Quality of life in young adults with head injury living in nursing homes: a comparative study

and

Clinical Research Portfolio

Volume I

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Firstly, I would like to thank all the participants, carers, families who gave up their time to participate in this study. I hope that this piece of research will in some way highlight the care and opportunities that are being provided at the moment as well as highlight areas needing improvement in the future.

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Chapter 1: Systematic Review

Evaluation of subjective quality of life measures for people with head injury: a systematic review

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Title: Evaluation of subjective quality of life measures for people with head injury: a systematic review

Abstract:

Head Injury (HI) can have a lasting effect on an individual's ability to return to previous functioning and can ultimately affect quality of life (QOL). In this literature review the clinimetric properties and practical characteristics of QOL measures suitable for use in the context of HI were evaluated. A systematic review was carried out to identify measures assessing multiple domains of QOL. An electronic database search using keywords identified 13 articles evaluating 6 QOL measures (4 generic and 2 disease specific) that met the predefined eligibility criteria. A quality rating checklist including a methodology quality rating assessment was used to describe the characteristics of the measures and rate the clinimetirc properties. No instrument had been adequately tested for all measurement properties. All six measures were assessed for construct validity and three measures received positive ratings. Six measures were assessed for test-retest reliability although only four measures received positive ratings. Five measures were assessed for internal consistency and all received a positive rating. Overall, the clinimetric quality of measurement properties of QOL measures varied greatly across the studies. The Quality of Life After Brain Injury Questionnaire (QOLIBRI) received the most favourable support for use with HI with regards to clinimetric properties and practical characteristics.

Key words: head injury, quality of life, outcome measures

Introduction:

Head Injury (HI) is one of the leading causes of death and disability among young adults (Maas et al., 2008). The physical, cognitive, behavioural and emotional difficulties experienced after a HI can severely impact on completion of daily life activities and independent functioning in the community. Traditionally, outcome following rehabilitation for HI has been assessed using objective indicators of disability or return to work (Jennet et al., 1981; Mazaux et al., 1997). However a goal of rehabilitation is also to return the individual to as high a level of quality of life (QOL) as possible (Koskinen, 1998), and the inclusion of an assessment of QOL may inform treatment and subsequent care.

QOL is 'an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns' (The WHOQOL Group, 1995). QOL is a multidimensional construct comprised of a number of domains including physical, cognitive and social factors (Aaronson, 1988). A difficulty with some objective measures of outcome is that they do not adequately capture the impact of HI in these domains. In response to this challenge, measures of QOL are increasingly being included in research within a number of neurological populations including HI (Meyers et al., 2000).

The assessment of QOL has similar elements to other assessments of outcome in that there are self report measures completed by significant others and one by the disabled person. It is the self-report measure of QOL which captures individuals' own perception of QOL which is of interest in the present review. To date, in HI populations, the assessment of QOL has relied heavily on generic measurements; e.g. the Short Form-36 (Ware and Sherbourne, 1992) or World Health Organisation Quality of Life Questionnaire (WHOQOL-BREF) (The WHOQOL Group, 2004). However, due to the increased recognition that disease specific measures may capture aspects of difficulty or impairment that generic measurement may not, there has been an increase in the development of a number of disease specific

measures, e.g. the Quality of Life after Brain Injury Questionnaire (QOLIBRI) (von Steinbuchel et al., 2010 (b).

There has only been one systematic review of QOL following HI (Berger et al., 1999). This recommended that a number of generic instruments could be considered for use with HI. This review also highlighted the need for instruments to be further validated. Since the publication of this review, a number of QOL instruments have been validated for use within a HI population (Chiu et al., 2006, Guilfoye et al., 2010, Hawthorne et al., 2011 and Griffen et al., 2010). However, to date there has not been a systematic review of the validity of these instruments for HI.

One difficulty in evaluating QOL measures is the lack of agreement about how measurement properties should be evaluated. Recently Mokkinck and colleagues (2009) evaluated the methodological quality of systematic reviews assessing measurement properties of health status assessment measures. They found that the methods used to evaluate the quality of studies varied greatly, hindering a clinician's ability to select the most appropriate tool. Some of these difficulties and variations have been resolved by Terwee and colleagues (2007). These authors propose that greater guidance and consensus regarding appropriate assessment of content and measurement properties would reduce the variation in assessment and evaluation. In response to this, a standardised assessment of content and measurement properties was developed called the COnsenus-based Standards for the selection of health Measurement INstruments (COSMIN).

The practicability of a measure can also be considered when selecting appropriate QOL measurement tools for use in clinical practice and research. To date, no systematic review evaluates the practicability of measures used with HI. Practical elements include target domains, number of items, responses, scoring algorithm, completion time, mode of administration, availability in the public domain, licence requirements and administration, scoring and interpretation guides. Such information would also aid the decision making

process as measures with excellent psychometric properties may not be available in the public domain.

Aim: This paper systematically reviews QOL measures that could be used routinely by researchers and service providers to measure subjective QOL for people with HI. It is hoped that this study will aid decision making regarding the most appropriate use of instruments in research and clinical practice.

The following key questions are addressed:

1. Which generic/disease specific instruments have demonstrated reliability and/or validity in a HI sample?
2. Which measures have been administered to a range of HI severities?
3. Which domains of QOL were assessed?
4. Which scales are accessible and provide standardized administration/scoring and interpretive guidelines?

Objectives: To review the practicability and clinimetric quality of QOL measurement instruments suitable for use in a HI.

Methods:

Search Strategy: As no systematic review of QOL measures used in a HI population has been completed, no date restrictions were imposed. The following electronic databases were searched: Medline, Embase, CINAHL, PsychINFO and ISI Web of Knowledge.

The following key words were used to identify eligible studies:

1. (Brain Injur* OR Head Injur* OR Traumatic Brain Injur*)
2. (Quality of Life OR quality of life)
3. (SF-36, QOLIBRI, SIP, EuroQOL-5D, EBIQ and WHOQOL-BREF)

'*' symbol denotes truncation character used to search different endings/ possible extra letters in the term to be included within the search.

