patients with TBI.

(For more details on the prevalence of TBI, and a more detailed literature review of carer strain, please turn to Appendix 1).

The current study

The current study aims to explore the factors associated with the presence or absence of significant carer strain via a postal survey. This study is needed in order to draw some conclusions on the prevalence of strain in carers of patients with TBI, as well as attempt to simplify the mixed results described above using a representative sample of carers. It was hoped that by employing a postal methodology a large sample size of adequate statistical power could be recruited. The study aimed to recruit a sample of patients with TBI with a range of injury severity in order to be more representative of the types of patients admitted to neurosurgical and intensive care units. This study was also able to study long term factors affecting strain in carers, as the patients were now between five and 14 years post-injury. Measures of disability which identify many of the common neurobehavioural difficulties following TBI, and were designed for use with TBI populations, were also employed in this study. A further extension of previous work was that a clinician's opinion of outcome was recorded for the patient. This aimed to offer an objective view on the patients' current abilities post-injury.

Method

Participants

Patients were identified from a database held by a Consultant of Anaesthetics and Critical Care at Queen's Medical Centre, Nottingham. This database included all patients who had been admitted between 1993 and 2003 with a TBI. The database included information about the date of injury, measures of injury severity and the patient's next of kin and GP. All patients from the database were considered for inclusion to the study.

Exclusion criteria

Patients were excluded from the study if: (a) they were deceased; (b) they were under 18 at the time of selection for the study; (c) they had no next of kin recorded on the database; (d) they had no GP details on the database and / or (e) their current living situation meant that relatives or friends were unlikely to be providing care on a daily basis (i.e. they receive formal / paid care).

Initially there were 1662 patients on the database who had experienced a TBI and been treated in the Neurosurgical Unit. Of these, 433 (26%) had died from their injuries or by one year follow-up; 168 (10%) were aged under 18 years at the time of selection; 64 (4%) had no recorded next of kin at the time of injury; and 60 (4%) had no registered GP at the time of injury.

Attempts were made to trace the remaining patients on the database by telephoning the patients' recorded GPs. Following this, there were a number of other patients who had to be excluded for other reasons: 61 (4%) had died since the one year follow-up; 409 (25%) had left their GP practice and could not be traced; three (0.2%) had only been temporary residents in Nottingham and current details were unavailable; two (0.1%) had moved to nursing homes; five (0.3%) were in prison; and the details of nine (0.5%) GP surgeries could not be found. Furthermore, 57 (3%) patients who had been confirmed as being alive by their GP could not be traced by the NHS Central Register, and so were excluded to ensure that no families were contacted about a deceased relative.

(For further information on the design of the study and the rationale behind the exclusion criteria, please turn to Appendix 2.1 and 2.2)

Demographics

This left 391 patients to be invited to take part in the study. Although 55 (14%) consent forms were received, only 48 (12%) carers returned the questionnaires and one carer did not return their demographic information. Therefore demographic information is only available for 47 carers. Four carers did not give their age, which could have been an accidental omission. Over half of the carers were partners / spouses of the patients with TBI, and just over a third were parents. Three quarters of patients lived with their carers. The demographic information for the patients was taken from the database. Demographic information is presented in table 1.

(For further information on demographics for patients who did not consent to take part in the study, please turn to Appendix 2.3)

Table 1 here

Measures

Injury severity

A measure of injury severity, the Virginia Prediction Tree Score (VPTS) [22], was recorded at time of injury and documented on the database. The prediction tree method consists of continually breaking the sample down into smaller subgroups based on identifying variables which produce the maximum separation between groups, whilst maintaining the minimal variation within each subgroup [22]. The VPTS categorises patients with TBI into subgroups according to the severity of their injury by comparing the patient's status with a number of prognostic variables, which are pupillary response, age, motor response and presence of intracerebral lesions. The patients are separated into eight categories based on these comparisons; one being a good outcome and eight being a very poor outcome, usually death. The authors of the VPTS showed this method to produce a predictive accuracy of 77.7% of outcome in 555 patients with TBI with known outcome data; higher than that for the logistic or discriminant analyses. The tree was particularly accurate when predicting good recovery or death as an outcome at 12 months [22].

Outcome

In this study, the patient's outcome was rated by the GP using the Glasgow Outcome Scale (GOS). The GOS is the most popular scale used to measure outcome following head injury [23]. It is divided into five categories: death; vegetative state; severe disability; moderate disability; and good recovery. These categories correspond to numbers one-five respectively. The strengths of the GOS are that: it produces a summary score, which covers all outcomes; the categories have been widely used and are easily understood by professionals; the differences in categories are clinically meaningful; and an examination of the patient is not necessary [24]. The GOS has also previously been used via postal assessment, and has been found to be a reliable way to assess outcome for large populations [25]. Guidelines regarding the different categories produced by Wilson, Pettigrew and Teasdale [26] were enclosed with the measure to aid the GP's decision in this study.

Neurobehavioral Functioning Inventory (NFI)

The NFI [27] was used in this study to capture the carers' perceptions of the patients' disabilities following a TBI. It combines six scales which cover common sequelae following TBI: depression, somatic symptoms, memory / attention, communication, aggression and motor abilities. Kreutzer, Marwitz, Seel & Devany Serio [28] found high internal reliability for all six scales of the NFI when used on patients with TBI. They also found that the scale was correlated with performance on neuropsychological

assessments, suggesting that poorer performance on those assessments indicated that the patient also had more neurobehavioral difficulties.

Items are rated on a scale of one to five corresponding to how often the patient faces that difficulty; one meaning 'never' and five meaning 'always'. The subscales are summed and compared with norms regarding the patient's age and injury severity (measured by length of unconsciousness). The NFI was chosen as it was designed for use with people with brain injury. In this study, the family form of the NFI was used in isolation to capture carers' perspectives. However, there has been research to show a high level of concordance between patient's and carer's responses on the NFI forms [29].

Carergiver Strain Index (CSI)

The CSI [3] was used as a self-report rating of the strain carers are experiencing. The CSI is a 13 item scale covering the major areas which have been found to contribute to feelings of strain, e.g. employment, social, physical, financial and time pressures. It has been designed to be used with carers of any age. Although the CSI was originally developed for use with carers of elderly patients returning home from hospital, the scale has been used in a variety of settings, including the TBI population [8, 30]. Sullivan and Terry [31] recommend the use of the CSI as the best tool in order to quickly establish which carers may have concerns about caregiving. An answer of 'yes' to an item is scored as one, whereas 'no' is scored as zero. The total score is zero-13. As an aim for this study was to assess prevalence of strain in the sample of carers, and the factors associated with strain, the carers' responses on the CSI were dichotomised into 'strain' or 'no strain' groups for the purpose of further analysis. A carer was identified as under strain if they scored seven or above on this measure (as recommended by the author [3]). The cut-off score of seven, which was employed in this study to establish prevalence rates, has previously been used in other populations (e.g. stroke; [32]).

In summary, the NFI and CSI are both self-administered forms which were completed by the carer. The GOS was sent to the patient's GP with guidelines for completion. The VPTS score was taken from the database.

(For further information on the scales, their strengths and weaknesses, and copies of the scales themselves, please turn to Appendix 2.4)

Procedure

Ethical approval was gained from Nottingham Research Ethics Committee 1.

There were 391 patients who met the study criteria and who could be traced through their GP. A further check was run by the NHS Central Register in order to ensure these

patients were still alive before trying to contact them. The majority of the demographic information for the patients was held on the database, such as age, gender, date of injury etc.

Invitation letters were sent out to all traceable patients explaining the purpose of the study. They were asked to identify a person, family member or friend, whom they felt had been most involved in their care since their brain injury. Within the information pack was a letter of invitation for the patient to pass on to this nominated 'carer'. Separate consent forms were enclosed for the patient and the carer.

Once signed consent forms were received, the NFI and CSI were sent to the carers. They were also sent a form to collect demographic information. A pre-paid envelope was enclosed for the carers to return the questionnaires. A GOS questionnaire with guidelines for completion was sent to the patient's GP, which was also to be returned by post.

(For further information about ethical approval and the procedure, and copies of the information sheets and consent forms used, please turn to Appendix 2.5)

Results

(For a comparison of the demographics for patients who were traced from the database and those who were not, please turn to Appendix 3.1. For a comparison of those who took part with those who did not, please turn to Appendix 3.2)

The completed NFI and CSI were returned by 48 carers. The GOS was returned by 43 GPs, with five not returned: in one case the patient had moved practice since giving consent to the study and in another the patient requested that his GP not be contacted. For four of these patients a GOS score from one year post-injury was available on the database and entered. For the remaining patient an average GOS score was calculated from other patients with the same injury severity.

Missing items were noted on 13 of the returned NFI forms, and were addressed using the recommended procedures from the manual. Less than 25% of the items were missing in each case. Missing items were not encountered on the CSI.

(For further information about how the analysis was carried out, the procedures for missing items and a comparison of GOS score at one year post-injury and now, please turn to Appendix 3.3)

Neurobehavioral Functioning of people with TBI

Raw scores were converted to T scores in accordance with the manual, based on patient norms for age and duration of unconsciousness. The mean and standard deviation for scores on each subscale is presented in table 2.

Table 2 here

Carer Strain

To assess the prevalence of strain in this sample, the scores from the CSI were transformed into a dichotomous variable representing whether carers were experiencing significant strain or not. For this, a score of seven or more was given a label of 'strain' and scores under seven a label of 'no strain'. High levels of strain (CSI score ≥ 7) were identified in 20 carers (42%). The frequency with which items on the CSI were reported by the carers is presented in table 3.

Table 3 here

From the CSI, the most reported reasons for carers experiencing strain was in terms of the person with TBI displaying behaviour which is upsetting (such as incontinence or memory problems) and emotional adjustments to caring for the person with TBI.

(For further information about the distribution of scores across the CSI, and how they relate to strain, please turn to Appendix 3.4)

Association with strain

The relationships between the dichotomous variable strain and the variables measured regarding the patients' injury (VPTS), remaining disability (NFI) and outcome (GOS) were analysed using Mann Whitney U tests ($p < 0.05$). The demographics reported in table 4 were also tested to assess whether they significantly related to strain. Carer gender and cohabitation with patient were analysed with strain using a Chi-Square test ($p < 0.05$).

Table 4 here

There was a significant relationship found between strain and the NFI Depression ($p < 0.001$), Memory ($p < 0.001$), Communication ($p < 0.001$), Aggression ($p < 0.001$) and Motor subscales ($p < 0.01$). Significant results were also found between strain and GOS ($p < 0.01$). The variables carer age, carer gender, cohabitation with patient, injury severity (VPTS) and NFI Somatic were not significantly related to strain.

Logistic regression analysis

Logistic regression analysis was conducted to assess what contribution the variables made to explaining the variance in the dichotomous variable strain. As this was an exploratory study of the data, the NFI subscales (minus Somatic) and the GOS were all entered as independent variables via a backward stepwise method using the likelihood ratio statistic (see Field [33]). The variables which were not significantly related to strain were not entered into the regression analysis. The dichotomised variable strain was entered as the dependent variable.

(For further information on testing the assumptions for regression analyses and correlations table for the variables included, please turn to Appendix 3.5)

Of the five different stages computed in the analysis, no step was found to significantly improve the predictive power of the model over the simultaneous entry of all six independent variables. The total variance explained by this regression equation for strain was significant, $F(6) = 26.65$, $p < 0.001$. The R^2 calculation ranged between 0.41 (Homer & Lemeshow) and 0.57 (Nagelkerke), meaning that 41-57% of the variance in strain was accounted for by the model. In total the six independent variables correctly predicted group membership in 72.9% of cases, with 82.1% of carers correctly identified as being in the 'no strain' group and 60% of carers as being in the 'strain' group. No individual variable made a significant contribution to the variability in strain alone, but the variables also did not reach the removal criterion, which would suggest no redundancy in the model.

On examining the residuals from the regression, three cases were found to fit poorly in the model, and had been misclassified: two being predicted as under 'no strain' and one as under 'strain'. As this resulted in more than 5% of residuals being outside of the recommended distribution boundaries (see Field, [33]), these carers were removed and the regression analysis repeated.

This secondary analysis continued to support the model containing all six of the independent variables, $F(6) = 35.67$, $p < 0.001$. The R^2 calculation ranged between 0.55 (Cox & Snell) and 0.74 (Nagelkerke), meaning that 55-74% of the variance in strain was accounted for by the model. The percentage of correctly classified cases rose to 84.4%. Again, no individual variable made a significant contribution to the model alone. However, when the variables were compared to the removal criterion, it suggested that the removal of the GOS would significantly affect the predictive ability of the model ($p < 0.05$). The results from this secondary analysis and the contribution of individual variables within the analysis is summarised in table 5.

Table 5 here

(For further information on the regression analyses and regression table, please turn to Appendix 3.6. For information about biased responding and the impact this had on the analyses, please turn to Appendix 3.7)

Discussion

(For a discussion about the limitations of previous methodologies and the aims for this study, please turn to Appendix 4.1)

This study aimed to explore what factors are associated with strain in carers of people who have experienced a TBI. Over two fifths of carers who returned their questionnaires were found to be under strain using the recommended cut-off score on the CSI [3]. It is difficult to know how this compares to other reports of carer strain, as studies differ in the terms they use to describe the experience they are measuring, and those studies that have used the CSI have not reported prevalence rates [8, 30]. If Pearlin, Mullan, Semple and Skaff's [9] model were to be used (as employed in Connolly & O'Dowd's [8] study), the terms strain, stress and outcomes such as depression would constitute different experiences altogether.

Emotional adjustments, upsetting behaviour and personality change were the most frequently reported items on the CSI. In terms of perceptions of disability; depression, concentration and memory problems (from the NFI subscales) were reported as the issues most often observed in the patients with TBI, although aggression and motor problems were also associated with strain. This is consistent with the studies discussed earlier, where behavioural, cognitive and motor difficulties were commonly reported by carers [8, 12]. Where aggression did occur, it appeared to be quite extreme, with 10% of carers scoring patients in the 'very high' range of the scale.

Scores on all subscales of the NFI (except Somatic) were significantly higher in the 'strain' group compared to the 'no strain' group. This suggests that carers in the 'strain' group perceived the patients they were caring for to have a greater degree of disability than carers in the 'no strain' group. The GP-rated GOS score was found to be lower for the 'strain' group, suggesting that the patients' outcome was not as favourable in this category. Therefore, there was concordance between the carers' reports on the NFI and the GP's rating on the GOS.

The measure of injury severity (VPTS) and the NFI subscale Somatic were not found to differ significantly between the 'strain' and 'no strain' groups. The lack of significance for injury severity is consistent with some previous research [12], although injury severity has

previously been found to mediate the relationship between carer burden and the patients' difficulties [18]. The somatic items may be experiences that do not unduly affect the carer's life, and thus does not cause strain for the carer.

Carers' demographic characteristics were not related to strain. Mixed findings have been reported regarding how strain relates to the relationship between carer and patient [5, 21, 34]. No difference was found between spouse and parent strain in this study. The previous findings regarding carer gender may well be a reflection of the fact that the majority of carers who generally participate in TBI research are female, and so the impact of the caring role upon them can be more readily discussed and recorded [35-36], and may be over-exaggerated in comparison to carer strain in males. The variable 'cohabitation' which recorded whether the patient and carer lived together did approach significance ($p=0.09$), which may suggest that this non-significant finding resulted from the lack of power produced by the small sample size.

(For further discussion about the results, please turn to Appendix 4.2)

Stepwise logistic regression analysis was used to explore the relationship between strain and measures of disability following TBI. The results of this suggested that the NFI (minus the Somatic subscale) and the GP-rated GOS could together significantly predict whether a carer would be experiencing strain, with 60-82% of carers being correctly categorised into the 'strain' or 'no strain' groups. However, despite the relatively high prevalence of cognitive and mood difficulties in people with TBI, the carers' responses on the NFI subscales in isolation were not predictive of whether a carer would be under strain. In the supplementary analysis, following the removal of three outliers, the GOS was found to approach significance ($p=0.07$), and the analysis suggested that removing the GOS from the model would considerably affect its predictive ability.