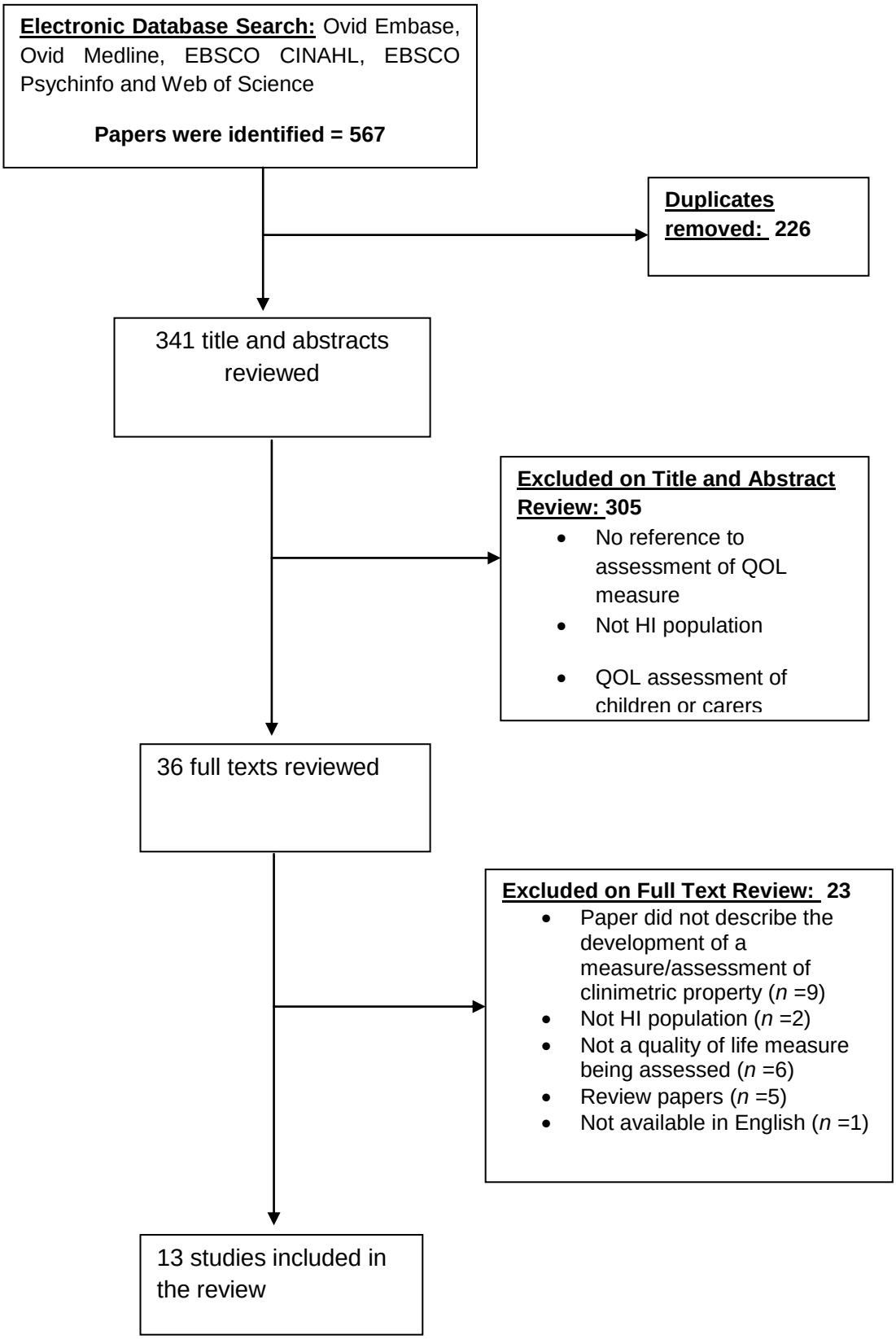
Searches 1 & 2 and 1 & 3 were combined with the word AND. Figure 1 provides a flow diagram of the search strategy and selection process.

Table 1: Inclusion/exclusion criteria applied in Systematic Review

Inclusion criteria	**Exclusion Criteria**
The study should describe the development or validation of a HRQOL measurement tool in TBI population	Studies assessing the QOL of carers or children
The measurement instrument should measure (at least one domain) of QOL	
The study investigated at least one property of the instrument	
The instrument should be validated in an English speaking population	

Search Selection: Articles from the electronic databases were pooled (*n* = 567) and duplicate articles removed (*n* = 226). Those with no reference to the systematic review topic in title or abstract were also removed (*n* = 305). Full texts were obtained and reviewed for 36 remaining articles that appeared relevant on the basis of the title and abstract. A further 23 articles were removed after reviewing the full texts. A total of 13 studies were included in this systematic review assessing generic (*n* = 6) and disease specific (*n* = 7) QOL measures within a HI sample (Figure 1).

Figure 1: Flowchart of search strategy and results



Data Extraction: The data on QOL measures extracted is based on the data collected by Albers' et al (2010) evaluation of QOL measures used in palliative care (*Appendix 1.1*). This information describes the design, content and application of measurement instruments. In addition, data outlining the measurement properties assessed/evaluated in each paper was also extracted. In the present review, the following measurement properties were rated:

Validity

- *Construct*: The degree to which scores on measure are consistent with hypotheses (e.g. relationships with other instruments or internal relationships) based on the assumption that the instrument validly measures the construct intended (Mokkinck et al., 2010). Construct Validity should be evaluated by the assessment of predefined hypotheses.

- *Structural*: The degree to which scores on a dimension are an adequate reflection of the dimensionality of the construct being measured (Mokkinck et al, 2010). Factor analysis should be performed to confirm the number of subscales present in the questionnaire (Mokkinck et al., 2009).

Reliability:

- *Interrater:* The extent to which scores for an individual are in agreement when repeatedly measured by different persons on the same occasion reflected by the calculation of an interclass correlation coefficient (ICC) or Cohen's Kappa (Mokkinck et al., 2010).

- *Test-retest:* the extent to which scores are stable over time reflected by the calculation of an interclass correlation coefficient (ICC) or Cohen's Kappa (Mokkinck et al., 2010).

Internal Consistency: The degree of interrelatedness among items demonstrated by the calculation of Cronbach's alpha α (Mokkinck et al., 2010).

Quality Assessment: A quality rating checklist was designed to evaluate the methodological quality of studies in this review. The checklist comprised of two sections, (a) the methodological quality rating by the COSMIN (COnsenus-based standards for the selection of health Measurement Instruments) (Mokkink, et al., 2009) and (b) a quality rating assessment that assessed further information to increase the utility of the quality rating assessment in the present review (*Appendix 1.2*). Only sections corresponding to the measurement property assessed in each paper were completed. Each item is scored on a 4 point rating scale (excellent, good, fair or poor) and the overall methodological quality of each study was determined by the lowest rating of the items for each measurement property. A final descriptive rating from the COSMIN assessment was assigned a number (excellent = 4, good = 3, fair = 2 and poor = 1) for each measurement property and was then transferred to the quality checklist.

The CONSORT guidelines were drawn upon when developing the quality rating checklist (Boutron et al., 2008). The quality rating checklist comprised 23 items and total scores depend on the number of clinimetric properties assessed in each paper (e.g. one property = 33, two properties = 37, three properties = 41, four properties = 45). Scores were converted to a percentage to provide an overall quality rating with higher percentages indicating superior quality. The COSMIN methodological descriptive rating (excellent, good, fair and poor) is reported independently of the overall quality rating of each paper to aid interpretation and decision making regarding individuals measures (*Appendix 1.3-1.4*).

All papers were rated by the author and ranked according to the quality rating checklist. A sample of 50% of the papers including top and bottom ranked papers were reviewed by a

second rater in order to examine the inter-rater reliability of the checklist. 80% agreement was found between the two raters and discrepancies were resolved by discussion.

Measure categorization and best evidence synthesis

To review QOL measures used in HI, studies were categorized into generic and disease specific measures. To summarise the evidence of the measurement properties of the different instruments; the results from each study were combined. The possible overall rating for the measurement property is ‘positive’, ‘indeterminate’ or ‘negative’. Criteria based on Terwee et al (2007) were used to assess the rating of measurement properties (Table 2).

Table 2: Quality Criteria for Measurement Properties (taken from Terwee et al, 2007)

Property	Rating	Quality Criteria
Validity		
Construct	+	(Correlation with an instrument measuring the same construct ≥ 0.50 OR at least 75% of the results are in accordance with the hypotheses) AND correlation with related constructs is higher than with unrelated constructs
	?	Doubtful design – no hypotheses, correlations determined with unrelated constructs
	-	Correlation with an instrument measuring the same construct < 0.50 OR at < 75% of the results are in accordance with the hypotheses OR correlation with related constructs is lower than with unrelated constructs
	*	Not Applicable
Structural	+	Factors should explain at least 50% of the variance
	?	Explained variance not mentioned
	-	Factors explain < 50% of the variance
	*	Not Applicable
Reliability (Test-Rest &Interrater)	+	ICC/weighted Kappa ≥ 0.70 OR Pearson's *r* ≥ 0.80
	?	Neither ICC/weighted Kappa nor Pearson's *r* determined
	-	ICC/weighted Kappa < 0.70 OR Pearson's *r* < 0.80
	*	Not Applicable
Internal Consistency	+	(Sub)scale unidimensional AND Cronbach's alpha (s) ≥ 0.70
	?	Dimensionality not known OR Cronbach's alpha not determined
	-	(Sub)scale not unidimensional OR Cronbach's alpha(s) < 0.70
	*	Not Applicable

Table 3: Description of instruments

Instrument / Abbreviation	Study	Disease Specific / Generic	Number of Items	QOL domains (number of items in each)	Accessible in Public Domain	Administration/ scoring/interpretive manual available?
WHO Quality of Life questionnaire / WHOQOL-BREF	Chiu et al., (2006)	Generic	26	Physical Capacity (7 items) Psychological Wellbeing (6 items) Social Relationships (3 items) Environment (8 items)	Yes	Yes
Short Form 36 Health Survey / SF-36	Guilfoyle et al., (2010) Van Baalen et al., (2006) Findler et al., (2001)	Generic	36	35 items grouped to form 8 domains: Physical Function (10 items) Role Physical (4 items) Bodily Pain (2 items) General Health (5 items) Vitality (4 items) Social Function (2 items) Role Emotional (3 items) Mental Health (5) The remaining item, reflects patients perception in change in health status over preceding year: change in Health (1) Two weighted domains (Physical and Mental Health) are derived from weighted combinations of the 8 domains	No – Licence required	Yes
The Sickness Impact Profile / SIP	Temkin et al., (1988) Van Baalen et al., (2006)	Generic	136	The statements are grouped into 12 categories/areas of living: Sleep and rest Emotional behaviour Body care and movement Home management Mobility Social Interaction Ambulation Alertness behaviour Communication Recreation and pastimes Eating Work	Fee depends on purpose of use how; individual clinical practice (free) vs. Research (may incur a cost)	Available when authorisation for use is provided
EuroQOL-5D	Alderman et al., (2001)	Generic	5 and a visual analogue scale	mobility (1) self-care (1)	Licence agreement and fee required.	Available when authorisation for

				usual activities (1) pain/discomfort (1) anxiety/depression (1)		use is provided
Quality of Life after Brain Injury / QOLIBRI	Von Steinbuchel et al., (2010) (a) Von Steinbuchel et al., (2010) (b)	Disease Specific	37	Cognition (7 items) Self (7 items) Daily life and autonomy (7 items) Social Relationships (6 items) Emotions (5 items) Physical Problems (5 items)	yes	Yes, further training available if required
The European Brain Injury Questionnaire / (EBIQ)	Soprena et al., (2007) Teasdale et al., (1997) Bateman et al., (2009) Caracuel et al., (2011)	Disease Specific There is a patient and carer version	63	Somatic (8 items) Cognitive (13 items) Motivation (5 items) Impulsivity (13 items) Depression (9 items) Isolation (4 items) Physical (6 items) Communication (4 items) Core (34 items)	Yes	Yes

Instrument / Abbreviation	Number of Response Options	Scoring Algorithm	Recall Period	Completion Time	Mode of administration	Full Copy Available?
WHOQOL-BREF	5 (1-5; higher scores indicate a higher QOL)	Mean scores from each domain are calculated to create a domain score. Mean scores are multiplied by 4. Potential score vary from 4-20. **Subscale and Total**	2 weeks	Not Reported	interview	Yes
SF-36	Varies; Likert method of unweighted summed ratings	Raw domain scores linearly transformed to scales ranging from 0 (worst health) -100 (best health). Higher scores indicate better health Physical and Mental Health summary scores **Subscales and summary scores**	Not reported	Not reported	Not clear	No
SIP	Patients endorse statements	Total percentage calculated by summing the values for the endorsed items, dividing them by the sum of the value for all items and multiplying by 100 **total score** **Subscale** totals can be calculated by summing the values of the items endorsed within the area and dividing by the sum of the values of all items within the area	Patients endorse statements if it describes them currently and is related to their state of health	Not reported	Structured interview	No
EuroQOL-5D	5 point likert scale: • no problems • slight problems • moderate problems • severe problems • extreme problems	Individuals endorse the most appropriate statement which is assigned a number (1-5). The 5 digits from each dimension are combined to create a 5 digit number. This number does not have any arithmetic properties. A total of 3125 health states can be defined in this way. Individual also rate their health on a 20cm vertical visual analogue scale with scores ranging from 0 (worst health) to 100 (best health).	Not reported	A few minutes	EQ-5D is designed for self-completion by respondents	No
QOLIBRI	5 point likert scale from 'not at all' to 'very'.	**Subscale and total QOL score**	Not reported	Not reported	Self-completed, assistance provided if required	No
EBIQ	3 Likert response alternatives : • Not at all	Responses are coded as 0, 1, 2. Scales are calculated as the average response score for all items in the scale (1-3)	4 weeks	Not reported. Described as brief to avoid excessive	Patients- interview Carer- self completion	Yes

	• A little • A lot			exertion and tiring effects	Control group- self completion	

Results:

Thirteen articles evaluating 6 QOL measures (4 generic and 2 disease specific) were included. The descriptive and practical characteristics of each measure are presented in Table 3. The clinimetric data concerning the instruments included in the review is presented in Appendix 1.3. The methodological quality of the studies is presented in Appendix 1.4 and in Table 4 for each measurement property. No instrument has been adequately tested for all measurement properties. Of the five measurement properties assessed in the present review; construct validity and test-retest reliability were the most frequently evaluated properties. No study evaluated interrater reliability. Overall, the QOLIBRI had the best clinimetric quality ratings for the most properties followed by the WHOQOL-BREF and the SF-36. The results are discussed below in terms of generic and disease specific measures and in order of methodological quality.

Table 4: Quality of measurement properties per questionnaire

Study	Validity: Construct	Validity: Structural	Reliability: Interrater	Reliability: Test-retest	Internal Consistency
Generic Measures					
SF36	+	+		?	+
WHOQOL-BREF	+			+	+
Sickness Impact Profile (SIP)	-			+	+
EuroQol-5D	-		*	?	
Disease Specific Measures					
QOLIBRI	+	+		+	+
EBIQ	?	?	*	+	+

Generic Measures of QOL

WHOQOL-BREF

Hypothesis testing, test-retest reliability and internal consistency were evaluated in mild to severe HI. Overall, the methodological quality of the studies was 'good' and the quality of the measurement properties were rated as 'positive' for those evaluated. Hypothesis testing demonstrated that the physical capacity on the WHOQOL-BREF was correlated with scores on a number of objective outcome measures; the Glasgow Outcome Scale-Extended (GOS-E: Wilson et al., 1998) (r = 0.31, p<0.001) and The Barthel ADL Index (Mahoney and Barthel., 1965) (r = 0.52, p<0.001). Scores on the psychological wellbeing and social relationships domains correlated similarly with the Social Support Survey (Sherbourne and Stewart., 1991) (r = 0.37, p<0.001). Finally scores between the psychological wellbeing domain and the CES-D (Radloff., 1977) were negatively correlated (r = -0.64, p<0.001). Cronbach's alpha varied between 0.75-0.89 and test retest reliability was high (ICC = 0.74-095).

SF-36

Structural validity, hypothesis testing and internal consistency of the SF-36 when used with mild to severe HI were evaluated positively for all, apart from reliability which received a 'doubtful' rating possibly due to a small sample size. Exploratory factor analysis of the 8 domain scores using Principal Component (PC) analysis showed a single PC rather than a 2 factor structure that is required to support the use of the two summary measures (Guilfoyle et al, 2010). These results imply that the effects of HI cannot be separated in to physical and mental health summaries and that the factors related are likely to covary and are not independent. Hence the validity of summary scores with a HI population is questioned. Questions regarding the validity of summary scores have been raised in other neurological samples (e.g. stroke) (Hobart et al., 2002).

Hypothesis testing confirmed that the SF-36 correlates with scores on a number of measures assessing similar constructs; Beck Depression Inventory (BDI-II: Beck et al., 1996) (Guilfoyle et al., 2010), The Symptom Checklist (SCL) (Derogatis., 1990) (r = -0.50—0.77, p<0.01) (Findler et al., 2001). All item scale correlations exceeded 0.4 indicating that items can be summed into domains with item-own scale correlations exceeding item-other correlations (Guilfoyle et al., 2010, Findler et al., 2001 & Hawthorne et al., 2011).