The above findings for the GOS in the regression analyses is not entirely consistent with previous research, from which we would expect strain to be predicted by carers' perceptions of the patients' mood and cognition. This may be an artefact of the broad categories associated with the GOS, which have been found to be highly correlated with the NFI scale [26]. Therefore there may have been multicollinearity between the predictor variables, which may subdue any significant contribution of an individual variable on the NFI.

The carers who were removed from the supplementary analyses were found to be significant outliers in this model. One was predicted to be in the 'strain' category, but had a score on the CSI of less than seven (suggesting non-significant strain), and two were predicted to be in the 'no strain' category, when their scores on the CSI were above seven

(suggesting significant strain). In the first carer's case the patient they cared for received the lowest GOS score and the second highest NFI score of all the patients cared for by 'non-strained' carers (suggesting poor recovery and high levels of disability). In the latter cases, the patients received high GOS scores (suggesting good recovery) and low NFI scores (suggesting little remaining disability). These incorrectly predicted responses on the CSI may reflect differences in the carers' expectations of what the patient they care for should be able to achieve post-injury, and therefore how they regard the patients' continuing disabilities. It may also indicate the different ways in which carers may deal with and make sense of their caring duties.

(For further information about biased responding on the questionnaires please turn to Appendix 4.3)

One aim for this study was to recruit a more representative sample that covers patients admitted to neurosurgical or intensive care units with a range of injury severity. Previous studies [16-19] have tended to include patients who have experienced severe head injuries only. Although this selection bias leads to a more uniform sample of patients, it does limit the generalisability of results. This study included patients who had experienced mild, moderate and severe head injury in an attempt to combat this bias and produce more generalisable results. Therefore, the results reported should be more representative of the population of people with a TBI who have been admitted to hospital.

Early assessments reported by the European Brain Injury Consortium Survey classified 58% of TBIs as severe, 17% as moderate and 19% as intermediate in 1005 admissions to "neuro" centres in 12 European countries over a three month period [37]. This is roughly equivalent to the distributions in the current sample. This would suggest that the level of severity found in the sample is representative of the wider population of hospital-admitted TBIs occurring in Europe, and means that the entire spectrum of head injury has been included.

Another strength of the current study is that this sample of carers was not recruited from the membership database of a voluntary organisation or support group. Previous studies have employed this methodology [8], which can introduce bias into the sample in terms of responses to questionnaires regarding strain or burden, as carers may be in receipt of active support or be more educated about the consequences of head injury.

Furthermore, this study was conducted at least five years post-injury, which gives some information about the long-term impact of caring. Patients also ranged in the time since injury, which again means that the results may be generalisable to a wider group of carers.

(For further information about the strengths of the study, please turn to Appendix 4.4)

Limitations

Limitations of the study should be acknowledged. The main limitation was the small sample size of carers. The response rate was much smaller than other postal surveys [8], which could be for several reasons. As to be expected in a sample of people with traumatic brain injury, there were a large number of deaths – approximately a third of the people on the database had died in the intervening period. Secondly, due to the length of time since the people had experienced their head injury, many of them had moved away or changed their GP practice, thus making them untraceable for this study. This problem was contributed to by the fact that the Neurosurgical Unit which this study is based around is located in a large teaching hospital, which receives admissions from the surrounding counties. Therefore, many of the patients had been transferred to the hospital from a great distance and did not return there for outpatients' appointments, meaning more up-to-date records were not available for those patients.

Another limitation of the findings is that the measures used in this study do show considerable overlap in terms of the concepts measured, which may have a confounding affect on the results reported. The NFI and GOS show high levels of inter-correlation, as previously mentioned. Also, there is obviously some overlap in the premise behind the CSI and NFI, as in both the carer is reporting on difficulties that the patient experiences, although in the CSI this is more in the context of how the difficulties affect the carer not the patient. However, this overlap in the scales may contribute towards the amount of variance explained in the model. It is also noteworthy that in standardising the raw scores on the NFI, patient age and injury severity variables were controlled for, which may have a bearing on how the scores related to strain and influence the amount of explained variance in the model.

There may also have been some form of response bias in the replies received, which may have contributed to the results reported. It could be that some patients chose not to take part as they did not want to be reminded of their injury, or they wanted to protect their family members from painful memories. Alternatively, they may not recognise their relative as their carer, as they may feel fully recovered and not think that the study is appropriate for them. Another possibility is that the patient and carer are experiencing such high levels of strain on a daily basis that they may not have been able to devote any time to the study.

(For further discussion about the limitations of the study and possible solutions, please turn to Appendix 4.5)

Clinical Implications

Although this study was limited by the number of participants, it does illustrate that a large proportion of carers continue to experience (or may develop) strain many years after the patients' brain injury, and confirms the findings that disabilities sustained tend to be long-lasting [19]. This illustrates the importance of following up the carer as well as the patient following discharge.

The fact that injury severity and carer demographics have not been found to be related to strain in this study suggests that initial variables that can be measured at the time of a person's injury cannot be used to predict the likelihood of strain in the future. This indicates that an 'at risk' group cannot be identified following admission to hospital, and that longitudinal monitoring is required in order to provide timely support to carers. It may be that GPs are in the best position to monitor patients and carers following TBI. As the results of this study suggests, the rating of GPs on the GOS may have relative importance in predicting carer strain, and as a very brief and crude measure could be used to identify carers who may require further screening from mental health professionals. The screening could be in the form of sending out copies of the NFI and CSI, which could be used to inform levels of strain and areas of possible intervention.

The results of this study give some indication about which areas of intervention would be useful. Carers most often reported cognitive, emotional and behavioural difficulties observed in the patients. Therefore it may helpful to have some joint therapy sessions with patients who have more severe disabilities and their carers, where strategies for improving memory, concentration and mood are provided. These sessions could be run by assistant psychologists, graduate mental health workers or nurse specialists. Information about behaviour management may also be relevant, especially if the patient is more disinhibited than they used to be. Kreutzer, Gervasio and Camplair [5] have described programmes with similar formats to this. If resources did not allow for these sessions to take place face-to-face, some information booklets could be produced to accompany the educational information about brain injury and its' sequelae.

Future research

An alternative way to view the above results is that although a fairly high number of carers were experiencing strain, there was also 58% of the sample who were experiencing low levels of strain – over a third of these reporting no experience of strain at all. It is possible that a more helpful and informative way of studying strain in carers is to study the carers who do not experience strain in more depth, in order to explore what skills / strategies they use to minimise the impact of caring on their daily lives and well-being. This may simply be down to coping strategies and personality traits which are predisposed to better adaptation to the caring experience [38-39]. This could be done via a postal

methodology, but with a qualitative focus in order to obtain the carers' views in their own words. Perlesz, Kinsella & Crowe [20] have suggested that an avenue for future research would be more qualitative approaches into adaptation within families, and perhaps a shift in focus to resilience and positive outcomes for carers. In terms of this study, an extension to the findings presented could be in the form of following up on the carers who did not report significant strain, in order to ascertain their ideas about the process of adaptation and how they cope on a daily basis.

(For further information on the clinical implications of this study and future research, please turn to Appendix 4.6 and 4.7.)

Table 1: Demographics for patients and carers who took part in the study

Nominated carers	
Age (n=44)	
Mean	55.77
SD	12.59
Range	30-87
Gender (n=48)	
Female	38
Male	10
Relationship to patient (n=47)	
Partner / spouse	28 (60%)
Parent	17 (36%)
Sibling	1 (2%)
Child	1 (2%)
Cohabits with patient (n=48)	
Yes	38 (79%)
No	10 (21%)
Patients	
Age (n=48)	
Mean	45.35
SD	17.65
Range	19-88
Gender (n=48)	
Female	9 (19%)
Male	39 (81%)
Injury Severity # (n=48)	
Mild	9 (19%)
Moderate	8 (17%)
Severe	31 (64%)
Years since injury (n=48)	
Mean	9.31
SD	2.91
Range	5-14

Note: # Injury severity categories taken from the Glasgow Coma Scale (GCS) for ease of classification and recognition. Mild = GCS \geq 13, Moderate = GCS 9 – 12, Severe = GCS \leq 8.

Table 2: NFI standardised subscale scores and percentage of carers reporting difficulties rated in 'average', 'high' or 'very high' categories

NFI	Mean T score	SD	Frequency 'average' # n (%)	Frequency 'high' * n (%)	Frequency 'very high' ** n (%)
Dep	47.94	10.59	15 (31)	13 (27)	1 (2)
Som	49.15	10.36	20 (42)	8 (17)	2 (4)
Mem	50.29	10.33	19 (40)	10 (21)	4 (8)
Com	52.31	11.17	17 (35)	13 (27)	6 (13)
Agg	51.25	9.98	24 (50)	7 (15)	5 (10)
Mot	45.56	10.23	16 (33)	6 (13)	1 (2)

Note: NFI = Neurobehavioral Functioning Inventory. Dep= depression, Mem= memory, Com= communication, Agg= aggression, Mot= motor. # 'Average' is considered as 2/3 SD above or below the mean, * 'High' is considered as over 2/3 SD above the mean, ** 'Very high' is considered as over 1.5 SD above the mean

Table 3: Frequency of carers' reports on CSI individual items

CSI item	Frequency n (%)
Sleep disturbance	10 (21%)
Caring inconvenient	10 (21%)
Physical strain	2 (4%)
Confining	14 (29%)
Family disruption	16 (33%)
Changes in personal plans	20 (42%)
Demands on time	21 (44%)
Emotional adjustments	27 (56%)
Upsetting behaviour	30 (63%)
Patient has changed	25 (52%)
Work adjustments	16 (33%)
Financial strain	16 (33%)
Feeling overwhelmed	20 (42%)

Note: CSI = Caregiver strain index.

Table 4: Comparison of variables measured and the dichotomous variable 'strain'

	Strain n=20	No Strain n=28	p value
Carer Age#			
Mean	57.78	54.38	0.48
SD	9.56	14.34	
Carer Gender			
Male	3	7	0.63
Female	17	21	
Cohabitation			
Yes	13	25	0.09
No	7	3	
Relationship of carer			
Partner / spouse	11	17	0.84
Parent	8	9	
Other / not stated	1	2	
NFI Depression			
Median	58.00	43.00	<0.001**
IQR	46.00-62.50	35.00-48.75	
NFI Somatic			
Median	48.00	45.00	0.36
IQR	43.25-59.50	39.00-55.75	
NFI Memory			
Median	58.00	42.50	<0.001**
IQR	51.25-64.00	38.25-51.50	
NFI Communication			
Median	60.00	46.00	<0.001**
IQR	53.25-65.75	39.25-54.25	
NFI Aggression			
Median	56.00	45.00	<0.001**
IQR	51.25-64.25	40.00-51.75	
NFI Motor			
Median	41.00	40.50	<0.01*
IQR	41.50-60.25	35.50-48.50	
GOS			
Median	4.00	5.00	<0.01*
IQR	4.00-5.00	5.00-5.00	
VPTS			
Median	3.00	4.00	0.74
IQR	2.00-5.00	1.00-6.00	

Note: *p<0.01, **p<0.001. Carer gender, cohabitation and relationship of carer were analysed with χ^2 , all remaining variables were analysed using Mann Whitney U tests. Strain was determined by a CSI score of seven or more. 'Cohabitation' = whether the carer answered 'yes' to currently living with the patient with TBI. NFI= Neurobehavioral Functioning Inventory. GOS= Glasgow Outcome Scale. GOS scored from one-five; one=death, five=good recovery. VPTS= Virginia Prediction Tree Score. VPTS scored from one-eight; one=good outcome, eight=very poor outcome, often death. # Carer age only available for 47 carers.

Table 5: Summary of independent variables entered into logistic regression to predict strain (with outliers removed)

IV	B	S.E.	Wald	Sig.	Exp (B)	95.0% C.I. for EXP(B)	
Dep	0.15	0.11	1.94	0.16	1.16	0.94	1.42
Mem	0.14	0.09	2.64	0.10	1.15	0.97	1.37
Com	0.14	0.09	2.78	0.10	1.15	0.98	1.36
Agg	-0.05	0.09	0.32	0.57	0.95	0.80	1.13
Mot	-0.08	0.08	0.83	0.36	0.93	0.79	1.09
GOS	-2.22	1.22	3.30	0.07	0.11	0.01	1.19

Note: * $p < 0.05$, 1 df . Variables in the logistic regression equation. IV = independent variable, B = Beta, S.E. = standard error, Wald = Wald's statistic, Sig. = p value, Exp (B) = odds ratio, 95.0% C.I. = 95% confidence interval for odds ratio. Following variables from Neurobehavioral Functioning Inventory, Dep= depression, Mem= memory, Com= communication, Agg= aggression, Mot= motor. GOS= Glasgow Outcome Scale

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$$3n + 3yz^2$$

But: $\underline{a/b + c/d + a/d}$

$$P = (a^2 + b^2)(c^2 + d^2)$$

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14. Numbers in text should take the following forms: 300, 3000, 30 000. Spell out numbers under 10 unless used with a unit of measure, e.g. nine pupils but 9 mm (do not introduce periods with measure). For decimals, use the form 0.05 (not .05).

Notes on tables and figures

The same data should not be reproduced in both tables and figures. The usual statistical conventions should be used: a value written 10.0 ± 0.25 indicates the estimate for a statistic (e.g. a mean) followed by its standard error. A mean with an estimate of the standard deviation will be written 10.0 SD 2.65. Contributors reporting ages of subjects should specify carefully the age groupings: a group of children of ages e.g. 4.0 to 4.99 years may be designated 4 +; a group aged 3.50 to 4.49 years $4 \pm$ and a group all precisely 4.0 years, 4.0.

1. Tables and figures should be referred to in text as follows: figure 1, table 1, i.e. lower case. 'As seen in table [or figure] 1 ...' (not Tab., fig. or Fig).

2. The place at which a table or figure is to be inserted in the printed text should be indicated clearly on a manuscript:

Insert table 2 about here

3. Each table and/or figure must have a title that explains its purpose without reference to the text.

4. Figures and tables must not be embedded in the text.

Thus tables and figures must be referred to in the text and numbered in order of appearance. Each table should have a descriptive title and each column an appropriate heading.

Citations in text

References should be cited using the numerical system (e.g. [3], [5-9]). They should be listed separately at the end of the paper in the order in which they appear in the text. 'Ibid.' (and the like) are not used when repeating citations.

Acknowledgements

Any acknowledgements authors wish to make should be included in a separate headed section at the end of the manuscript.

Book reviews

1. The following header material should appear in all reviews in the following order (note also the punctuation):

Student Engagement and Achievement in the American Secondary School.

Edited by Fred M. Newmann (Teachers College Press, New York, 1992), 240 pp., \$38.00 (hbk), ISBN 8077-3183-8, \$17.95 (pbk), ISBN 8077-3182-X.

2. Page references within reviews should be given as follows: (p. 337) or (pp. 36-37).

References

References should follow the Council of Biology Editors (CBE) Citation & Sequence format. Only works actually cited in the text should be included in the references. Indicate in the text with Arabic numbers inside square brackets. Spelling in the reference list should follow the original. References should then be listed in numerical order at the end of the article. Examples are provided as follows:

Journal article: [1] Steiner U, Klein J, Eiser E, Budkowski A, Fethers LJ. Complete wetting from polymer mixtures. *Science* 1992;258:1122-9.

Book chapter: [2] Kuret JA, Murad F. Adenohypophyseal hormones and related substances. In: Gilman AG, Rall TW, Nies AS, Taylor P, editors. *The pharmacological basis of therapeutics*. 8th ed. New York: Pergamon; 1990. p 1334-60.

Conference proceedings: [3] Irvin AD, Cunningham MP, Young AS, editors. *Advances in the control of Theileriosis*. International Conference held at the International Laboratory for Research on Animal Diseases; 1981 Feb 9-13; Nairobi. Boston: Martinus Nijhoff Publishers; 1981. 427 p.