Two studies (Findler et al., 2002, & Guilfoyle et al., 2010) evaluated the internal consistency of the SF-36. Cronbach's alpha α ranged from 0.79-0.95 indicating that the SF-36 is highly internally consistent when used with a HI population.

All studies assessing the SF-36 included a range of HI severities in their sample. Therefore the results indicate that the SF-36 is a valid and reliable measure for use with a range of HI severities and the brief completion time and range of administration methods makes this measure clinically useful.

SIP

The SIP received 'positive' ratings for reliability and internal consistency and a 'poor' rating for hypothesis testing. Internal consistency was assessed via correlations rather than Cronbach's alpha. Reliability was assessed as r = 0.93- 096. One of the biggest limitations of the studies (Temkin et al., 1988 & and van Baalen et al., 2006) evaluating clinimetric properties of the SIP has been the methodological quality. The COSMIN checklist rated the methodological quality of both studies as fair/poor; therefore the results should be interpreted with caution.

EuroQOL 5D

Findings concerning the evaluation of hypothesis testing and test-retest reliability have been reported in a heterogeneous sample of individuals with severe to very severe acquired brain

injury. The principal causes of injury were traumatic HI (55.8%) and cerebrovascular accidents (11/23 of the remaining cases). Hypothesis testing received a 'poor' rating due to a lack of information provided regarding the comparator instruments and reliability received 'doubtful' due to neither ICC nor Pearson's *r* being calculated. A main limitation when interpreting the results from the EuroQOL validation study (Alderman et al., 2001) is the poor methodological rating as assessed by the COSMIN guidelines. The small sample size limited the analyses that could be carried (e.g. unable to calculate the ICC to assess for test retest reliability). The lack of clarity regarding expected relationships between the EuroQOL-5D and other measures also contributed to a poor methodological rating. Alderman et al (2010) highlights this issue and discusses the impact of not being able to exclude Type 1 error on the interpretation of results.

Disease Specific Measures of QOL

QOLIBRI

On the QOLIBRI; structural validity, hypothesis testing, inter-rater reliability and internal consistency has been evaluated. A majority of studies evaluating the QOLIBRI had good or excellent methodological quality; therefore the results can be interpreted with a degree of confidence that there is limited bias. All of the studies sampled individuals with mild to severe traumatic HI. The measurement properties evaluated in the QOLIBRI were all rated as 'positive'. Rasch analysis of items indicated a satisfactory fit with relevant item subscales. Exploratory factor analysis showed that items in the first three scales had good fit with a unidimensional model, thus providing support for a single factor PCA. These results are consistent with the Rasch analysis indicating a unidimensional component to the QOLIBRI, particularly in relation to cognitive function, self-perception and independent living.

Hypothesis testing demonstrated significant correlations between the QOLIBRI and objective measures of outcome (GOS-E); particularly with the Daily life and autonomy scale (r = 0.42) demonstrating convergent validity. Relationships were also found between the QOLIBRI

scales and the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith., 1983) (*r* = 0.37-67). The QOLIBRI was found to be a valid measure of QOL when relationships with the GOSE are compared. Similar results have been found with the SF-36; QOLIBRI (*r* = 0.39) & SF-36 MCS (*r* = 0.20). The studies that assessed construct validity were rated methodologically as fair according to the COSMIN guidelines. It is worth noting that this rating was given due to a lack of information regarding the comparator measures (GOSE, HADS). The QOLIBRI has demonstrated good internal consistency (α = 0.92-097) and good test-retest reliability has also been demonstrated in a sample of participants after 2 weeks, (ICC = 0.78-0.85).

EBIQ

No specific information is provided regarding severity of HI in the studies evaluating the EBIQ. The EBIQ received a 'positive' rating for internal consistency and test-retest reliability. However it received doubtful ratings for validity (hypothesis testing and structural) because it does not report how missing items were handled and hypotheses were vague. The EBIQ has demonstrated good test-retest reliability (ICC = 0.55-0.90) and internal consistency; Cronbach's alpha ranged from α =0.47-0.90 on self-ratings.

Discussion

This is the first systematic review that focuses specifically on studies evaluating the use of subjective QOL measures in people with HI. In addition to reporting information regarding the quality of measurement properties; the current review also includes information regarding the practicability of measures within HI population. Such information can aid clinical decision-making when deciding on the most appropriate measure to utilise.

Six questionnaires were evaluated as part of the review of QOL measurements used within HI populations. Of these, four were developed as generic measures of QOL and two were HI specific. The characteristics and clinimetric properties of the instruments varied

considerably, with hypothesis testing, internal consistency and test-retest reliability being the most frequently evaluated properties. No instrument has received satisfactory ratings for all these properties. The SF-36 and the QOLIBRI are the most frequently evaluated questionnaires. The QOLIBRI received the best ratings for its measurement properties followed by the WHOOL-BREF and the SF-36. The variation in clinimetric properties assessed and the quality of these properties is consistent with other evaluations of outcome measures utilised in health settings (e.g. Albers et al. 2010 and Schellingerhout et al. 2012).

The most frequent methodological shortcomings that resulted in a 'fair' or 'poor' rating concerned general design limitations; e.g. a lack of information regarding missing items. Reporting percentage and how missing items were handled is important as a high number of missing items introduces a bias in the results. In the current review two studies did not report percentage of missing items (Hawthorne et al., 2011 & von Steinbuchel et al., 2010a), or how missing items were dealt with (Caracuel et al., 2011). Five studies did not provide information on both (Alderman et al., 2001, Bateman et al., 2009, Findler et al., 2001, Soprena et al., 2007 and Temkin et al., 1988).

The ability of an instrument to measure the variable under question (validity) is a fundamental measurement property to be assessed (Jones and Kaplan, 2003). Whilst every instrument included in the review evaluated a type of validity; the QOLBRI is the only measure to have received a positive rating for both hypothesis testing and structural validity. Lack of hypotheses regarding the expected direction and strength of relationships between measures frequently led to instruments being rated as 'fair' or 'poor' on the methodological rating as well as 'doubtful' as rated by Terwee et al's (2007) quality rating. Albers et al (2010) highlighted the importance of the theoretical dimensional structure of an instrument being evaluated using factor analysis. Results from the current review indicate that only three of the six instruments (SF-36, QOLIBRI and EBIQ) have examined the factor structure.

The standards set for the assessment of measurement properties in the current review may have been too high as some instruments did not receive a positive evaluation. A lack of positive evaluation does not indicate that it is not appropriate to use an instrument with a HI population. Rather further testing and clearer reporting of design and methodological issues of existing measures is required.

It has also been of interest to consider the samples included in the studies assessing measurement properties of instruments. In the current review nine studies utilised a homogenous sample and four utilised a heterogeneous sample. Having different types of brain injury (BI) in a sample may introduce an element of bias into the results as factors relating to outcome and QOL may vary for different BI types. The results of studies which utilised a homogenous HI sample are interpreted as having greater utility in the current review as those instruments provide more meaningful data on performance of individuals with specific BI types. The range of injury severity included in sample participants has also been evaluated. The current review indicated that a majority instruments have been evaluated with a sample of HI across all severity types (*n* = 8). The EuroQOL-5D has only been evaluated in a sample with severe to very severe HI. No information was provided regarding the level of HI severity in the evaluations of the EBIQ which limits the findings regarding validity across all HI types.

Different instruments may be more appropriate depending on the question of interest and the QOL domains that the instrument targets. In the current review, the number and types of QOL domains evaluated varied greatly across measures, from four (WHOQOL-BREF) to twelve (SIP). Of interest is the difference in domains included between generic and disease specific. Disease specific measures included a cognitive domain. As both measures were developed from an evidence base specific to a HI population; the inclusion of a measure of cognition when assessing QOL is important and may increase the utility of a disease specific measure.

The practicability of measures has also been evaluated to aid the decision making process regarding choice of appropriate measure to assess QOL following HI. Of the six instruments included in the current review three are available in the public domain (WHOQOL-BREF, EBIQ and the QOLIBRI). All instruments have administration, scoring and interpretation guides to assist clinicians, however; only three are available in the public domain (WHOQOL-BREF, EBIQ and the QOLIBRI). The three remaining instruments (SF-36, SIP, and the EuroQOL-5D) require licence agreements and fees before the instruments and associated guidelines/manuals can be accessed.

The instrument's included in this current review varied in item length; the EuroQOL-5D had the fewest items followed by the WHOQOL and the SIP had the most items. The lack of information regarding estimated completion time limits the present review's ability to report findings on which measures require the longest amount of time to complete. However it can be anticipated that the greater the number of items, the greater the amount of time required to complete. This may impact on whether a measure is practical depending on the nature of use in routine clinical practice. Mode of administration is also important to consider when choosing an instrument; three instruments were delivered via an interview (WHOQOL-BREF, EBIQ and the SIP). Information regarding mode of administration was unavailable for the SF-36 from the papers reviewed in the present study; however the measure can be completed by individual respondents or an interview with a clinician. The QOLIBRI and EuroQO-5D were designed for self-completion, with assistance provided if required. Information on recall period was reported for four measures included in the review (WHOQOL-BREF, EBIQ, QOLIBRI and the SIP). Recall periods varied between whether patients were experiencing difficulties currently (SIP) to up until four weeks (EBIQ). The degree to which recall period impacts on choice of measure will ultimately depends on the purpose of inclusion of a QOL instrument.

The current review has a few limitations. This review evaluated the use of subjective QOL measures in individuals with HI and does not provide any guidance with regards to choice of objective QOL measures suitable for use with a HI population. Whilst many studies were identified during the systematic search, only published studies were included in this review. Inclusion only of studies in English may also introduce an element of bias, although only one study was excluded due to the language criteria.

Conclusion

This review draws together subjective assessment measures used to assess QOL in the context of individuals with HI. The methodological quality as well as quality of measurement properties varied considerably across the instruments and no measure has been adequately evaluated across all clinimetric properties. On the basis of this review the QOLIBRI is provisionally recommended for use to assess QOL after HI as it has the most information available and has received the best ratings for its measurement properties. This review has also drawn together information regarding the practicality of using instruments in clinical practice. Again, the QOLIBRI has presented favourably as it is available in the public domain and has guidelines to assist with administration, scoring and interpretation. The selection of a measure of QOL with HI population depends on a number of factors including purpose of use, severity of HI and QOL domains of interest. It is hoped this review will provide information which will facilitate this decision making process as well as inform future research requirements.

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Chapter 2: Major Research Project Paper

Quality of life in young adults with head injury living in nursing homes: a comparative study

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Lay Summary

The impact of Head Injury (HI) on quality of life (QOL) is increasingly being used as a measure of outcome in rehabilitation research. However, little is known about young adults with HI who are discharged to nursing homes and the impact of living environment on QOL. This study aims to compare QOL of young adults with HI in nursing homes with young adults with HI who live in the community with a care package and a healthy control group. It is also of interest to explore whether QOL is associated with a number of psychosocial variables. Participants completed a number of questionnaires relating to their QOL. The HI groups also completed measures assessing their functional ability, completion of recreational activities and contact with family and friends. Information regarding HI participants' experience of depression and their self-esteem was also gathered. No evidence was found to suggest the QOL was poorer for young adults with HI living in nursing homes. The finding that depression and self-esteem were associated with QOL may highlight areas where intervention could be targeted. Further research is required to replicate and extend these findings.

Structured Abstract

Background: Little is known about young adults with Head Injury (HI) who are discharged to nursing homes; particularly with regards to the impact that living environment has on their quality of life (QOL). To date QOL profiles in HI are limited and much of this research has also been confined to those who live in the community. The degree to which existing profiles are meaningful in young adults with HI living in nursing homes is uncertain and further investigation is required.

Methods: The present study aims to investigate whether QOL differs for individuals with HI living in nursing homes compared to individuals with HI living in the community and healthy peers. 33 participants were recruited into one of three groups; HI nursing home (*n* = 11), HI community group (*n* = 11) and a healthy control group (*n* = 11). The groups were compared on generic and disease specific self-report measures of QOL. In order to create a picture of factors which are associated with QOL following HI; the HI groups completed a number of measures assessing psychosocial variables (depression, self-esteem, contact with family and friend and completion of recreational activities).

Results: No differences in ratings of QOL between the HIN group and HICC and healthy control groups were found. Relationships were found between levels of depression, self-esteem and QOL after HI.

Conclusion: No evidence was found to support the hypothesis that QOL is poorer for young adults with HI living in nursing homes. Further support is provided for a number psychological variables associated with QOL. Further research is required to replicate and extend these findings.

Keywords: Head Injury, Quality of Life, Nursing Homes

Introduction:

Head injury (HI) has been defined as “a blow to the head or the presence of a scalp wound or those with evidence of altered consciousness after a relevant injury” (Jennett and MacMillan, 1981). The incidence of HI requiring admission to hospital is around 100-150 per 100,000 of the UK population each year with the highest incidence in adults occurring in males between 15-24 and >75 years of age (Thornhill et al, 2000 & Barnes et al ,1998).

Memory impairment, difficulties with attention and executive dysfunction are common cognitive consequences of HI (Buchanan et al, 2003) along with a range of emotional and behavioural difficulties including; physical aggression, social disinhibition, impulsivity and depression (Buchanan et al , 2003). These physical, cognitive, behavioural and emotional difficulties can severely limit a person’s ability to complete daily life activities, function independently in the community and may ultimately affect their quality of life (QOL) (Truelle et al, 2010).

Such impairments can impact on individuals returning to live in the community. McMillan and Laurie (2004) surveyed all adults with HI discharged to nursing homes following injury in Glasgow and found 92 individuals with HI under the age of 65. Concerns regarding the appropriateness of nursing homes for young people with HI compared to a community placement with a care package have been expressed for several reasons. Firstly, ‘nursing homes which have a primary focus on supporting elderly people’ have ‘limited capacity to support the complex social and rehabilitation needs of young people with disabilities’ (Stringer, 1999). The potential limits in meeting rehabilitation needs is a concern in light of the evidence provided by McMillan and Herbert (2004) which suggests that with continued support and review, functionally significant improvements can be made up to ten years post injury.

In Scotland The Mental Health Welfare Commission (2010) has also highlighted that suitable programmes of social and recreational activities are found less frequently in nursing homes compared to those living in the community and that involvement with family and friends was variable. If nursing homes are unable to meet the complex needs of young adults with HI; they may be not be encouraged to continue to participate in their community life and this may ultimately impact on their QOL. To date, little is known about people who are discharged to a nursing home, their QOL or why nursing homes become an option.

The assessment of QOL is increasingly used to compliment traditional medical and psychological outcome measures in neurological rehabilitation settings including HI (Meyers et al, 2000). The inclusion of subjective QOL measures ensures that the patients' perspective of QOL can be captured to inform treatment and subsequent care.

The measurement of QOL within rehabilitation populations has faced a number of challenges due to the lack of consistent definition amongst researchers and the impact of societal, cultural and religious views on subjective QOL (Kalpakijan et al, 2004). Quality of Life has been defined by the World Health Organisation (WHO) as: "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (WHOQOL Group, 1993, P153).