Dissertations or Thesis: [4] Mangie ED. A comparative study of the perceptions of illness in New Kingdom Egypt and Mesopotamia of the early first millennium [dissertation]. Akron (OH): University of Akron; 1991. 160 p. Available from: University Microfilms, Ann Arbor MI; AAG9203425.

Journal article on internet: [5] Loker WM. "Campesinos" and the crisis of modernization in Latin America. *Jour of Pol Ecol* [serial online] 1996; 3(1). Available: http://www.library.arizona.edu/ej/jpe/volume_3/ascii-lokeriso.txt via the INTERNET. Accessed 1996 Aug 11.

Webpage: [6] *British Medical Journal* [Internet]. Stanford, CA: Stanford Univ; 2004 July 10 - [cited 2004 Aug 12]; Available from: <http://bmj.bmjournals.com/>

Internet databases: [7] Prevention News Update Database [Internet]. Rockville (MD): Centers for Disease Control and Prevention (US), National Prevention Information Network. 1988 Jun - [cited 2001 Apr 12]. Available from: <http://www.cdcnpin.org/db/public/dnmain.htm>

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- a.** Any figure submitted as a colour original will appear in colour in the journal's online edition free of charge and can be downloaded.
- b.** Paper copy colour reproduction will only be considered on condition that authors contribute to the associated costs.

Ethical approval letter

Version 2, Re issued to amend the list of approved documents. 10 December 2007



National Research Ethics Service

Nottingham Research Ethics Committee 1

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21 November 2007

Miss Naomi E Boycott
Trainee Clinical Psychologist
University of Nottingham
I-WHO, William Lee Buildings 5-8
Science & Technology Park, University Boulevard,
Nottingham, NG7 2RQ

Dear Miss Boycott,

Full title of study: Exploring factors associated with strain in carers of patients with traumatic brain injury
REC reference number: 07/H0403/123

Thank you for your letter of 05 November 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

The Chair has considered the further information on behalf of the Committee.

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.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

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

Document	Version	Date
Application		02 August 2007
Investigator CV	Chief	08 August 2007

This Research Ethics Committee is an advisory committee to East Midlands Strategic Health Authority.
The National Research Ethics Service (NRES) represents the NRES Directorate within the
National Patient Safety Agency and Research Ethics Committees in England.

	Investigator	
Investigator CV	Educational Supervisor	07 August 2007
Protocol	2	10 July 2007
Letter from Sponsor		06 August 2007
Peer Review		
Questionnaire: NFI Questionnaire		
Questionnaire: Caregiver Strain Index	2	10 July 2007
Questionnaire: Glasgow Outcome Scale	2	10 July 2007
Letter of invitation to participant	4 - Patient	05 October 2007
Letter of invitation to participant	1	10 October 2007
Letter of invitation to participant	4 - Carer	05 October 2007
GP/Consultant Information Sheets	2	10 July 2007
Participant Information Sheet: Carer	4	05 October 2007
Participant Information Sheet: Patient	4	05 October 2007
Participant Consent Form: Carer	4	05 October 2007
Participant Consent Form: Patient	4	05 October 2007
Participant Consent Form: Assent	2	10 July 2007
Response to Request for Further Information		05 November 2007
Questionnaire Instructions	2	10 July 2007
Letter from Dr Holland		12 January 2001
Letter from Dr Yeoman		05 November 2007
Section 30 Supplementary Information		
Questionnaire Covering Letter	2	10 July 2007

R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.

Guidance on applying for R&D approval is available from
<http://www.rdforum.nhs.uk/rdform.htm>.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

Here you will find links to the following

- a) Providing feedback. You are invited to give your view of the service that you have received from the National Research Ethics Service on the application procedure. If you wish to make your views known please use the feedback form available on the website.

- b) Progress Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
- c) Safety Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
- d) Amendments. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
- e) End of Study/Project. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nationalres.org.uk.

07/H0403/123	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project

Yours sincerely



Dr K Pointon / Ms Trish Wheat
Chair / Co-ordinator

Email: trish.wheat@nottspct.nhs.uk

Enclosures: *Standard approval conditions*

Copy to: *Mr P Cartledge, University of Nottingham*

R&D Department for NHS care organisation at lead site – NUH-QMC

Appendix 1: Literature Review

Around 1 million people in the United Kingdom are treated in hospital each year after sustaining a head injury (Gronwall, Wrightson & Waddell, 1997). It is also estimated that every year around 5.2 per 10,000 of the population experience a serious head injury in the UK (Wenden et al., 1998), although the figure may in reality be much higher than this (Jacobs, 1988). As Gravell & Johnson (2002) explained, the terms 'head injury' and 'traumatic brain injury' (TBI) are typically used interchangeably within the literature, meaning that a large majority of these hospital admissions will be as a result of TBI. TBI is often defined as an external force applied to the head which affects the brain and results in a period of unconsciousness (Kay & Lezak, 1990), but TBI can also result from a penetrating injury to the brain (University of Utah Health Sciences Center, 2002).

The consequences following TBI have been well documented and can affect cognitive, emotional, communicative and social functioning (Lezak, 1988; Livingston & Brooks, 1988; Liss & Willer, 1990; Kosciulek, 1994; Stratton & Gregory, 1994). Even following a mild head injury, patients can show neuropsychiatric sequelae one year later, including problems such as irritability and impatience (Deb, Lyons & Koutzoukis, 1998). These problems may well be long-lasting, as Thomsen (1984) reported, "... no one escaped permanent sequelae" (p.260) even 10-15 years after their injury.

As Bond (2002) explained following her daughter's head injury "After a TBI, patients and their families are changed forever" (p.61). Relatives may need to help with a variety of activities following the patient's discharge, including feeding, bathing and help with physical tasks (Bond, 2002). Family members may be required to take on more responsibility and new roles to those previously held in the family (Douglas & Spellacy, 1996), and spouses may have to take on more responsibility without the peer support they previously received from the injured person (Ziegler, 1999). For the purposes of this review, family members (or friends) who care for patients following a TBI will be referred to as carers.

Linn, Allen and Willer (1994) reported that 73% of spouses of patients with brain injury showed symptoms of depression and 55% showed symptoms of anxiety, which are higher proportions than for the patients themselves. Kreutzer, Gervasio and Camplair (1994a) found that 47% of carers displayed significant emotional distress and that caring for someone who has experienced TBI had more of an impact on carers' health than caring for people with other chronic conditions, for example Multiple Sclerosis. Indeed, carers' reports of burden in TBI are found to be comparable to that of parents caring for children with cystic fibrosis and muscular dystrophy (Allen, Linn, Gutierrez & Willer, 1994). The burden and distress that carers experience can often be displayed in physical symptoms,

such as ulcers, weight loss, and sleep problems (Bond, 2002). Carers are also found to have lower perceived health when compared with the general population (McPherson, Pentland & McNaughton, 2000). Also, some research has suggested that a carer's response to a person with TBI can impact on that person's recovery and adjustment following their injury (Ponsford, Sloan & Snow, 1996; Verhaeghe, Defloor & Grypdonck, 2005).

Despite the many problems associated with the care-giving role, many carers do find their roles to be a positive experience (Machamer, Temkin & Dikmen, 2002). In fact it has been reported that many carers do not wish to give up their role as a carer, but do need more support and information in order to deal with the daily challenges they experience (Smith & Smith, 2000). However, the experience is more likely to be seen as negative if there are many changes to the carers' life, if the patient's injury is more severe, if the patient is more dependent and if the patient is perceived to have changed considerably (Machamer, Temkin & Dikmen, 2002). Feelings of loneliness and difficulties in the interpersonal relationships with the patient have also been reported by carers following a TBI (Wedcliffe & Ross, 2001). Nevertheless, it appears that having a strong belief in the ability to cope with the situation predicts whether the care-giving role will be a positive one (Wells, Dywan & Dumas, 2005). Of all family carers, wives appear to be at the greatest risk of displaying psychological distress whereas male relatives display signs of anger and fatigue rather than anxiety and depression (Perlesz, Kinsella & Crowe, 2000).

The research conducted in this area has produced mixed findings regarding what factors are most associated with strain in carers. The strengths and weaknesses of these studies are discussed below.

Several studies have investigated the long term effects of caring for patients with TBI on a carer's health and wellbeing. Thomsen (1974) was one of the first to investigate these experiences. This study followed up patients and their families 30 months after a TBI, and found that changes in the patient's personality caused difficulties for families in terms of adjustment. The finding that emotional and personality changes in the patient with TBI have more effect on the family than physical changes has been widely replicated (Oddy, Humphrey & Uttley, 1978; McKinlay, Brooks, Bond, Martinage & Marshall, 1981; Brooks & McKinlay, 1983; Brooks, Campsie, Symington, Beattie & McKinlay, 1986a; 1986b). Indeed, the burden reported by carers due to personality change in the person with TBI has been found to increase between 1 year and 5 years post-injury, and then remain at that level even at 7 years post-injury (Brooks, Campsie, Symington, Beattie & McKinlay, 1986a; 1986b).

In this latter series of studies, McKinlay, Brooks, Bond, Martinage and Marshall (1981) assessed 55 severely brain injured patients and their carers, and found that emotional problems, difficulties with memory and subjective symptoms, such as tiredness, were the most common problems reported by close relatives of the injured patients. In a structured interview, relatives were asked what areas of the patients' life had changed since the injury and were also asked to rate their subjective burden on a single 7-point scale. This procedure was repeated at 3, 6 and 12 months post-injury. Initially, burden was found to be linked to injury severity (as measured by length of post traumatic amnesia, PTA), however, this trend did not reach significance at 12 months. The mean level of burden was consistent in relatives over the 3 time periods. Subjective burden was linked to mental and behavioural changes in the patient, as reported by the relative.

Forty-two of these patients and relatives were followed up again at 5 years post-injury (Brooks, Campsie, Symington, Beattie & McKinlay, 1986a) and found that over half of the relatives were experiencing high levels of burden and a third experiencing medium levels of burden. These figures were higher than at 1 year post-injury. The changes in patients which caused the most distress were behavioural and personality changes. The authors again found that injury severity was a predictor of burden, but only because it mediated between subjective burden in relatives and areas of difficulty for the patients. Other studies have also suggested that injury severity is a significant predictor of burden in carers (Livingston, 1987; Groom, Shaw, Howard & Pickens, 1988; Sander, High, Hannay & Sherer, 1997).

Koskinen (1998) assessed quality of life in 15 patients with very severe TBI 10 years following their injury. These patients had subsequently received rehabilitation at a centre in Finland. Patients and carers were asked to complete a questionnaire regarding psychosocial factors and outcome. The Barthel Index (Wade & Collin, 1987) was used to assess the patients' independence, and the clinician rated the patients' behavioural consequences from the TBI using the Neurobehavioural Rating Scale (Levin et al., 1987) and their psychological functioning using the Rehabilitation Institute of Chicago – Functional Assessment Scale (Cichowski, 1992). Patients completed a quality of life questionnaire, and carers rated their level of burden using the same method as McKinlay, Brooks, Bond, Martinage and Marshall (1981).

As with previous studies, the author found emotional and behavioural difficulties in the patient more important than physical problems at predicting burden. Burden was found to be moderate to high in half of the carers, even at 10 years post-injury. Neurobehavioural and emotional problems (as rated by the clinician) were significantly correlated with carers' levels of burden and the life satisfaction rated by the patient. Unsatisfied and dependent patients had relatives with the highest burden.

Similar findings have also been reported when using a postal methodology instead of in-depth interviews with carers. Watanabe, Shiel, Asami, Taki & Tabuchi (2000) studied the levels of stress and anxiety in families of patients with TBI in Japan, and the types of difficulties relatives identified in patients following their injuries. The authors looked retrospectively at referrals to an emergency department over the previous two years. Those relatives who agreed to take part were asked to rate the patients' functional ability and their ease of completing tasks using the Barthel Index and the Patient Competency Rating Scale (PCRS; Prigatano, Fordyce, Zeuner et al, 1986). The PCRS form for relatives was used, which asks relatives to rate on a five-point scale of how easily the patient completes behavioural tasks. Relatives were also asked to complete the Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983) and a modified version of the Caregiver Strain Index (Robinson, 1983) which acknowledges the carers' personal circumstances. They found that carers with higher levels of strain, anxiety and depression tended to report that patients had more difficulty with cognitive and behavioural tasks.

Carers' appraisals of the patients' difficulties appear to be very important for perceived levels of burden, stress and strain, although carers may show huge variations in their perceptions of how the patient's difficulties affect them (Knight, Devereux & Godfrey, 1998). These differences in perception could be due to a number of factors, including personality traits or type of coping strategies used. Therefore, it may be interesting to obtain some measure of objective outcome for the person with TBI, in order to see how this relates to the carers' perceptions of strain. Kreutzer, Gervasio and Camplair (1994b) have criticised the lack of reliable and objective ratings from clinicians in previous studies, even though these ratings can be very accurate and show good correlations with carer burden (e.g. Koskinen, 1998). Conversely, a clinician's opinion of the severity of a person's difficulties has not always been found to be a good predictor of carer experience (e.g. Zarit, Orr & Zarit, 1985).

In summary, consistent findings have been reported which link the experience of distress, strain or burden in carers of patients with TBI to changes in the patient's behaviour, emotions and personality post-injury. These results have been produced from a number of long-term studies, with differing methodologies and measures employed, taken from the carer's perspective. However, the studies described above, and a number of other published reports have important methodological limitations, which may confuse the overall picture of carer strain in TBI.

Many of the studies exploring carer strain have used very limited inclusion criteria – often only including patients who have experienced a severe TBI. From the studies described above this is the case for Thomsen (1974), McKinlay, Brooks and colleagues (1981;

1986a; 1986b), and Koskinen (1998). This was also the criteria used by Oddy, Humphrey and Uttley (1978), who conducted a prospective study of 54 patients at 1 month, 6 months and 12 months following their head injury. All patients were from the severe or very severe category of TBI (PTA over 24 hours). Their relatives were interviewed at their homes using the Wakefield Depression Inventory (Snaith, Ahmed, Mehta & Hamilton, 1971), and the Katz Adjustment Scale (Katz & Lyerly, 1963). The authors found that just over half of the relatives reported feeling stress due to the patients' injury, and the number of symptoms that relatives reported as present in the patients was correlated with their depression. Also, the stress reported by relatives did not recede over time. This stress was again found to be particularly associated with personality changes in the patient, and not simply to the severity of the injury or disability.

In some studies, the nature of the study has meant that the more disabled patients with TBI are unable to take part. In a postal survey by Wells, Dywan & Dumas (2005), the Brock Adaptive Functioning Questionnaire (BAFQ; Dywan & Segalowitz, 1996) was used to measure the cognitive and behavioural functioning of the patient with TBI. The BAFQ examines behavioural changes in day-to-day experience following a brain injury. This was rated by both the patient and family member separately. The BAFQ has 12 subscales which include emotionality, aggression and empathy, as well as more neuropsychologically-based measures such as planning and memory. Among other findings, they reported that the level of behavioural problems can seriously impact on stress and negative experience of caring. However, patients who were unable to fill in the questionnaires were excluded from the study. Although including these patients may have made the issue of consent more complicated (as assent may have had to be given on the patient's behalf), this action may have served to exclude the most disabled patients from this study. This may mean that the families experiencing most stress may not have been represented here. This limits the ability to generalise from the findings.

McKinlay, Brooks and colleagues rationalise the use of a strict inclusion criteria of injury severity for their studies, as they report that it has been difficult to draw conclusions in previous studies due to the variability in levels of severity of the patients included. However, this criterion does limit the sample size and makes it difficult to generalise to a wider population of TBI patients. Therefore, the results published are always going to be limited in terms of their validity for general clinical application.

Another limitation with some of the studies is the use of non-validated measures in order to capture feelings of strain or measure patient's difficulties. From the studies already described, McKinlay, Brooks and colleagues (1981; 1986a; 1986b) and Koskinen (1998) both used a single seven-point scale for carers to rate their level of burden. This may not fully capture the level of stress or the areas of life that caring affects. Carers may not feel

that their whole life is affected by the caring role and so may underestimate their feelings of burden when asked to give an overall rating. Kay and Cavallo (1991) criticised this seven point scale, as it simplified the experience of caring and may have missed some of the more subtle aspects that cause burden. Kreutzer, Gervasio and Camplair (1994b) also criticise studies which use a “single question with unknown reliability and ambiguous meaning” (p.213) in order to measure strain or burden.