Within the HI population specifically; profiles of QOL are rare (Brown and Gordon, 1999). Kalpakijan et al (2004) carried out a cross-sectional study describing the QOL and psychosocial outcomes in a sample of 50 people with HI living in the community. The wide range of scores across all of the rating options on the QOL measure suggests QOL varies after HI. Emanuelson et al (2003) carried out a comparison study of QOL of individuals with HI at 3 weeks (*n*=107) and 3 months (*n*=101) post injury compared to a healthy control group. Findings indicated that QOL was significantly poorer in the HI groups compared to the controls on all subscales.

The diverse nature of perceived QOL in individuals with HI indicated in studies may be due to the different variables investigated. Demographic variables such as age and injury severity have yielded a weak relationship with perceived QOL (Kalpakijan et al, 2004), whereas psychosocial variables such as depression are consistently related to lower ratings of QOL and self-esteem (Corrigan et al, 2001 & Steadman et al, 2001). Brown and Vandergoot (1998) highlight the contextual base for an individual with HI may be very different compared to an individual without a HI because individuals with HI have two contexts for judging their QOL; their current context after a HI and the context they perceive from before their HI.

Much of the previous research on QOL after HI has focussed on those living in the community or who have been recently injured (Brown and Vandergoot, 1998). To date there is no research on the QOL of young adults with HI living in nursing homes. Given that recent findings show that adults with HI living within nursing homes have limited social activities and contact with family and friends, they may have poorer QOL. Measures of QOL can help create a picture of the impact of the multiple consequences of HI and inform services about areas of care which require investment.

Aims

This study (I) compares QOL in individuals with HI living in nursing homes, individuals with HI with care support living in the community and a healthy control group. (II) Explores whether subjective QOL is associated with psychosocial variables. (III) Identifies how nursing homes become a placement option for young adults with HI.

Hypotheses

1. Subjective ratings of QOL of individuals with HI living in nursing homes is poorer than in individuals with HI living in the community and the general population.

2. Poorer QOL is associated with depression and lower self esteem, less contact with family and peers and fewer recreational activities.

Methods

Ethical Approval: This study was approved by the West of Scotland Research Ethics Committee *(Appendix 2.2*).

Design: This study employed a between subjects design comparing people with HI living in nursing homes, with care in the community and a healthy control group. A correlational design was also used to explore the impact of a number of psychosocial variables on perceived QOL.

Participants: There were 27 male and 6 female participants. Of these, 11 lived in a nursing home, 11 lived with care in the community and 11 were healthy controls (see Figure 1). Of a further 10 initially recruited; 3 did not meet inclusion criteria and 7 did not respond to an invitation and were not recruited.

Inclusion Criteria:

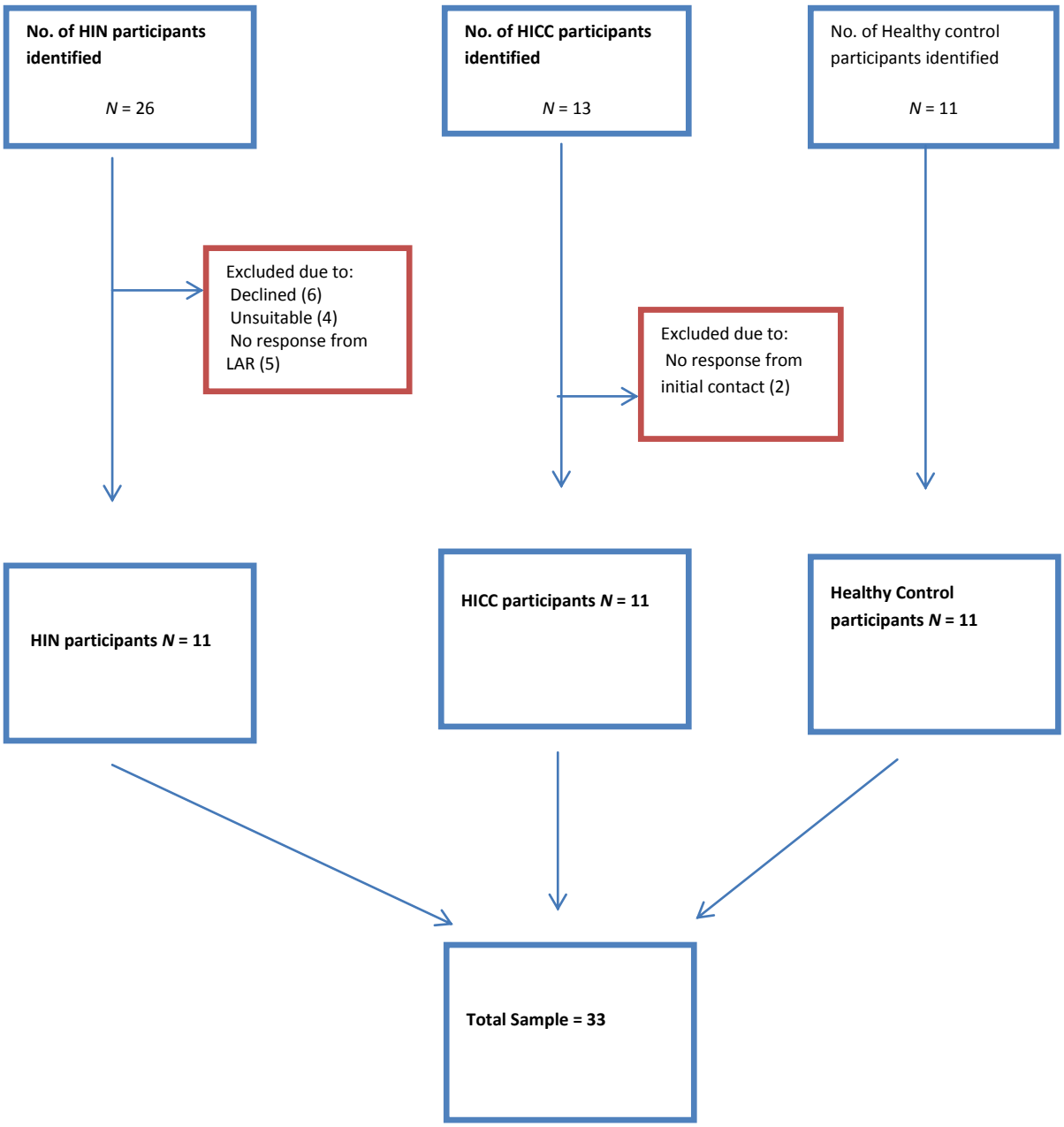
1. All participants aged 18 to 65 years at injury living in a nursing home (HIN) or with care in the community (HICC).
2. First language English (requested for the validity of the measures).

Exclusion Criteria:

1. Participants with profound motor, cognitive and communication problems if unable to provide self-report or complete measures or are unable to attend to the assessment.
2. Participants with severe challenging behaviour.
3. Participants currently undergoing rehabilitation as this may temporarily impact on perceived QOL.

4. Participants with current alcohol and/or drug related dependency due to impact substance misuse may have on QOL.
5. Healthy controls with a history of severe HI.

Figure 1: Recruitment Flowchart



Recruitment and Research Procedure: Participants were recruited from community and voluntary sector settings. The HIN & HICC groups were identified by the Scotbase database. This is a NHS GGC referral database of extra-contractual rehabilitation of people with HI. If the individual could provide consent the nursing home manager asked them if they were interested in participating and would consent to the researcher (AB) meeting with them to discuss the study. If the potential participant was not able to give consent, a legally authorised representative (LAR) was contacted to provide consent. The researcher (AB) liaised with Social Work and Headway Glasgow to recruit the HICC group. An information sheet outlining the aims of the study was sent to potential HICC participants (*Appendix 2.3*). Researcher (AB) then met to discuss the study, answer any queries and obtain written consent (*Appendix 2.4*). The Healthy Control Group was recruited from families of HI participants, and friends/partners of the researcher's colleagues. Information sheets were provided and potential participants were asked to complete a consent form. Once consent was obtained, the study measures were administered in a single interview. Family members or carer/staff members were interviewed to gather information participants were unable to provide. Carers/Staff were provided with an information sheet and given the opportunity to ask any questions prior to providing written consent. Most of the measures were administered in a semi-structured interview format with printed responses provided to aid participants answering questions. Regular breaks were offered to each participant to limit the impact of fatigue.