Other studies have used measures which have not been designed or validated for the TBI population, which assumes that the experiences of strain and distress is similar when caring for different populations with presumably different types of disability. For example, in Oddy, Humphrey and Uttley’s (1978) study, they used Wakefield Depression Inventory and the Katz Adjustment Scale to capture the experiences of their carers. However, these measures were originally designed for the psychiatric population, and therefore may be measuring qualitatively different experiences in the TBI carers.

Another difficulty in attempting to generalise between the findings from different studies is that the carer samples are often recruited from very different sources. This may create discrepancies in how much input and support patients (and carers) have received post-injury, which may influence the level of remaining disability or the strategies used to cope with it. Koskinen’s (1998) study was conducted at a rehabilitation centre following intensive input from professionals. This may have affected the level of burden reported by carers in this study. It is also important to note that injuries of moderate severity may have limited or no rehabilitation provided (Oddy & Herbert, 2003), which may lead to increased strain.

Ponsford, Olver, Ponsford and Nelms (2003) recruited carers during routine follow-up appointments after patients had received substantial rehabilitation. However, they still found a high proportion of patients and their relatives were experiencing significant anxiety and depression (between 46-55% of patients, and 22-25% of relatives). This was reported to be even higher when focusing on those relatives who were directly involved in caring for the person with TBI.

Some studies have chosen to recruit carers from head injury associations or voluntary organisations. For example, Wells, Dywan & Dumas (2005) invited participants from the Ontario Brain Injury Association in their study. It is important to note that these carers may be inherently resourceful and motivated to cope, as they were able to seek information and support independently. They may have been members of the Association because they were in need of support, and so may be more likely to report feelings of distress. This study may have neglected to include the carers who are unable to seek

appropriate support, and is unlikely to be representative of the general population of carers.

Finally, other studies, such as Watanabe, Shiel, Asami, Taki & Tabuchi (2000) contacted patients and their families following admission to hospital with TBI. Unfortunately, in this case, the initial sample of patients were from only one district hospital in Japan, which may have overlooked a large number of TBI admissions at other hospitals in this area of Japan. The authors also reported that, as a retrospective study conducted by examining hospital admission notes, they may have missed some of the TBI admissions into this hospital due to the inadequacy of the notes being studied. These methodological flaws resulted in a very small sample size, which may not greatly increase our knowledge of strain after TBI due to lack of statistical power. However, this study did have the potential for recruiting a representative sample of patients and carers (i.e. those who may receive rehabilitation in the future and those who do not, and those who may or may not join a head injury association).

In a similar study, Marsh, Kersel, Havill and Sleight (1998a; 1998b) recruited 69 patients selected from consecutive admissions to a critical care unit at Waikato Hospital. Carers were asked to complete the Beck Depression Inventory (Beck & Beck, 1972), the Trait Anxiety Inventory (Spielberger, 1983), the Social Adjustment Scale (Weissman & Bothwell, 1976), the Head Injury Behaviour Rating Scale (HIBS; Smith & Godfrey, 1995) and the Caregiver Questionnaire (which was designed specifically for the study). They found that at one year post-injury the patients' behavioural and physical impairments and social isolation most strongly predicted burden in carers. Cognitive, physical, emotional and social difficulties were also related to distress in carers. However, despite recruiting a sample from hospital admissions, the patients were selected from a group of admissions who had already enrolled in a larger brain injury study, which may suggest that their level of motivation or received input may differ from the average hospital admission.

Many studies have chosen to use face-to-face interviews in order to conduct their research into carer strain. This is an adequate methodology to use as it allows for richer qualitative information to be gained from the carer, as well as enables the researcher to clarify or expand upon any of the carers' responses. However there is the possibility that the presence of an interviewer may affect the carer's responses, due to feelings of guilt, shame and the bias towards social desirability (Verhaeghe, Defloor & Grypdonck, 2005). Postal methodologies have been employed in a small number of cases (e.g. Watanabe, Shiel, Asami, Taki & Tabuchi, 2000; Wells, Dywan & Dumas, 2005), which may serve to avoid this problem. It is also possible to reach a larger number of potential participants using this methodology, and thus a larger sample size is likely.

One major difficulty with the research into carer strain in TBI is that a variety of terms are used to describe and measure the experience of the carer, with little definition of how these factors fit together. From the studies described above, the terms have included adjustment, adaptation, strain, burden, distress, depression and anxiety. This makes the findings more difficult to interpret and generalise from. If Pearlin, Mullan, Semple and Skaff's (1990) model is to be followed, this would suggest that everyday stressors are involved in caregiving, and that these may result in strain if they were to affect carers' roles and activities outside of the caregiving situation. This experience may then result in outcomes such as physical and / or mental illness. If this process were to be regarded as accurate, it would suggest that researchers in this field have been measuring the experience of caregiving on carers from very different perspectives, which may explain the variability in the prevalence and conclusions reported. Therefore, the current study has identified those carers under strain, whose lives are adversely affected by the everyday stressors involved in caregiving, but may not yet be experiencing ill-health.

This focus is clinically useful in terms of finances, as the entire population of carers cannot feasibly be monitored indefinitely following the patient's discharge, but on the other hand, identifying carers once they are experiencing physical or mental health problems could be construed as being too late. This is especially poignant if the carers' health and coping can affect the patients' health and recovery (Ponsford, Sloan & Snow, 1996; Verhaeghe, Defloor & Grypdonck, 2005). Therefore it seems more clinically meaningful to be able to identify carers who are experiencing strain or at risk of experiencing strain, and monitor them to ensure that health problems do not develop. This would also make more financial and practical sense in terms of the services providing this after-care.

In summary, there have been some consistent findings regarding the areas of patient disability following TBI which are linked to strain and distress in carers. However, a number of methodological flaws have made it difficult to create a clear picture regarding carer strain, meaning that it is challenging to generalise to future populations of carers. Inclusion criteria, sources of sample recruitment, inadequate measures of strain or distress and inconsistent terms used have all contributed to this situation. Therefore, the current study aims to improve this situation by recruiting a more representative sample which can be generalised from, as well as using validated measures in the conduct of the study.

Appendix 2: Method

Appendix 2.1: Design

This study was a cross-sectional cohort study of the factors related to strain in carers of patients who have experienced TBI. The patients for this study had all experienced a TBI in the previous five - fourteen years, and had been treated in the Neurosurgical Unit at Queen's Medical Centre, Nottingham. The severity of the TBI had been assessed using a number of physiological measures, including the Glasgow Coma Scale (Teasdale & Jennett, 1974) and the Virginia Prediction Tree (Choi, Muizelaar, Barnes, Marmarou, Brooks & Young, 1991). This study followed up these patients in order to determine the prevalence of strain experienced by their carers following the patients' injury and the factors that contribute to that experience.

Appendix 2.2: Exclusion criteria

Patients were not approached if details of their GP or next of kin had not been recorded at the time of injury. The GP's details were required to confirm that the patient was still alive before contacting them, and a next of kin was needed so that the patient would presumably be able to nominate someone to fill out the questionnaires for the study. Patients under 18 were excluded, as it was presumed that the caring relationship between a parent and child, and someone caring for an adult with a brain injury may involve different issues and strains, such as the adult patient being no longer able to provide financial input at home. All patients who had died shortly after admission or at one year follow-up were also excluded from the study, so that their families were not caused any unnecessary distress through being contacted about the research. The exclusions were made by studying the information on the database. The exclusion criteria were supported by the Ethics Committee.

Those patients who were in prison or had moved to a nursing home since their injury were excluded as it would be unlikely that a family member were closely involved in their day-to-day care. Those who had changed GP surgeries or had been temporary residents in Nottingham were excluded as their contact details and health status could not be confirmed. Patients were also excluded if they did not nominate a carer to complete the questionnaires on being invited to take part in the study, and thus a consent form was not received for both the carer and patient. This happened in eight (2%) cases.

Appendix 2.3: Demographics

From the patients who could be traced in order to invite them to take part in this study, 73 were female and 318 were male. The mean age was 40.96 years (SD=16.53, range=18-91). Of these, 55 patients and carers gave consent to take part in the study. Of the 55 carers, 46 were female and 11 were male (two couples answered the questionnaires jointly). The mean age of patients who gave consent was 44.38 (SD=17.166, range=19-88).

Appendix 2.4: Measures

Injury severity

There are many ways to measure injury severity following head injury, the most widely used of which is the Glasgow Coma Scale (GCS; Teasdale & Jennett, 1974). This scale records the level of consciousness of the patient, and is often one of the first assessments following injury. In the revised version of the GCS (Jennett & Teasdale, 1977) three components are assessed: motor response, verbal response and eye opening. As it is a standardised measure of consciousness, which has been simplified to make it easy for all medical teams to use, it is the most often used measure in research involving people who have sustained head injury (McNett, 2007). However, there has been little research evaluating the reliability and validity of the scale.

Many studies have been conducted to assess whether the GCS score correlates with measures of outcome following brain injury. Lokkeberg and Grimes (1984) reported, however, that even when combining the GCS score with the age of the patient, 60% of the variance in predicting the patient's outcome was still unaccounted for. Also, the motor component of the GCS score has been found to better predict outcome in patients than the summed total score, which questions the validity of the scale being used as a whole (McNett, 2007). The GCS score was not used in this study (apart from to initially categorise patients) as it has been found to be limited in predicting functional outcome and can be insensitive in the intermediate range of the scale (Bastos, Sun, Wagner, Wu & Knaus, 1993; Zafonte et al., 1996).

Post traumatic amnesia or PTA is another measure that is commonly used following a TBI to indicate severity of the injury, and refers to the time immediately after the injury, where the patient is confused or unable to remember what is happening (Lee, 2007). This can last for minutes to hours or days, with longer durations being associated with poorer outcome (Novack, Bush, Meythaler, Canupp, 2001). PTA is usually determined using a retrospective interview with the patient following their injury (Alexander, 1995). Although the measure of PTA has been shown to be reliable in predicting outcome in previous

studies (e.g. van der Naalt, van Zomeren, Sluiter, Minderhoud, 1999), it is often in practice measured retrospectively, with long delays between assessments, which can affect its accuracy (King et al, 1997). It is also open to bias if there are intense isolated memories recalled by patients instead of the resumption of continuous memory, which may prematurely end the measurement of PTA (Gronwall & Wrightson, 1980). As PTA was not recorded on the database at the time of the patients' injuries and is not routinely used on the ward, it cannot be accurately used for this study.

Choi, Muizelaar, Barnes, Marmarou, Brooks and Young (1991) studied 555 patients with severe brain injury who had a known outcome at 12 months post-injury. Twenty three prognostic factors were studied in relation to outcome measured on the Glasgow Outcome Scale (see below). These variables were: age, race, sex, motor response, pupillary response, oculocephalics, eye opening, verbal response, midline shift, intracerebral lesion, extracerebral lesion, intracranial pressure, systolic blood pressure, diastolic blood pressure, pulse, respiration, temperature, hematocrit, pCO₂, pO₂, pH, blood alcohol and intracranial pressure. Logistic regression analysis, discriminant analysis and the prediction tree method (see research paper, p. 6) were then assessed for their predictive accuracy in assessing outcome from the prognostic factors. The four factors found to be most associated with outcome were age, pupillary response and motor response on admission, and mass lesion data. Interestingly, previous studies have also found the first three factors to be particularly predictive of outcome (e.g. Choi, Ward & Becker, 1983).

The prediction tree method is easier for healthcare teams to understand in order to give predictive outcomes for patients soon after admission (Choi et al, 1991). Identifying subgroups can be helpful as it allows predictions to be made, rather than treating all head injured patients as a single population (McQuatt, Andrews, Sleeman, Corruble & Jones, 1999). However, there are some limitations to the prediction tree. As the sample is continually broken into smaller subgroups, the resulting subgroup sizes are quite small, making it more difficult to generalise to other samples. Nonetheless, the authors felt that they had produced a sufficient balance between number of factors included and sample size. Also, as the splitting into subgroups has been based on a specific sample and their prognostic data, the reported predictive accuracy could vary when different samples are used (Choi et al., 1991).

Outcome

The Glasgow Outcome Scale (GOS) was developed as a method of describing social outcome six months post-injury, with clear categories which could be widely used by different clinicians (Jennett, Snoek, Bond & Brooks, 1981). Jennett, Snoek, Bond &

Brooks (1981) reported a 95% agreement rate between two observers using the GOS scale to assess 150 patients at 6 and 12 months post-injury.

The GOS has been criticised for having categories which are too broad, and thus insensitive to change (Hall, Cope & Rappaport, 1985; Gouvier, Blanton & Kittle, 1986; Hall, 1992). Wilson (2001) suggested that when the scale is treated as ordinal rather than dichotomous in outcome (i.e. either 'favourable' or 'unfavourable'), the sensitivity to change becomes greater. Nevertheless, Jennett and colleagues (1981) have discussed an extended version of the scale (eight points), which allows classification within each of the original categories and is more evenly spread across the distribution of disability than other published scales (e.g. Stover and Zeiger, 1976). In fact, when the 5- and 8-point scales were compared regarding the amount of agreement found between physicians using each of the scales, the 5-point scale was found to be more reliable (Maas, Braakman, Schouten, Minderhoud & van Zomeren, 1983). The authors of the scale also believe that in terms of long-term survival, having many classifications is not particularly useful, although may be helpful immediately after injury in terms of support required (Jennett, Snoek, Bond & Brooks, 1981). Also, the scale is intended to give an idea of degree of disability, rather than analysing the details of the disability and thus does not need to specifically record such details.

Another criticism has been that the GOS focuses on physical rather than emotional, cognitive or behavioural changes post-injury (Anderson, Housley, Jones, Slattery & Miller, 1993). However, Wilson, Pettigrew and Teasdale (1998) give guidelines for making the scale more reliable by use of a structured interview to assign categories, which produced a high reliability rating when tested on patients. Using these guidelines produced by Wilson, Pettigrew and Teasdale (1998) and incorporating a semi-structured interview appears to have improved the focus of the scale to cognitive, emotional and behavioural changes post-injury, as well as physical. This has reduced the possibility of using the scale in an "impressionistic, subjective way" (Teasdale, Pettigrew, Wilson, Murray & Jennett, 1998; p.587). Although the reliability increased with the use of a structured interview to assign categories to the GOS, Wilson, Edwards, Fiddes, Stewart and Teasdale (2002) acknowledged that postal assessment does avoid any observer bias.

At a conference developing recommendations for outcome measures for clinical trials (Clifton, Hayes, Levin, Michel & Choi, 1992), the GOS was recommended as the scale to use in severe and also moderate brain injury, as well as the Disability Rating Scale (DRS; Rappaport, Hall, Hopkins, Belleza & Cope, 1982). The criteria used to guide this recommendation were that both scales have: clinical relevance; unambiguous definitions; adequate inter-rater reliability; and sensitivity to change. The DRS has been suggested as a better alternative to the GOS (Hall, Cope & Rappaport, 1985), although Wilson

(2001) reported that other scales are not “convincingly superior to the GOS, but can usefully supplement the information collected” (p.1549).

The GP was asked to complete the GOS in this study, as it was thought they may be less biased in their perception of outcome from the patient’s immediate state following their injury. Jennett and colleagues (1981) commented that clinicians who had been directly involved in the patient’s treatment following the brain injury would be biased to consider the patient’s outcome in light of this change, rather than comparing the current status to how the patient was before the injury occurred. A GP is more likely to have seen the patient before and after their head injury, but not in the acute stages of recovery, meaning that they may be best placed to have an unbiased view. A more detailed questionnaire was not sent to GPs, as it would have required the GP to have regular and detailed contact with the patient, and would have been more time-consuming to complete. It was thought that this may also decrease return rates. Therefore, a more subjective assessment had to be used. However, the advice from Wilson, Pettigrew and Teasdale’s report (1998) was followed when sending the GOS out to GPs, in the hopes that they would also consider emotional, behavioural and cognitive factors in their rating.