Measures:

Demographic Information: Age, Gender (Male / Female), Education (Primary / High / trade / certificate / diploma or degree) and Relationship Status (single/ married/ separated/ divorced/widowed).

Subjective Quality of Life (i)**:** The Medical Outcome Study Short-Form-36 Health Survey (SF-36) is a generic instrument for the assessment of health related QOL. It consists of 36 items

across eight domains; physical functioning, social functioning, physical role and emotional role, mental health, vitality and bodily pain and general health. Scores range from 0 (worst possible functioning) to 100 (best possible functioning). This scale is valid and reliable in the HI population (Findler et al, 2001).

Subjective Quality of Life (ii)**:** The Quality of Life after Traumatic Brain Injury Scale (QOLBRI) (Von Steinbüchel et al, 2005), is a 37 item self-report disease specific measure of QOL. It has four satisfaction domains: cognition, self, daily life and autonomy, and social relationships and two bothered domains; Emotions and Physical Problems. Internal consistency and test-retest reliability of the QOLIBRI are acceptable to good (Von Steinbüchel et al, 2010).

Objective Indicator of QOL (Functional Impairment): The Barthel ADL Index (Mahoney and Barthel, 1965) was used to assess activities of daily living. Scores on this measure vary between zero to 100; higher scores indicating increased independent functioning. Scores will also be interpreted according to categories used by Sinoff and Ore (1997).

Disability following TBI**:** Glasgow Outcome Scale-Extended (GOS-E: Wilson et al, 1998). The GOS-E is a structured clinician administered outcome measure that assesses functional and social disability following HI.

Self Esteem**:** The Rosenberg Self-Esteem Scale (Rosenberg, 1965) is a 10 item questionnaire. Responses are selected from a 4 point likert scale. Scores range from 0-30 and higher scores indicate greater self-esteem.

Depression and Anxiety: The Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983) is a self-report questionnaire used to assess anxiety and/or depression symptoms. Participant's rate symptoms experienced over the past week on a 4 point scale. Total scores

of 8-10 identify mild cases, 11-15 moderate cases and 16+ severe cases of anxiety and/or depression. Only scores for Depression were of interest in the current study.

Participation in recreational activities: Participants were asked whether they participate in any recreational activities (*sports activity, eating out, shopping, club, hobbies, and contact with friends/family)* and the frequency of participation (weekly/ monthly) (*Appendix 2.5*).

Contact with family and friends: The frequency of contact with family and friends was categorised as follows (*Appendix 2.5*):

- Birthday/Christmas card and occasional phone call
- Phone call/letter once a month
- Visits two times a year
- Visits at least once a month
- Visits at least once a week
- No contact/unknown

Reason for Placement: Information was gathered from social work and nursing home files. The possible reasons for placement (*Appropriate place/ Family Preference/ Unavailability of a more appropriate service/ Person's own choice*) were drawn from a previous study on learning disability placements in generic residential services for older people (Thompson et al, 2004) (*Appendix 2.5*).

Sample Size: Sample size was calculated for the primary hypothesis that individuals with HI would have a poorer QOL as rated by the SF-36 and the QOLIBRI. Findler et al (2001) validated the use of the SF-36 in a HI sample (n=229) and report means and standard deviations for HI and healthy controls. A total of 45 participants (as determined by a priori power analysis with an 80% chance of a medium effect size, 0.48 and $p < 0.05$) were required for this study (15 participants in each group). A power calculation was also carried

out using data from a validation study of the QOLIBRI in a large clinical population (*n*=795) (Truelle et al, 2010). Comparing QOL scores for participants with HI in independent accommodation (*M* = 68.32, *SD* = 17.39) and those in sheltered accommodation (*M* = 63.06, *SD* = 17.67) indicated a total sample size of 32 participants was required for this study (16 participants in each HI group). The target number for recruitment was 48 (16 participants in each group).

Statistical Analyses: Data were analysed using SPSS 18. Reasons for placement in nursing home were explored using descriptive statistics. To investigate whether predicted differences exist between the groups of interest, inferential statistical analyses were carried out to look at the variance between the groups on dependent variable measures. Non parametric tests were used if assumptions of normal distribution and homogeneity of variance were violated.

- Hypothesis 1: Subjective ratings of QOL (SF-36) between the HIN and the healthy control groups and Subjective QOL (QOLBRI) between the HI groups were analysed using Mann-Whitney *U* tests. Effect sizes were calculated for the dependent variables and classified according to the criteria set out by Cohen (1992).
- Hypothesis 2: Relationships between QOL in the HI groups and depression, self-esteem, contact with friends and family and completion of age/ability related recreational tasks were analysed using correlation coefficients. Scores on psychosocial measures between HI groups were compared using Mann-Whitney *U* tests. Chi square tests explored the relationships between contact with friends and family and completion of age/ability related recreational tasks and QOL.

Results:

Demographic Variables

Descriptive information of the participants in each group is provided in Tables 1-3. Inspection of the demographic profiles of the HI groups indicated that a majority of HIN participants had a severe disability (n = 11) when compared with the HICC group. A Fisher Exact probability test confirmed that there was a statistically significant association between the HI groups and disability, X^2 $(1, n = 22) = 15.32$, $p = < 0.01$ with HIN participants having a greater disability than HICC group. A majority of the HIN sample (81.8%) required 24 hour care compared to n = 2 (18.1%) of the HICC group as measured by the GOS-E.

On objective indicators of QOL (The Barthel ADL Index) there was a greater impairment in functional ability in the HIN group. Three participants were categorised as very/totally dependent. This is comparison to the HICC group where all participants (n = 11) were functionally independent. No significant association was found in the distribution of functional ability scores across the HI groups, X^2 (1) = 4.889, p = .180. Mann-Whitney U tests also revealed no significant differences in depression and self-esteem between the HI groups.

Table 1: Demographic characteristics of participants

	HIN *N* = (11) *M (SD)*	**HICC** *N* = (11) *M (SD)*	**Healthy Control** *N* = (11) *M (SD)*
Age: At Interview	46.45 (7.88)	43.91 (12.79)	46.18 (10.27)
Time of injury	41.27 (7.20)	37 (12.43)	
Gender	**N (%)**	**N (%)**	**N (%)**
Male	9 (81.8)	9 (81.8)	9 (81.8)
Female	2 (18.2)	2 (18.2)	2 (18.2)
Education	**N (%)**	**N (%)**	**N (%)**
Secondary	5 (45.4)	3 (27.3)	1 (9.1)
Trade	2 (18.2)	2 (18.2)	5 (45.4)
Certificate/Diploma	2 (18.2)	5 (45.4)	1 (9.1)
University	2 (18.2)	1 (9.1)	4 (36.4)
Relationship Status	**N (%)**	**N (%)**	**N (%)**
Single	5 (45.4)	4 (36.4)	2 (18.2)
Married	1 (9.1)	2 (18.2)	8 (72.7)
Separated/Divorced/Widowed	5 (45.4)	5 (45.4)	1 (9.1)
Reason for Placement in Nursing Home	**N (%)**		
Appropriate place	8 (72.7)		
Family preference	1 (9.1)		
Unavailability of a more appropriate service	2 (18.2)		
Person's own choice	0		

Note. M = Mean, SD = Standard deviation

Table 2: Frequency of distribution of Disability and functional ability scores

Measure	**Head Injury Nursing Home** *N* = (11)	**Head Injury Community** *N* = (11)	**Fisher exact test**
GOS-E (Disability)			
Lower Severe Disability	6	1	
Upper Severe Disability	5	1	
Lower Moderate Disability	0	2	
Upper Moderate Disability	0	7	
GOS-E Total Score	*Md* = 3, *IQR* = 1	*Md* = 6, *IQR* = 1	X^2 *(1, n* = 22) = 15.32, *p* = < 0.01
The Barthel ADL Index (functional ability)			
Totally Dependent (<20)	1		
Very Dependent (20-39	2		
Partially Dependent (40-59)	1		
Independent (80-100)	7	11	
The Barthel ADL Index Total Score	*Md* =85, *IQR* = 70	*Md* =100, *IQR* = 5	X^2 *(3, n* = 22) = 4.889, *p* = .180

Note. Md = Median, IQR = interquartile range.