A copy of the GOS is shown in Figure 1.

Figure 1: The Glasgow Outcome Scale as sent to GPs

Glasgow Outcome Scale

Please rate the recovery of the patient named in the accompanying letter on the scale below by marking the appropriate box. A short description has been given for each category to help you. The patient's recovery should be judged with regard to their pre-injury status and not compared to their status immediately post-injury. Please remember that impairments may be physical or mental in nature.

Death – the patient has since died.

☐

Persistent Vegetative State – the patient has remained unresponsive and speechless for many weeks or months. May have spontaneous eye opening and follow moving objects. May swallow food placed in their mouths.

☐

Severe disability (conscious but disabled) – the patient is dependent on others for daily support with at least one activity of daily living (e.g. dressing) as they are significantly mentally or physically disabled. They require supervision on tasks for their own safety. The patient may be capable of self-care within their own environment. Resumption of normal life is not possible. Communication possible but may be severely limited.

☐

Moderate disability (disabled but independent) – the patient can travel alone on public transport and work in sheltered environments. Independence in activities of daily living. There may be persisting disability, such as some level of dysphasia, ataxia, hemiparesis, cognitive difficulty or personality change. Resumption of activities at a lower level possible.

☐

Good recovery – A resumption of normal life with minor neurological and psychological deficits.

☐

Date of last consultation with patient

Ratings are as described in Jennett & Bond (1975) and adapted using guidelines from Wilson, Pettigrew & Teasdale (1998).

Neurobehavioral Functioning Inventory (NFI)

The NFI was used in this study to measure the carers' perceptions of the patients' disabilities following head injury. In a study by Seel and Kreutzer (2003), they assessed the internal consistency of the NFI depression subscale to identify depression in patients who had experienced TBI and found it a very useful screening tool with a high level of consistency ($\alpha=0.93$).

The NFI has also been adopted in the mini-battery of tests recommended by the American and European Brain Injury Consortiums (Marmarou, 1996; Teasdale et al., 1997). In addition, all subscales correlate quite highly with the GOS, particularly when using family informants (Wilson, Pettigrew & Teasdale, 2000). Indeed, Wilson (2001) suggests that this scale could be used in parallel with the GOS for more detailed information about the precise areas of disability.

The family form of the NFI was used in isolation in this study. However, there is a moderately high concordance between patients' and carers' perceptions at one year post-injury, although for more severe TBI this becomes less reliable as patients underreport their symptoms (Hart et al., 2003). Therefore, carers' perspectives may be a more accurate representation of the level of disability of the patient. A complete transcript of the NFI Family Form is shown in Figure 2.

Figure 2: Complete transcript of the Neurobehavioral Functioning Inventory: Family Form

How often does the patient CURRENTLY have any of the following problems?					
	Never	Rarely	Sometimes	Often	Always
1. Blackout spells	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Seizures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Threatens to hurt self	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Cannot be left at home alone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Misses or cannot attend work/school	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Double or blurred vision	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Feels hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Stomach hurts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Forgets yesterday's events	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Difficulty pronouncing words	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Curses at others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Difficulty lifting heavy objects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Feels worthless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Nauseous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Forgets if he or she has done things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Writes slowly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Hits or pushes others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Moves slowly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Sad, blue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Headaches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Forgets or misses appointments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Trouble understanding conversation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Argues	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Loses balance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Lonely	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Dizzy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Forgets people's names	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Making spelling mistakes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Inappropriate comments or behaviour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Weak	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. No confidence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Stomach bloated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. Forgets what he or she reads	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Difficulty thinking of the right word	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. Breaks or throws things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. Drops things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Frustrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. Nightmares	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. Loses track of time, day, or date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. Difficulty making conversation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41. Screams or yells	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. Muscles tingle or twitch	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. Sits with nothing to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44. Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45. Forgets to do chores or work	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
46. Speech doesn't make sense	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
47. Rude to others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
48. Difficulty performing chores	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
49. Scared or frightened	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
50. Poor appetite	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
51. Misplaces things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
52. Writing is hard to read	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
53. Threatens to hurt others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Figure 2 (cont.)

	Never	Rarely	Sometimes	Often	Always
54. Trips over things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
55. Concentration is poor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
56. Loses train of thought	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
57. Forgets phone numbers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
58. Loses way, gets lost	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
59. Bored	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
60. Confused	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
61. Reads slowly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
62. Easily distracted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
63. Talks too fast or slow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
64. Forgets to turn off appliances	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
65. Difficulty enjoying activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
66. Trouble following instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
67. Uncomfortable around others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
68. Curses at self	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
69. Forgets to take medication (If none prescribed, respond 'never'.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
70. Can't get mind off certain thoughts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
71. Disorganized	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
72. Restless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
73. Late for appointments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
74. Trouble falling asleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
75. Trouble hearing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
76. Food doesn't taste right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Carer Strain Index (CSI)

The CSI is a brief screening tool used to give an indication of whether a carer is under strain or not due to their caregiving role. Internal reliability is found to be high ($\alpha = 0.86$), and scores correlate strongly with physical and emotional well-being of the carer, suggesting good construct validity (Robinson, 1983).

McGartland Rubio, Berg-Weger and Tebb (1999) used structural equation modelling to validate the CSI, and found 11 of the 13 items to have good validity for the factors they were attempting to measure. Van Exel et al. (2004) studied a number of measures of burden for their feasibility and validity of use with carers of stroke patients. They found that the CSI was a very feasible tool for use in clinical practice and research and just as valid as other, longer measures of burden, such as the Caregiver Reaction Assessment (Given et al., 1992). The authors concluded that the CSI should be used in the diagnosis of burden in caregivers.

The limitations are that the scale is brief, and is suggested as a tool to indicate when more in-depth assessment of strain is needed (Sullivan and Terry, 2004). However, this is appropriate for clinical practice, where the questionnaire would be used as a screening

tool to identify those carers who may need further input. The measure is also quick and easy to complete, which is likely to improve return rates. The scale has also previously been used as a postal questionnaire (e.g. Watanabe, Shiel, Asami, Taki & Tabuchi, 2000; Connolly & O'Dowd, 2001), and hence meets the requirements of this study. A transcript of the CSI is shown in figure 3.

Figure 3: Transcript of the Caregiver Strain Index

Caregiver Strain Index		
I am going to read a list of situations. They may relate to your experience in looking after _____. Would you tell me if any of these apply to you?		
	Yes	No
Sleep is disturbed (e.g. Because _____ needs help to go to the toilet.)		
It is inconvenient (e.g. Because helping takes so much time)		
It is a physical strain (e.g. Because of lifting in and out of bed)		
It is confining (e.g. Helping restricts my free time)		
There have been family changes (e.g. Because helping has disrupted routine there has been no privacy)		
There have been changes in personal plans (e.g. Could not go on holiday)		
There have been other demands on my time (e.g. From other family members)		
There have been emotional adjustments (e.g. Because of sever arguments)		
Some behaviour is upsetting (e.g. Because of incontinence/ _____ has trouble remembering things)		
It is upsetting to find _____ has changed so much from his/her former self (e.g. He/she is a different person than he/she used to be)		
There have been work adjustments (e.g. Having to take time off)		
It is a financial strain		
Feeling completely overwhelmed (e.g. Because of worry about _____/ concerns about how you will manage)		
TOTAL SCORE		
Scoring (Yes = 1, No = 2)		

Appendix 2.5: Ethical Approval and Procedure

Ethical Approval

The ethics committee emphasised the importance of checking that the patient was still alive before sending out invitation letters. Following an incident involving inaccurate information from a GP surgery during the pilot phase, a secondary check using the NHS Central Register was introduced. The Committee were also concerned about contacting patients who had no relatives or friends to ask to take part. Therefore any patients without a next of kin recorded on the database were excluded in the initial stages. The Committee suggested that a summary letter be offered to patients and carers following the study's completion, which was also employed.

Procedure

Patients who had experienced TBI were identified from a database held at Queen's Medical Centre over the period 1993-2003 for audit purposes. This included every patient admitted to the Neurosurgical Unit at the hospital over this time with a diagnosed TBI. Severity of brain injury was assessed using a number of measures including the Glasgow Coma Scale and Virginia Prediction Tree. The database included demographic information for the patient as well as date of injury, next of kin and details of the patient's GP.

Following the initial exclusions described in the paper, the GPs for the remaining 937 patients were contacted by telephone and the current status of the patient was checked. If the patient had since died or had left their GP practice they were excluded. The traceable patients were then sent a letter inviting them to take part in the study, as well as an information sheet about what the study involved. An additional information sheet was also enclosed for the patient to pass on to the person they considered their 'carer'. These letters are shown in figures 4 and 5, along with the consent forms required for both the patient and carer.

Figure 4: Information sheet and consent form sent out to patients traced from the database inviting them to be included in the study

Patient Information Sheet

Exploring Strain in Carers of Brain-Injured Patients

We would like to invite you to be included in a research study. It is important that you know what research is being done and what will be involved for you before you decide if you wish to be involved. Please take your time to read the following information carefully. Feel free to discuss the study with others if you wish.

(Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to be included.

Part 1

What is the purpose of the study?

This study is designed to understand more about how family members or friends cope after someone they know has suffered a brain injury. We are asking for a family member or close friend to fill out a questionnaire about your recovery since your brain injury. For some people, they may have recovered fully since their injury and life has returned to the way it was before. For others, there may be some areas of your life which have changed since your brain injury.

In this study we would like to send two questionnaires to the person you feel has been most involved in your recovery since your injury. This could be a relative such as a spouse, or a close friend. They will be referred to as a 'carer' due to their involvement in your care following your injury, although it is understood that this may no longer be an accurate description of their role. These questionnaires will ask about any difficulties you may still be having following your brain injury and how these difficulties affect their lives.

Why have I been chosen?

You have been invited to take part in this study as you have been identified from our records as having experienced a head/brain injury and received subsequent care in the Neurosurgical Unit at Queen's Medical Centre, Nottingham. All patients who suffered a brain injury and were discharged from this unit in the period 1995-2003 are being invited to take part in this study.

It is up to you to decide if you wish to be included in the study. This sheet has been sent to you for you to read carefully and consider if you are interested in being involved. A consent form has also been enclosed which you may sign and send back to show that you agree to be included in the study. You are free to withdraw at any time, without giving a reason. If you still receiving any aftercare then your withdrawal will not affect the care provided.

What will happen in the study?

If you give your consent to be involved you will then need to nominate a relative or friend to take part in the study. The envelope enclosed contains information which should be passed onto this person. If they also agree to be included in the study, they will be sent two questionnaires to fill in. They will be asked to comment on how they think you have recovered since your brain injury, and how any difficulties you are having affect them. These questionnaires will only be sent out to them once we have received both consent forms (yours and theirs).

You will not be required to fill out any forms yourself or attend any appointments and there will be no visits to your home. All postage for the forms will be pre-paid and so you will not incur any costs by taking part in this study.

What risks / benefits are there in taking part?

There will be no intended clinical benefit to you, but the research may lead to a better understanding about strain in people who are in close contact with patients who have suffered a brain injury, and how services can help reduce this strain.

If you do feel that you need further support for whatever reason, you should contact your GP or the support services mentioned below.

What if there is a problem?

Any complaint about the way you have been dealt with will be treated seriously. More detailed information about this is available in Part 2.

Will my information be kept confidential?

Yes. We will follow ethical and legal practice, and all information about you and your spouse / family member / friend will be handled in confidence. More information on this is available in Part 2.

If the information in Part 1 has interested you and you are considering taking part, please read Part 2 before giving consent.

Part 2

If you wish to withdraw from the study at any point, the data collected up to your withdrawal may still be used in the analysis, but you will not be contacted further by the research team.

Complaints

If you have any concerns about any aspect of this study, you should speak to Naomi Boycott who will do her best to answer your questions (tel. 0115 9249924 ext. 64619). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained through the hospital (tel. 0115 9249924).

Confidentiality

All information which is collected about you during the course of this study will be kept strictly confidential. All information will be coded so that you cannot be recognised from the forms, and these forms will be stored in a locked filing cabinet. Only authorised persons (the research team) will have access to the identifiable information which you send to us. The information collected about you will be stored for 7 years in a secure storage facility before being destroyed.

You have the right to view any information that is held about you as laid out in the Data Protection Act (1988).

GP Involvement

If you agree, your GP will also be contacted and asked to be involved in this study. GP's will be sent a form which asks for their opinion on how you have recovered following your brain injury. This is merely to gain an additional point of view. You will be asked to consent to their involvement on the enclosed consent form.

Scientific results of the trial

It is the intention of this study to publish the results in a professional journal. The information collected about you in this study will not be recognisable or identifiable in a publication. If the study is published you will be notified as to where you may access it.

If you would like to receive a summary of the overall findings of the study, please indicate this at the bottom of the consent form enclosed.

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Nottingham Research Ethics Committee 1.

Thank you for taking the time to read this information sheet.

What to do now

Enclosed is a consent form for you to sign if you wish to be included in the study. The information sheet is for you to keep. Should you agree to take part in the study you will receive a copy of your signed consent form to keep.

Please note that if you do not wish to be included in the study, and choose not to sign the consent form you will not be contacted further by the research team.

If you wish to be included in the study, please sign the form enclosed and pass the enclosed envelope to your nominated 'carer'. If they also agree to take part, they will be asked to sign a consent form. Once both consent forms have been received (envelope provided) the questionnaires will be sent out.

If you have any difficulty understanding the information presented in this sheet, or have any queries, please feel free to contact the lead investigator on the number below. Alternatively, you could ask a representative to contact the lead investigator for you.

Please return signed consent forms by 10th March 2008

Queries

If you have any queries about the research please contact:

Naomi Boycott
Clinical Psychologist in Training
c/o Dr Patrick Vesey
Adult Neuropsychology,
Neurosciences,
Queen's Medical Centre,
Nottingham,
NG7 2RD

Tel: 0115 9249924 ext. 64619

Or, alternatively:

Dr Paddy Yeoman,
Consultant in Intensive Care and Anaesthetics,
Adult Intensive Care Unit,
Queen's Medical Centre,
Nottingham,
NG7 2RD

Tel: 0115 9249924 ext. 63339

Further support / information about head injury

Headway - the brain injury association
4 King Edward Court
King Edward Street
Nottingham
NG1 1EW
United Kingdom

Telephone: 0115 9240800 Helpline: 0808 800 2244

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project: Exploring strain in carers of brain-injured patients: version 4

Name of Researcher: Naomi Boycott, Trainee Clinical Psychologist

Please put initials in the boxes

1. I confirm that I have read and understand the information sheet dated 5th October 2007 (version 4) for the above study. I have had the opportunity to consider the information, contact someone to ask questions and have had these answered satisfactorily.

☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by researchers from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

☐

4. I agree to my GP being contacted in the study.

☐

5. I agree to the research team contacting my nominated 'carer'.

☐

6. I agree to take part in the above study.

☐

7. I wish to receive a summary of the overall findings of the study.

☐

Name of Patient Date Signature

Name of Researcher Date Signature

Figure 5: Information sheet and consent form inviting carers to take part in the study

Research Information Sheet

Exploring Strain in Carers of Brain-Injured Patients

We would like to invite you to take part in a research study. It is important that you know what research is being done and what will be involved for you before you decide whether to take part. Please take your time to read the following information carefully. Feel free to discuss the study with others if you wish.

(Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1

What is the purpose of the study?

This study is designed to understand more about how family members or friends cope after someone they know has suffered a brain injury. We are asking for your opinion of that person's recovery following a brain injury. After a brain injury, some people recover and life returns to the way it was before. For others, there may be some areas of their life which have changed since their brain injury.

In this study we are contacting people who have been nominated as caring for somebody who has had a traumatic brain injury and asking them to fill out some questionnaires. These questionnaires will ask about any difficulties the person may still be having following their brain injury and how this affects people who care for them.

Why have I been chosen?

You have been invited to take part in this study as you have been nominated by the person who experienced the traumatic brain injury. They feel that you have been most closely involved in their recovery following their injury. For the purposes of this study you have been referred to as a 'carer' due to this early involvement in the person's care. However, it is understood that you may no longer feel that this description is accurate. All patients who suffered a brain injury and were discharged from this unit in the period 1995-2003 are being invited to take part in this study.

It is up to you to decide if you wish to take part in the study. This sheet has been sent to you for you to read carefully and consider if you are interested to take part. A consent form has also been enclosed which you may sign and send back to show that you agree to be involved in the study. You are free to withdraw at any time, without giving a reason. Deciding not to take part will not affect any treatment you receive from the NHS in the future.

What will happen in the study?

If you agree to take part in the study, you will be sent two further forms through the post. You will be given information on how to fill out these forms. You will be asked to comment on how you think the person has recovered since their brain injury, and how any difficulties they are having are affecting you. You will then be asked to send these forms back to us.

You will not be required to attend any appointments and there will be no visits to your home. All postage for the forms will be pre-paid and so you will not incur any costs by taking part in this study.

What risks / benefits are there in taking part?

There will be no intended clinical benefit to you, but the research may lead to a better understanding about strain in people who care for people with brain injuries, and how services can help reduce this strain.

If you feel that you are in need of support for whatever reason you should contact your GP or the support services mentioned below.

What if there is a problem?

Any complaint about the way you have been dealt with will be taken seriously. More detailed information about this is available in Part 2.

Will my information be kept confidential?

Yes. We will follow ethical and legal practice, and all information about you and the person who suffered the brain injury will be handled in confidence. More information on this is available in Part 2.

If the information in Part 1 has interested you and you are considering taking part, please read Part 2 before giving consent.

Part 2

If you wish to withdraw from the study at any point, the data collected up to your withdrawal may still be used in the final analysis, but you will not be contacted further by the researcher.

Complaints

If you have any concerns about any aspect of this study, you should speak to Naomi Boycott who will do her best to answer your questions (tel. 0115 9249924 ext. 64619). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained through Queen's Medical Centre (tel. 0115 9249924).

Confidentiality

All information which is collected about you during the course of this study will be kept strictly confidential. All information will be coded so that you cannot be recognised from the forms, and these forms will be stored in a locked filing cabinet. Only authorised persons (the research team) will have access to the identifiable information which you send to us. The information collected about you will be stored for 7 years in a secure storage facility before being destroyed.

You have the right to view any information that is held about you as laid out in the Data Protection Act (1988).

GP Involvement

The GP for the person who suffered a brain injury will be contacted and asked to be involved in this study. GPs will be sent a form which asks for their opinion on how the person has recovered following their brain injury. This is merely to gain an additional point of view. As a carer, your GP will not be contacted about your involvement in this study.

NHS Duty of Care

In the health service there is a duty of care for all patients and relatives we come into contact with. As such, if I were to be made aware that you were experiencing significant strain in your caring role I would need to act on this information. If this were to happen I

would contact you to discuss whether you would want this information passing on to your GP.

Scientific results of the trial

It is the intention of this study to publish the results in a professional journal. The information collected about you in this study will not be recognisable or identifiable in a publication. If the study is published you will be notified as to where you may access it.

If you would like to receive a summary of the overall findings of the study, please indicate this at the bottom of the consent form enclosed.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Nottingham Research Ethics Committee 1.

Thank you for taking the time to read this information sheet.

What to do now

Enclosed is a consent form for you to sign if you wish to take part in the study. The information sheet is for you to keep. Should you agree to take part in the study you will receive a copy of your signed consent form to keep.

The person who suffered the brain injury has received a similar information sheet for them to read and a consent form for them to sign if they wish to be included. If you wish to take part, please sign the enclosed consent form. Once **both** consent forms have been received (yours and theirs) the questionnaires will be sent out to you.

Please return signed consent forms by 10th March 2008***Queries***

If you have any queries about the research please contact:

Naomi Boycott
Clinical Psychologist in Training
c/o Dr Patrick Vesey
Adult Neuropsychology,
Neurosciences,
Queen's Medical Centre,
Nottingham,
NG7 2RD

Tel: 0115 9249924 ext. 64619

Or, alternatively:

Dr Paddy Yeoman,
Consultant in Intensive Care and Anaesthetics,
Adult Intensive Care Unit,
Queen's Medical Centre,
Nottingham,
NG7 2RD

Tel: 0115 9249924 ext. 63339

Further support / information about head injury

Headway - the brain injury association
4 King Edward Court
King Edward Street
Nottingham
NG1 1EW
United Kingdom

Telephone: 0115 9240800 Helpline: 0800 800 2244

Centre Number:
Study Number:
Carer Identification Number for this trial:

CARER CONSENT FORM

Title of Project: Exploring strain in carers of brain-injured patients: version 4

Name of Researcher: Naomi Boycott, Clinical Psychologist in Training

Please initial the boxes

1. I confirm that I have read and understand the information sheet dated 5th October 2007 (version 4) for the above study. I have had the opportunity to consider the information, contact someone to ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
3. I agree to take part in the above study.
4. I wish to receive a summary of the overall findings of the study.

Name of Carer	Date	Signature
---------------	------	-----------

Name of Researcher
Date
Signature

Once the questionnaires were received back from the carers, the data was collated and analysed. No reminder letters were sent to patients or carers regarding the study. If carers did not return the questionnaires they were removed from the study. If items from the returned questionnaires were missing, the recommendations from the respective measures were followed (see Appendix 3.3). GPs were prompted by telephone if they had not returned the GOS within two months.

If carers or GPs had any difficulties with completing the questionnaires, contact details of the first author (NB) were provided to give information and answers to any queries over the phone.

Appendix 3: Results

Appendix 3.1: Comparison of traceable and non-traceable patients

As many patients from the database could not be traced at follow-up, it was important to establish whether there were any significant differences between the patients who could be traced and those who could not in terms of demographics and injury severity. Therefore, Chi-square tests (for categorical variables) and Mann Whitney U tests (for continuous variables) were conducted between the two groups regarding demographic information from the database. The results are displayed in table 1 below.

Table 1: Comparison of demographics for those patients who could be traced and those who could not.

	Traceable patients n=391	Non-traceable patients n=485	Comparison p value
Age			
Mean	40.89	40.11	0.54
SD	16.41	16.13	
Gender			
Male	318	336	<0.05 *
Female	73	119	
Years since injury			
Mean	9.43	10.17	<0.001**
SD	2.89	2.88	
Injury Severity (VPTS)			
Median	2.0	3.0	0.37
IQR	1.0-5.0	1.0-5.0	

*p<0.05, **p<0.001. Gender analysed using χ^2 , the remaining variables using Mann Whitney U tests. VPTS = Virginia Prediction Tree Score. VPTS scored from one-eight; one=good outcome, eight=very poor outcome, often death.

In the non-traceable group of patients, there was a significantly higher proportion of female to male patients, and the length of time since injury was longer for these patients. There was no significant difference between age or injury severity between the two groups.

Appendix 3.2: Comparison of participants and non-participants

Of the 391 patients who were traced from the database and approached to take part in the study, only 48 patients and carers returned the consent forms and the questionnaires sent to them. It was also important to establish how representative this sample was of the patients traced. Therefore, Chi-square and Mann Whitney U tests were conducted on the demographic information for the two groups. The results are presented in table 2.

Table 2: Comparison of demographics for those patients participating in the study and those not participating

	Participant patients n=48	Non- participant patients n=343	Comparison p value
Age			
Mean	45.35	40.30	0.05
SD	17.65	16.23	
Gender			
Male	39	278	1.0
Female	9	65	
Years since injury			
Mean	9.31	9.43	0.76
SD	2.91	2.92	
Injury Severity (VPTS)			
Median	3.5	2.0	<0.05*
IQR	1.25-5.0	1.0-5.0	

*p<0.05. Gender analysed using χ^2 , the remaining using Mann Whitney U tests. VPTS = Virginia Prediction Tree Score. VPTS scored from one-eight; one=good outcome, eight=very poor outcome, often death.

Patients who gave consent to take part in the study tended to have more severe head injuries (as measured by the VPTS) than those patients who did not wish to take part in the study. There was no significant difference between the ages, gender or time since injury between the two groups.

Appendix 3.3: Data analysis, missing items, comparison of GOS scores at 1 year post-injury and subsequent GOS, and distribution of the CSI

Data Analysis

Once the responses had been returned by carers, the NFI and CSI were scored and entered into SPSS v16. The GP's score for the GOS was also entered. At this point, decisions were made regarding missing data on questionnaires. Deleting cases where carers had left some items missing on the questionnaires was not thought to be a viable option, as this would have reduced the sample size and may have introduced bias into the study. It may have been the case that some carers found it more difficult to complete forms, or found the items too distressing to admit to. Deleting these carers from the study could have resulted in removing the carers under most strain.

Procedure for missing items

Where responses were missing on the NFI, the instructions from the manual were followed. Therefore, if more than 25% of the items for a scale or for the entire inventory were missing, these forms were considered invalid, and these carers removed from the analysis. This only happened in one case, where both the CSI and NFI were returned

completely blank without explanation as to why the forms could not be completed. If only a few items were missing (i.e. <25%), a mean for that subscale was calculated from the carer's other responses and inserted for those items.

Missing items from the CSI were scored as 0, so as not to inflate the chance of the carer being viewed as under 'strain' and making a Type I error. This did not occur for any of the returned forms.

No GOS score was available for five patients. In one case the patient had requested that their GP not be contacted and in another case the patient had left their GP surgery. When GPs failed to return the GOS measure, they were contacted by phone for their responses. In three cases the GP still did not return the GOS. Therefore, in four cases the previous GOS score completed at 1 year post-injury was entered instead. Jennett, Snoek, Bond & Brooks (1981) reported that it was very unlikely for a patient to change categories on the GOS after 1 year, so this score should be quite accurate. In the remaining case, an average outcome score was calculated for patients with the same level of injury severity to them and inserted.

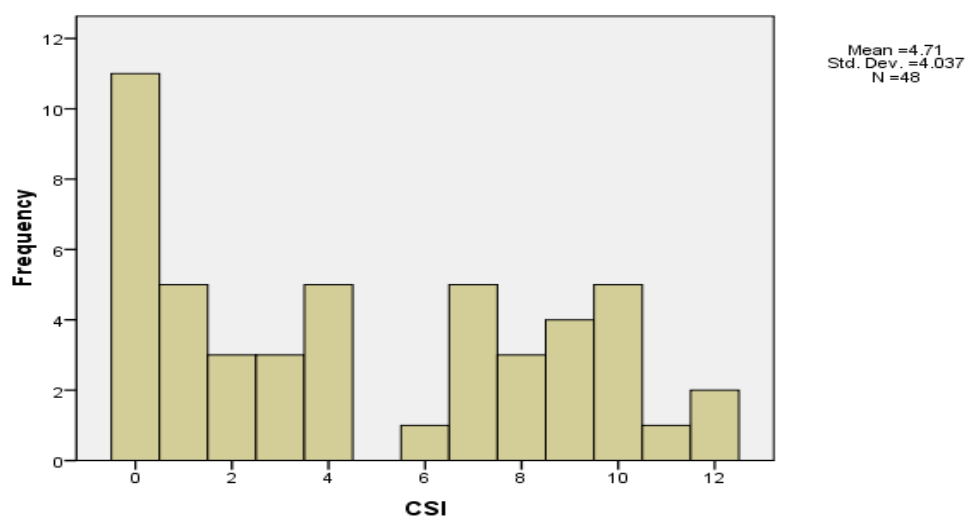
Comparison of GOS scores at one year post-injury and subsequent GOS

A Mann Whitney U test was conducted to assess whether there was any significant change between the GOS score recorded at one year post-injury, and the score recorded for this study. This would serve as support for the use of the one year post-injury score when a current score was unavailable. There was no significant difference ($p=0.06$) between the GOS score taken at one year and the more recent score taken for this study.

Distribution of the CSI

Figure 6 shows the distribution of scores on the CSI. The distribution appears to be bi-modal, with one peak occurring at a score of zero (indicating no strain) and another peak beginning at seven (the cut-off score for the CSI).

Figure 6: Distribution of scores on the CSI



Appendix 3.4: Distribution of strain across the CSI items

Chi-squared tests were used to assess whether strain is evenly distributed across each item of the CSI and whether each item contributes to the overall score on the CSI. This was done to examine the distribution of answers (yes/no) for each item of the CSI, which could illustrate which factors are most linked to a significant level of strain. The results are displayed in table 3.

The results suggest that a carer being identified as under 'strain' is significantly related to positive responses on the CSI items regarding sleep disturbance, inconvenience, confining lifestyle, family changes, changes in personal plans, other demands on the carer, emotional and work adjustments, upsetting behaviour, changes in the patient, financial strain and feeling overwhelmed. However, being identified as under 'strain' is not related to the item on the CSI about physical strain, which most carers responded negatively to. Therefore the experience of strain is not distributed evenly across all items of the CSI.

Table 3: Distribution of yes/no answers across individual items on CSI

CSI item	Strain	No Strain	χ^2	p value
Sleep disturbance				
Yes	9	1	9.76	<0.01*
No	11	27		
Inconvenience				
Yes	9	1	9.76	<0.01*
No	11	27		
Physical Strain				
Yes	2	0	0.95	0.33
No	18	28		
Confining				
Yes	13	1	18.44	<0.001**
No	7	27		
Family changes				
Yes	14	2	18.01	<0.001**
No	6	26		
Personal plans				
Yes	18	2	29.6	<0.001**
No	2	26		
Other demands				
Yes	15	6	11.52	<0.01*
No	5	22		
Emotional adjustment				
Yes	19	8	18.31	<0.001**
No	1	20		
Upsetting behaviour				
Yes	19	11	13.17	<0.001**
No	1	17		
Patient changed				
Yes	17	8	12.71	<0.001**
No	3	20		
Work adjustment				
Yes	15	1	23.67	<0.001**
No	5	27		
Financial strain				
Yes	14	2	18.01	<0.001**
No	6	26		
Completely overwhelmed				
Yes	17	3	23.52	<0.001**
No	3	25		

*p<0.01, **p<0.001. CSI = Caregiver strain index.

Appendix 3.5: Assumption testing for regression analysis

Prior to entering the data into the logistic regression analysis, the variables were tested for the degree of inter-correlation between them. All variables showed some degree of relationship with each other (> 0.3), and whilst the NFI subscales all showed high inter-correlations, there were no other indications of multicollinearity, as the Tolerance and Variance Inflation Factor (VIF) values were at an acceptable level. All variables showed good correlation with the CSI. Table 4 below presents the inter-correlations between variables and table 5 shows the coefficients and correlations between variables, including the collinearity statistics.

Table 4: Summary of inter-correlations between variables measured and correlation with CSI

	CSI	Dep	Mem	Com	Agg	Mot	GOS
CSI	1.00	0.72	0.76	0.69	0.65	0.60	-0.53
Dep	0.72	1.00	0.71	0.63	0.79	0.67	-0.40
Mem	0.76	0.71	1.00	0.70	0.63	0.71	-0.50
Com	0.69	0.63	0.70	1.00	0.56	0.72	-0.38
Agg	0.65	0.79	0.63	0.56	1.00	0.47	-0.31
Mot	0.60	0.67	0.71	0.72	0.47	1.00	-0.38
GOS	-0.53	-0.40	-0.50	-0.38	-0.31	-0.38	1.00

CSI=Caregiver strain index. Following variables from Neurobehavioral Functioning Inventory: Dep= depression, Mem= memory, Com= communication, Agg= aggression, Mot= Motor. GOS= Glasgow Outcome Scale

As the Tolerance level for all of the variables does not go below 0.1 (see table 5), this suggests that multiple correlations between the variables are low. Tolerance indicates the amount of variability in one independent variable that is not explained by the other independent variables in the model. The VIF value is the inverse of the tolerance value. As this does not reach 10 or above for any of the variables, this again suggests that multicollinearity is not present in these variables.

Table 5: Summary of collinearity statistics for the variables measured

Model	Unstandardised coefficients		Standardised coefficients	t	Sig.	95% Confidence Interval for B		Correlations		Collinearity statistics	
	B	SE	Beta			Lower Bound	Upper Bound	Partial	Part	Tolerance	VIF
Constant	-0.08	0.78		-0.10	0.92	-1.66	1.50				
Dep	0.01	0.01	0.25	1.10	0.28	-0.01	0.03	0.17	0.12	0.24	4.13
Mem	0.01	0.01	0.28	1.42	0.16	-0.01	0.03	0.22	0.16	0.31	3.25
Com	0.01	0.01	0.30	1.62	0.11	0.00	0.03	0.25	0.18	0.36	2.79
Agg	0.01	0.01	0.13	0.67	0.51	-0.01	0.03	0.11	0.07	0.31	3.25
Motor	0.00	0.01	-0.07	-0.39	0.70	-0.02	0.02	-0.06	-0.04	0.34	2.98
GOS	-0.15	0.11	-0.18	-1.37	0.18	-0.38	0.07	-0.21	-0.15	0.73	1.36

Following variables from Neurobehavioral Functioning Inventory: Dep= depression, Mem= memory, Com= communication, Agg= aggression, Motor. GOS= Glasgow Outcome Scale

Appendix 3.6: Logistic regression

Before entering the variables measured in this study, a constant was found to correctly predict group membership in 58.3% of cases. The variables from the NFI subscales (minus NFI Somatic) and the GOS were then entered into the equation. A backward stepwise approach using the likelihood ratio statistic was employed in order to explore the best model to fit the data. The backward entry method begins with all predictor variables included and then tests whether removing the variables one by one substantially affects the fit of the model. The backward method is thought to guard against suppressor effects and the chances of making a Type II error, which is associated with forward selection (see Field, 2009). The likelihood ratio statistic method assesses how the removal of each predictor variable would affect the model and removes those variables which do not make a substantial contribution.

When all of the variables were entered into the equation in the first step of the analysis, this improved the fit of the model and the amount of explained variance for strain. The Hosmer and Lemeshow test finds the model a good fit, $F(8) = 5.10$, $p = 0.75$. The Hosmer and Lemeshow measure of R^2 was calculated by dividing the chi-square for the model by the value when the constant alone was in the equation. In this case this would be $26.65 / 65.20 = 0.41$.

The residuals of the regression analysis were analysed to assess whether there were any cases for which the model fitted poorly. For this, the Studentized residual, standardized residual and deviance statistics were analysed. Three cases; 13, 34 and 45 had absolute standardized residual values greater than 1.96, although none had absolute values greater than 2.58, meaning that they all lie within the boundaries of 99% of the distribution of scores. However, as this constituted 6.25% of the scores being outside of the 95% boundaries, it was felt that these carers' responses should be removed and the analysis repeated to assess any change in results (see Field, 2009).

The model containing all six variables remained a good fit (see research paper, p. 10). The number of correctly identified cases also rose to 77.8% for the 'strain' category and 88.9% for the 'no strain' category. On analysing the residuals from this model, less than 5% were found to lie outside the 95% boundaries of the distribution, and thus the model was judged to be a good fit for the data. Table 6 gives the model summary for the initial and supplementary analysis, along with all R^2 values.

Table 6: Regression table for both stages of logistic regression analysis

	-2 Log likelihood	Homer & Lemeshow R^2	Cox & Snell R^2	Nagelkerke R^2
Stage 1	38.55	0.41	0.43	0.57
Stage 2	24.91	0.59	0.55	0.74

Stage 1 = model for 48 carers' responses, stage 2 = supplementary analysis once three outliers removed. -2 Log likelihood = approximate chi-square distribution and measure of deviance between observed and predicted categories. Homer & Lemeshow statistic calculated by dividing the chi-square for the model by the value when the constant only was entered into the equation.

Appendix 3.7: Biased responding

Following the guidance from the NFI manual (Kreutzer, Seel & Marwitz, 1999), some carers' responses were regarded as biased. These responses were identified where carers described patients as 'Never' displaying various behaviours on 95% or more of the items for the entire scale. In three of the returned questionnaires, 100% of the items were checked as 'Never' occurring. These responses were regarded with some suspicion, as these questionnaires may have constituted biased responding by the carer. Therefore a further regression calculation was conducted after having removed these carers' responses from the data.

From this edited data, the constant alone was found to correctly categorise group membership in 55.6% of cases. The independent variables were found to significantly improve the model's explanatory power $F(6)=23.36$, $p=0.001$. The pseudo R square suggested that between 40.5% (Cox & Snell) and 54.2% (Nagelkerke) of the variance was explained by the predictor variables, with 71.1% (60% in the 'strain' group and 80% in the 'no strain' group) being correctly categorised, and the model was found to be a good fit $F(7)=6.10$, $p=0.53$. Again, no individual variable was found to account uniquely for a significant amount of variance in strain.

On removal of these potentially 'biased' carers, a number of cases were still found to be significant outliers of the model. Therefore, the removal of these biased responders was not felt to improve the model beyond the removal of the outliers alone (described above), and it was important not to further reduce the power of the analysis by removing more carers from the model. As such, only the initial analysis and removal of the three outliers (detailed in section 3.6) is described in the research paper, with the potentially 'biased' responders remaining in the analysis.

Appendix 4: Discussion

Appendix 4.1: Previous methodological limitations

Previous studies have been limited in their findings due to employing stringent inclusion / exclusion criteria, and methodologies which may encourage biased responding (e.g. social desirability from face-to-face interviews). Previous studies involving carers have also recruited samples which may not be representative of the population of TBI patients and their carers, as they have taken samples from brain injury associations rather than systematic admissions to hospital. Also, very few studies have included objective ratings of outcome in addition to the views of patients and carers, whilst many have used simplistic measures of strain or burden which are unable to capture the intricacies of the caring relationship (Kay & Cavallo, 1991).

This study aimed to record carers' perspectives on caring which could be generalisable to the general population of carers for patients with TBI. An aim was to recruit a large, representative sample of patients who had been admitted to a neurosurgical unit and their carers. Therefore patients were recruited with the spectrum of injury severity and age over 18 years. It was hoped that carers with a range of education about head injury and motivation / ability to seek support would also be recruited. The postal methodology was hoped to make it easier for carers to take part and to respond with honesty. In addition, the measures described in Appendix 2.4 were chosen to combat some of the criticisms of previous studies.

Appendix 4.2: Results

From the proportions of reported difficulties in the six areas of disability measured by the NFI, emotional and cognitive factors were found to be categorised as high or very high in 29-40% of carers, compared to 15-21% for physical problems (as measured by the Somatic and Motor subscales). This is consistent with previous research which describes the prevalence of reported emotional, cognitive and behavioural problems as higher than physical disabilities (Thomsen, 1974; Oddy, Humphrey & Uttley, 1978; McKinlay, Brooks, Bond, Martinage & Marshall, 1981; Brooks & McKinlay, 1983; Brooks, Campsie, Symington, Beattie & McKinlay, 1986a; 1986b; Allen, Linn, Gutierrez & Willer, 1994).

The level of injury severity has not been found to be directly related to strain in this study. This may be because as people recover over time and adapt to their disabilities, they may present as less of a burden on their family members or carers. However, if this were true, time since injury would be expected to be significantly related to strain, with those carers

who have been caring the longest being the least strained. No differences were found between strain and time since injury.

Another explanation for the non-significance of injury severity is that it is not the injury itself which affects the carer, but more the specific manifestation of that injury. This is likely to be due to the area of the brain that is damaged, and not how much of the brain is damaged. For example, damage to the frontal lobes is associated with personality change (Blumer & Benson, 1975), which is found to affect strain in carers more than physical problems (e.g. Brooks, Campsie, Symington, Beattie & McKinlay, 1986a), which may be associated more with damage to the motor areas of the brain.

The finding that disabilities of a somatic nature were not related to strain may not necessarily be consistent with previous research, which has found that burden is associated with reports of subjective symptoms at three – 12 months post-injury (McKinlay, Brooks, Bond, Martinage & Marshall, 1981). The items in the somatic category of the NFI included complaints such as dizziness, hearing difficulties and headaches, which could be compared to the subjective symptoms reported in the above study, for example tiredness, slowness and headaches. Some of the subjective symptoms discussed by the authors above are probably more related to the Motor and Communication subscales on the NFI, which may suggest why these two were found to be related to strain whereas Somatic was not. The fact that the subscale Somatic was not found to be significant may be because the items may relate more to the internal experiences of the person with TBI, which the carer may either not be aware of at the time, or these experiences just may not create extra demands on the carers compared to other aspects of caring, as they do not impede on the carers' functioning.

An unexpected result was that the carers' gender and whether the patient lived with the carer were not significantly associated with whether the carer was categorised as under strain. This finding contrasts with previous research which suggests females are more likely to experience psychological distress in caring (as opposed to anger and fatigue in males), and the amount of time spent caring for the patient relates to unmet personal needs, which in turn can lead to illness in the carer (Serio, Kreutzer & Gervasio, 1995; Perlesz, Kinsella & Crowe, 2000). In terms of time spent caring, it would be expected that if the patient resides with the carer, they are likely to be the patient's primary caregiver and primary caregivers have been found to experience more distress than other relatives (Perlesz, Kinsella & Crowe, 2000). This is likely to be because they may come into contact with more difficulties and burden on a daily basis, and therefore may more readily recognise and be impacted upon by the caring role.

As mentioned in the research paper (p. 12), the variable 'cohabitation' did approach significance in the relationship with strain, and this finding may be the result of insufficient power in the analysis owing to the small sample size. The finding regarding gender may well be due to the fact that female carers are over-represented in research studies, as the majority of respondents are wives and mothers of patients (Kay & Cavallo, 1991; Kreutzer, Marwitz & Kepler, 1992). Therefore, the insignificant finding in this study may be the result of differences in the sample demographics compared to previous studies, as the male to female ratio of carers in this study may have been more balanced.

The results also suggest that no differences are found between levels of strain and the relationship with the patient. These findings contrast with the evidence published about the differences between the impact of caring on a spouse and a parent. Kreutzer, Gervasio & Camplair (1994a) explained that spouses were consistently more distressed and more likely to show symptomology than other caring relatives (specifically parents). The authors suggested that this increased distress may be due to loss of a reciprocal relationship with a fellow peer. The authors suggest that a parent returning to their caring role for their child is less of a difficult transition to make. This finding has been replicated in a longitudinal study by Hall, Karzmark, Stevens, Englander, O'Hare and Wright (1994), who suggested that a marriage may be more vulnerable to behavioural problems displayed by the patient than a parental relationship is, and that parents may have more financial and social support, which may serve as protective factors. However, other studies have reported that similar prevalence of carer strain is found in parents and spouses, which is consistent with the findings of the current study (e.g. Allen, Linn, Gutierrez & Willer, 1994; Serio, Kreutzer & Gervasio, 1995).

It may be that strain in spouses and parents becomes more comparable over time, and that spouses may only react differently to parents in the immediate aftermath of the patient's discharge. This may be because spouses need more time to adjust to the situation. Therefore, the result reported here may be due to the length of time since the patient's injury, as spouses may adapt to the lack of a reciprocal relationship over time, and that as the marriage has survived for this long despite the caring responsibilities, it suggests that some adaptation has taken place. Conversely, it may be that initially parents do not feel high levels of strain when returning to their role as a carer, as they have practice in these duties. However, over time, as the parents grow older and realise that their plans for later life / retirement may have to change, or they themselves suffer from ill health, they may begin to experience more strain.

An alternative explanation for these non-significant results may be due to the small sample size, which may have had inadequate power for the regression calculation, and

thus increased the likelihood of making a Type II error. Reasons for the limited sample size are discussed more fully in Appendix 4.5.

Appendix 4.3: Biased responding

When consulting the manual for the NFI (Kreutzer, Seel & Marwitz, 1999), it suggested that some carers may have responded in a biased way. Three carers replied 'Never' to every item of the NFI, which arouses some suspicion that they may not have been entirely objective in their responses. Of course, it may be that they believe the patient has recovered completely and does not display any of the difficulties described in the NFI. However, this would seem implausible when some of the items naturally occur even for people who have not experienced TBI, such as 'headaches', 'forgets people's names' or feeling 'sad, blue'. This possible bias could be due to a number of reasons, discussed below.

This bias may reflect a different frame of reference from which the carer is answering the questionnaire. It may be that they are comparing the patient with how they were immediately following the injury when they were presumably more disabled than the present day. They may also be comparing the patient to what they expected the recovery would be like given the seriousness of the patient's injury. On admission to the hospital, the medical team may have prepared relatives for the worst, and hence any signs of recovery are seen in the most optimistic and positive of lights, and a sign that the doctors may have been wrong (Oddy & Herbert, 2003).

Another possibility for this finding may be due to the recruitment of the carers. In this study, the patient was asked to nominate a person to answer these questionnaires as their 'carer'. Therefore, this person may not have been their primary caregiver and may have varying contact with the patient. This hypothesis seems unlikely, as all of the carers who appeared to respond in a biased way were living with the patient and were either a parent or spouse, suggesting that they were most likely involved in care or at least aware of any difficulties the patient may have.

The carer's responses may have been influenced by the patient, as the questionnaire may have been completed jointly or the carer may have consulted the patient when answering the questions. Although the carer was requested to complete the questionnaires alone, this may have been difficult if they reside with the patient and the patient already felt invested in the study (by giving consent to being involved). Carers may have found it difficult to be honest about the strain they were feeling or the problems they have observed in the patient. It is also possible that the patient completed the questionnaires themselves and did not involve a carer in the study, despite returning a consent form on

their behalf. This is unlikely, as the two consent forms required separate signatures from the patient and carer, but it is still a possibility.

Finally, denial may also play a role in these responses. Romano (1974) explained that sometimes families can identify progress in recovering patients, when objectively there is none, or may explain any difficulties the patient is having as long-standing traits that have always been present. Although these perceptions are objectively inaccurate, they can occasionally serve as positive coping strategies to adapt to the person's brain injury and its' consequences (Thomsen, 1984).

Three carers were found to be misclassified by the model, and were thus considered outliers. One carer did not consider themselves under strain on the CSI, but were predicted to be in the 'strain' group, and two carers reported significant strain, but were predicted to be in the 'no strain' group.

In the case of the carer who reported little strain, the patient they care for was judged to be 'severely disabled' by their GP. This score on the GOS may be for several reasons: the patient is severely disabled post-injury; or the GP may have not been particularly familiar with the patient or the GOS, and may thus have overestimated the patient's disability level. The first possibility is quite likely, however, considering this patient's average score on the NFI was the second highest of all the patients in the 'no-strain' carer category, which implies that they are more disabled than the other patients being cared for by this group.

In the case of the other two misclassified carers, the patients they care for were judged to have made a moderate to good recovery by their GPs, and the carers themselves rated the patients low on most subscales on the NFI compared to other carers in the 'strain' group. Indeed, they gave two of the three lowest overall average ratings on the NFI subscales, rating the patients below the lower end of the inter-quartile range for over 80% of the subscales. This responding would suggest that they did not feel the patients they care for have a high degree of remaining disability. Similar to above, this could suggest an underestimation of the patients' disability level by the GPs and carers involved, but it may also reflect how realistic the expectations for recovery were of the carers involved. They may have expected the patient to have recovered completely and have therefore found the patients' difficulties affect them more as they were unprepared. The results could also reflect how different people react and cope with the caregiving role, with some finding even relatively minor difficulties impacting greatly on their lives.

Appendix 4.4: Strengths of study

One of the major strengths in this study is the use of a more representative sample of patients with TBI who have been admitted to hospital in terms of distribution of injury severity. Despite this, using a sample of patients with heterogeneous levels of injury severity has been criticised in the past due to the difficulty in drawing clear conclusions (McKinlay, Brooks, Bond, Martinage and Marshall, 1981). However, in terms of being inclusive and being able to draw conclusions which are clinically relevant to the majority of people who have been admitted to neurosurgical or intensive care units following a TBI, the sample selection appears to be justified in this study.

In terms of demographics, the patients from the recruited sample consisted of roughly one female to every four males. This ratio is slightly higher than that found in other studies, where one female is reportedly injured to every two or three males (Wilier, Abosch, & Dahmer, 1990). However, the ratio from this study is consistent with the results published from the European Brain Injury Consortium (Murray et al., 1999) who reported that 74% of TBI admissions into 12 European hospitals were male. As is often reported in these studies, females made up the majority of the sample of carers, again roughly in a ratio of one female to four males.

The representation of the recruited sample was compared against the other patients on the database who could not be traced to invite to the study. A slightly higher proportion of females were found in the non-traceable group, although this was still in line with the statistics quoted above. The non-traceable group had also experienced their head injury significantly longer ago than the traceable group. This may be because those people who were injured longer ago may have moved house and GP surgery several times since their admission to hospital, making them harder to trace. However, some caution may be needed in generalising the results to those patients and their carers who were recorded further back in the database.

In terms of the patients who were invited to take part, there were no differences found between those who gave consent and those who did not, except for scores regarding injury severity. Those patients who gave consent were likely to have a more severe injury than those who did not. This may be because patients with more severe injuries were keen to demonstrate how well they had recovered from their injury and this gave them the opportunity. Conversely, it could be because the patients who were more severely injured may suspect that their relatives are under significant strain, and that this study would be appropriate for them. In terms of those who did not consent, they may feel that they have recovered sufficiently and the study does not apply to them. As injury severity was not

found to be related to strain in this study, it is difficult to extrapolate from this as to how many carers who did not consent may be experiencing significant strain.

Carers were not recruited from support groups or voluntary organisations in this study. There may be a potential bias involved in recruiting carers from a voluntary organisation. Members of a support group or rehabilitation programme may be more aware of the potential for experiencing stress and strain through a caring role, and may be more likely to recognise even minor signs of strain, which may lead to an increase in reporting. Then again, they may have already been experiencing strain which caused them to join the support group in the first instance, which again may lead to an increase in reporting of strain (Perlesz, Kinsella & Crowe, 1999). Alternatively, members of a voluntary organisation may be more pro-active and motivated people, which could artificially inflate the response rate and the types of responses received, as these may not be the carers most in need of support and assistance. Again, the sample collected in the current study should be more representative of the population of carers of people with TBI in this country, as they were selected by people admitted to hospital following a head injury. Although the sample was recruited from only one hospital in this study, the patients came from at least four counties in the surrounding area which adds to the likely representation of the sample.

Appendix 4.5: Limitations of study

The small sample size in this study limited the power of the results and their implications. Following Howell's (1997) recommendations, 10 participants would have been needed per variable in order to maintain adequate power for the regression calculation. Therefore, 60 participants would have been needed for this study. However, only 48 carers returned the completed questionnaires. Only a small percentage of those who could be traced agreed to take part in the study (12%). This again could be for a number of reasons. The length of time since the patients' injury may be a factor in this, as the person may have recovered fully or to such an extent that they feel their participation would not be appropriate / helpful in the study. However, there were no significant differences between time since injury in those patients who gave consent to the study and those who did not, which makes this hypothesis unlikely. Alternatively, it could be that the person with TBI does not want to be involved, as they do not wish to be reminded of their disabilities or that they do not want their relatives / carers to be reminded of their injury and the time spent in recovery. Qualitatively, this is quite plausible, as several letters were received from patients who did not want to participate in the study, but wanted to describe their recovery since leaving hospital. Several had recovered with no ill effects and one felt reluctant to put their family through further distress by participating in the study.

There may be another group of patients who were too cognitively disabled to read or comprehend the information sent to them regarding the study, which would have been most likely discarded. Alternatively, the patient and carer may experience high levels of strain on a daily basis and may not have the time to spend on something which is superfluous to everyday needs. Another possibility is that the relatives who live with the patients with TBI may not recognise themselves as carers and may not have felt that the study applied to them. Previous research has suggested that this can be a factor when measuring numbers of carers in particular areas (Nolan, Keady & Grant, 1995). It is acknowledged that carers may have different views as to what constitutes 'caring' (Jarvis & Worth, 2005), and this may influence their motivation to take part. Alternatively, the patient who received the initial invitation to the study may not recognise their spouse / parent / relative as their carer, which is another recognised problem (Travers, 1996). Again, this may have caused the patient to feel that the study was not really appropriate to them.

One possible solution to the small sample recruited could be to post the questionnaires out with the initial invitation letters and consent forms. It could be that the study sounded very time-consuming and requiring substantial effort in the letters explaining the aims and requirements. Patients and carers may have thought that the questionnaires sounded upsetting or lengthy and hence opted out of the study. If people received the questionnaires they may have felt more motivated to complete them, or may have seen how little would be required of them in order for them to be involved. This method could however have presented some ethical dilemmas if the questionnaires were delivered to an inaccurate address or if someone had wished their injury to remain forgotten / unknown. Also, the Ethics Committee approved of the approach taken, as they felt this was less intrusive for those patients who did not want to take part. There were a number of late replies of consent forms, suggesting that people may forget or not have the opportunity to commit to returning forms. Therefore maybe reminder letters could have been sent out.

Another weakness is the fact that up-to-date and complete information was not available for all of the carers and patients who took part in the study. The GOS was not returned by five GPs, meaning that a previous score had to be used or an average calculated. Therefore, the reliance on the accuracy of these scores may be ill-founded. This, however, seems unlikely as a comparison between previous and current GOS scores (for those patients who had both available) was not significantly different. This implies, as Jennett, Snoek, Bond & Brooks (1981) suggested, that the GOS score for patients does not change drastically after one year of recovery, and means that the scores supplemented for the five patients without a current score should be fairly reliable.

Appendix 4.6: Clinical Implications

In terms of informing practice, two out of five carers for patients with TBI may be experiencing significant strain in their caring role, most of whom may agree that they are feeling 'overwhelmed' (taken from an item on the CSI). This may be helpful information for professionals when they are presented with a carer who may be experiencing seemingly unconnected symptoms of a physical or emotional nature and may provide another line of enquiry when assessing the person. If the results for this sample are representative of the population from which they came, and extrapolated to the carers on the original database, this would suggest that 491 carers of the surviving patients could be experiencing significant strain. Although it is not known how many of these carers may develop physical and mental health difficulties through the strain of their caring role, this could constitute a large and expensive reliance on services in the future.

As discussed in Appendix 1, if the model of Pearlin, Mullan, Semple and Skaff (1990) were followed, the idea of identifying strain before it develops into mental or physical illness would be of clinical relevance here. This model would support the monitoring of carers who experience significant levels of strain in order to intervene before these carers experience adverse effects. The findings of the study may also provide some evidence for the construction of a screening tool for strain in carers. This could be used early after the patient with TBI has returned home and then repeated at various intervals during the patients' recovery. As this study has identified the GOS as associated with strain, this could be used by the patients' GP to identify which carers may be at risk of strain. The CSI could then be sent out to those carers in order to identify if any of them are experiencing significant levels of strain. For those who are experiencing significant strain, the NFI could be employed to obtain more details about the difficulties faced by the carer on a daily basis, which will provide some information regarding intervention. All measures are quite brief and easy to complete, which may improve the likelihood of people returning them. The GOS also does not require the GP to have physically examined the patient, which should mean that the completion of the scale would not take up much of the GP's time or require much effort. These scales could even be incorporated into the routine check-up assessments employed by the GP after discharge.

The strength of this idea is that it may be possible to identify early on which carers are most likely to experience strain. From this, carers at risk of strain could be monitored for some time after the patient has returned home and offered help before the strain of caregiving begins to affect the carers' health. As previous research suggests, the offer of information and education on brain injury can be extremely helpful for carers to form realistic expectations for the future (Kreutzer, Gervasio & Camplair, 1994a). Information on sources of support including local support groups could also be offered within this.

Kreutzer, Gervasio and Camplair (1994a) described group programmes where cognitive and behavioural changes could be discussed, along with ideas of behavioural management. However, few of these groups have been formally tested as to the impact they have on carer strain or patient recovery (Oddy & Herbert, 2003).

Although resources within the NHS are increasingly limited, the identification of carers in need of further support would not necessarily introduce a burden which could not be met by the health service, as carers' own perceived needs have been found to be quite humble (Yee & Blunden, 1995). Carers have been reported to desire acknowledgment and information about support services, and the identification as co-workers who may also require some support themselves, rather than demanding significant service provision (Twigg & Atkin, 1994; Yee & Blunden, 1995).

In terms of the contribution of clinical psychology, there are several key skills highlighted in the role of psychologists that would be beneficial in developing services for carers. As documented in the *New Ways of Working* information (British Psychological Society, 2007), Clinical Psychologists have fundamental skills in leadership, teaching and consultancy. In designing new services for carers, psychologists would be well placed to put together service development bids based on their knowledge of carer issues and how this can affect mental health. Their skills would also be valued in delivering psycho-education about the consequences of head injury for patients and carers to other professionals, as well as service users. Finally, their consultancy skills may well be helpful in advising other professionals about mental health when they are working with carers.

Appendix 4.7: Future research

In terms of improving the study in the future, the original database has proven how large numbers of patients are admitted to Neurosurgical Units on a yearly basis with TBI. If a prospective design were harnessed, a large sample size of patients and carers could possibly be recruited soon after injury and followed longitudinally, possibly up to 15 years and beyond. This would largely combat the problems faced when trying to trace patients many years after admission. It may also combat the problem of following up on inaccurate information on the database, such as dates of birth and patient addresses.

Although it was thought to be beneficial to use a postal methodology to conduct the study in order to reduce the potential for social desirability influencing responses and to contact a large number of people over a large geographical area, it did limit the amount and the quality of information obtained. It made it impossible for answers to be clarified or expanded upon when the questionnaires were returned. It was also not possible to

establish how strain affected carer's daily lives and whether it had had an impact on their health in any way. This would have been useful in order to endorse the cut-off criterion on the CSI that was put in place to describe a carer as under strain or not, which could be assessed with further information.

One improvement may be to send the questionnaires out via post but to have the option of a follow-up home visit or appointment, in which the carer could be spoken to alone and their answers discussed in more detail. This could be analysed qualitatively using thematic analysis. This may reduce any possibility of bias or patient influence on the carers' responses. It may also be therapeutic for them to speak to someone independent from the patients' medical care about how the patients' difficulties affect them. It may be that carers find it difficult to talk to medical professionals about the strain of caring due to a sense of duty to the patient and the feeling of guilt that they feel they should be grateful the patient survived. This may be similar to a bereavement process described by Lezak (1978), where the carers mourn their injured relative, despite the fact that they are still alive.

A criticism held at many studies regarding carer strain which could also be levelled at the present study is that very few standardised measures of strain are available or have been employed in these studies. This limits the validity and reliability, as well as the ability to generalise from the current findings (Perlesz, Kinsella & Crowe, 1999). The CSI has been tested for validity and reliability, but there are no norms for levels of strain in the general population or the TBI population. These would have been helpful when dichotomising the measure in the analysis, as a cut-off recommended by the author had to be relied upon when categorising the carers into two groups. Norms for the TBI population in terms of levels of strain in primary caregivers may have altered this criterion level. However, this appeared to be a reasonable cut-off criterion to use considering the distribution of scores on the CSI was bi-modal, with the second peak beginning at seven (the cut-off employed for this study). A future study could repeat the general design, but use a standardised measure of strain instead.

One reason why it may be difficult to predict strain in carers is that strain may occur as the result of a culmination of many factors, some of which may not have been measured in the present study. It is also important to note that different carers may deal with situations differently; some experiencing strain, and some not. This could be more due to the carer's own personality, style of coping or beliefs about the caring role. Some of these aspects have already been studied to some extent, although with different methodologies to the current study (e.g. Kosciulek, 1994). These factors were not captured in this study, and may prove to be important in determining the likelihood of perceived strain. These dimensions should be included in future research to establish the role they play in strain.

Appendix 4.8: Reflection

There were a number of ethical considerations in conducting this study. The first was concerned with the invitation of patients to be included in the study. The database was developed for the purposes of an audit on the Neurosurgical Unit in 1993. Therefore, patients were likely to be unaware that their details had been stored on the database, and would not have expected to be contacted again between five and fourteen years following their injury. It was possible that patients would be contacted who did not want to be reminded about their injury, or who had not told their new family / partner about the injury. However, the Ethics Committee were satisfied that it would be acceptable to contact these patients providing that the invitation letter came from the second author (PY), who would have been involved in their care during their admission to hospital. It was also reassuring that several letters were received from patients who wished to pass on their gratitude to the medical staff who had cared for them on the ward.

Another concern was that some patients may be so severely cognitively disabled that they were unable to comprehend the information in the letter or incapable of giving consent to the study themselves. This may have placed their carers in a difficult position of deciding what was in the patient's best interests. In order to address this possibility, contact details for all of the researchers were made available on the information sheets, so that relatives could receive information and advice on the possibility of giving assent on the patient's behalf. Contact details were also enclosed in the information sheet for independent advice from Patient Advice and Liaison Services (PALS), and Headway, a head injury association. The approach taken was in accordance with the Mental Capacity Act (2005) and ethical approval.

The impact on the carer was also a consideration in this study, especially as there was no intervention available for those carers who were found to be under high levels of strain. It is also possible that the questionnaires themselves may have had some effect on the carers, as it may have provided them with insight as to how much their (and the patient's) life has changed following the injury, and may mean that they are more aware of the impact this is having on their own well-being. To attempt to address this, details were given within the information sheet about how to contact Headway, and carers were advised to contact their GP if they felt distressed in their current situation. It was also made clear in the information sheet that further intervention was not available in connection with the study.

In terms of the study design, a cut-off score was employed on the CSI to categorise the carers into 'strain' and 'no strain' groups. Although this was done in order to explore

prevalence of strain and what factors contribute to the presence of strain in a carer, there is a possibility that this cut-off segregated carers who would have categorised themselves as strained into the 'no strain' group. It also does not take into account the fact that some types of strain may not be included on the CSI, and hence some carers may have felt that they could not portray an accurate picture of how they find their caring role. Another possibility is that some carers may have only checked one or two items on the CSI, but these areas of strain cause significant detriment to their health and well-being. Although this study was focused on prevalence of strain, and thus required a cut-off to be used in order to dichotomise the variable, these possibilities could be investigated in a future study by utilising a qualitative design.

Furthermore, the use of a quantitative measure to assess strain in carers needs to be justified in itself. It is plausible that this measure may not be an entirely accurate way to measure strain, due to the limitations mentioned above. The CSI, by nature, reduces the intricacy of human experiences and feelings generated by a caring role to 13 statements, and therefore can never be deemed as an all-encompassing measure. The other measures used in this study could also be criticised for reducing the complex behaviour and outcome they measure down to numbers. This has been a long-held criticism of 'positivist' approaches to research (see Meehl, 1954), although the term 'positivist' in research has often been employed inaccurately (see Miller, 1999). However, a measure is appropriate in research if it adequately measures the valued variables in the model being tested (Miller, 1999). The reliability and validity of the measures employed was discussed earlier in the paper (Appendix 2.4). Despite the imperfections of this methodology, the measure did serve to provide an approximate prevalence rate for strain, which is hoped to portray an accurate reflection of this population of carers.

By employing a quantitative design, positivist assumptions have been introduced into the study. The results of this study have suggested that carer's perceptions of a patient's difficulties with depression, memory, communication, aggression and motor abilities are associated with strain, as is a GP-rated outcome on the GOS. However, Popper (1959) may argue that this study has only proved that these findings are refutable, and that, in fact no findings can ever be fully proven. Also, as this study involves human beings as the participants, there is likely to be huge variation in terms of a person's life experiences, thought processes, personality types and coping styles in the people taking part. Therefore, it would be impossible to produce definitive results which would fit for every person caring for someone with a TBI. This is in addition to the variation that will exist in the patient population also, whose behaviour appears to contribute to the feelings of carers. There is unlikely to be one uniform reason which causes strain in carers of people with TBI, and therefore it may be judged as misguided to attempt to identify that reason in a study like this. However, in terms of clinical practice, knowledge of possible reasons

which may be contributing to strain can be very helpful for targeting and developing appropriate interventions with the aim of reducing the negative impact of strain.

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