Table 3: Frequency of distribution of Psychological health scores

Measure	**HIN** *N* = (11) *Md (IQR)*	**HICC** *N* = (11) *Md (IQR)*	**Mann Whitney *U* Test**
HADS (Depression)	6 (8)	4 (9)	U = 57, z = -.233, p = .816, r = 0.05
Rosenberg Self Esteem Scale (Self-Esteem)	20 (14)	21 (10)	U = 41, z = -0.989, p = .323, r = 0.12.

Hypothesis 1

Table 4: Group differences on the SF-36 and the QOLIBRI.

	HIN *N* = (11) *Md* (IQR)	**HICC** *N* = (11) *Md* (IQR)	**Mann Whitney U Test**
SF-36 Subscale			
General Health	65.00 (30.00)	57.00 (70.00)	*U* = 53, *z* = -0.494, *p* = .621, *r* = .11
Physical Functioning	30.00 (95.00)	60.00 (45.00)	*U* = 47.5, *z* = -0.861, *p* = .389, *r* = .18
Physical Role	43.75 (95.75)	62.50 (56.25)	*U* = 52, *z* = -0.563, *p* = .537, *r* = .12
Bodily Pain	52.00 (58.00)	51.00 (68.00)	*U* = 51.5, *z* = -0.601, *p* = .548, *r* = .13
Vitality	68.75 (50.00)	75.00 (68.75)	*U* = 58, *z* = -0.165, *p* = .869, *r* = .04
Emotional Role	83.33 (83.33)	74.2 (34.5)	*U* = 53, *z* = -0.518, *p* = .604, *r* = .11
Mental Health	70.00 (25.00)	80.00 (55.00)	*U* = 57.5, *z* = -0.198, *p* = .843, *r* = .04
Social Functioning	100.00 (50.00)	52.75 (87.50)	*U* = 35.5, *z* = -1.705, *p* = .088, *r* = .36
QOLIBRI			
Cognition	46.5 (60.61)	46.43 (28.57)	*U* = 57, *z* = -0.231, *p* = .818, *r* = 0.05
Self	67.86 (25.04)	64.29 (28.57)	*U* = 51, *z* = -0.625, *p* = .532, *r* = 0.12
Daily Life and autonomy	53.5 (60.72)	53.57 (39.29)	*U* = 57, *z* = -0.230, *p* = .621, *r* = 0.05
Social relationships	62.5 (17.85)	66.67 (62.50)	*U* = 52.5, *z* = -0.528, *p* = .598, *r* = 0.11
Emotions	25.00 (80.00)	55.00 (70.00)	*U* = 38, *z* = -1.496, *p* = .135, *r* = 0.32
Physical Problems	20.00 (46.00)	58.00 (75.00)	*U* = 42, *z* = -1.226, *p* = .220, *r* = 0.26
QOLIBRI Total	56.08 (31.08)	50.75 (29.73)	*U* = 59, *z* = -0.099, *p* = .921, *r* = 0.02

Table 5: HIN and Healthy Control group differences on the SF-36.

	HIN Group *N* = (11) *Md* (IQR)	**Healthy Control** *N* = (11) *Md* (IQR)	**Mann Whitney U Test**
SF-36 Subscale			
General Health	65.00 (30.00)	72.00 (30.00)	*U* = 45.5, *z* = -0.987, *p* = .324, *r* = 0.21
Physical Functioning	30.00 (95.00)	90.00 (35.00)	*U* = 634.5, *z* = -1.720, *p* = .085, *r* = 0.37
Physical Role	43.75 (95.75)	87.50 (37.50)	*U* = 32.5, *z* = -1.889, *p* =.059, *r* = 0.40
Bodily Pain	52.00 (58.00)	62.00 (31.00)	*U* = 55.5, *z* = -.332, *p* =.740, *r* = 0.07
Vitality	68.75 (50.00)	62.50 (25.00)	*U* = 52.5, *z* = -0.529, *p* =.597, *r* = 0.11
Emotional Role	83.33 (83.33)	83.33 (25.00)	*U* = 58, *z* = -0.169, *p* = .886, *r* = 0.04
Mental Health	70.00 (25.00)	60.00 (30.00)	*U* = 51.5, *z* = -0.594, *p* = .553, *r* = 0.13
Social Functioning	100.00 (50.00)	75.00 (62.50)	*U* = 46, *z* = -0.992, *p* = .321, *r* = 0.21

Shapiro Wilks tests revealed that the majority of the data for analysis violated the assumptions of normality, linearity and homoscedasticity, therefore non-parametric statistical tests were used.

Mann-Whitney *U* tests revealed no significant differences in scores on all QOLIBRI and SF-36 domains between individual HI groups. When comparing subjective QOL scores (SF-36)

between the HIN group and the healthy controls; Mann-Whitney *U* tests also revealed no statistical difference in scores (Table 5) However, a non significant trend was obtained for two domains on the SF-36 (Physical Role & Physical Functioning).

Overall, evidence for a difference in subjective ratings of QOL between HI groups and healthy controls was not found.

Hypothesis 2

The second hypothesis which investigated whether measures of QOL (SF-36 and QOLIBRI) are associated with psychosocial variables was explored using Spearman's Rank Order Correlation (rho) coefficients (Tables 6-7).

Table 6: Spearman's rho Correlations between measures of QOL and psychosocial measures for the HIN Group (N=11)

	QOLIBRI	**SF-36**	
	Total Score	**Physical Role**	**Emotional Role**
Depression	-.786*	-.596	-.559
Self-esteem	.534	-.110	.257
Recreational Activities	.065	.104	-.148
Contact with family	.129	-.264	.067
Contact with Friends	.176	-.233	-.018

Table 7: Spearman's rho Correlations between measures of QOL and psychosocial measures for the HICC Group (N=11)

	QOLIBRI	SF-36	
	Total Score	**Physical Role**	**Emotional Role**
Depression	-.807*	-.429	-.605*
Self-esteem	.904*	.578	.827*
Recreational Activities	.323	.104	.063
Contact with family	.500	-.201	.327
Contact with Friends	.021	-.054	-.070

i. Depression

Lower levels of depression was found to be associated with higher levels of QOL on the QOLIBRI in HIN, r = -.786, p = .004, and HICC groups, r = -.807, p = .003.

On the SF-36, lower levels of depression were also associated with higher levels of QOL on the SF-36 (Emotional Role domain) in HICC group, r = -.605, p = .048. Significant negative relationships between depression and QOL were also found on two other SF-36 domains in the HICC group (Vitality, r = -.651, p = .03 and Mental Health, r = -.677, p = .02) (*Appendix 2.7)*. In the HIN group; a negative relationship was found between depression and two domains of the SF-36 (General Health, r = -.854, p = 0.01 and Social Functioning, r = -0.727, p = 0.11) (*Appendix 2.7*).

To explore whether there was an association between HI group and clinically significant HADS score (11 +) a Chi-squared test for independence was carried out. The Chi-squared test for independence (with Yates Continuity Correction) indicated no significant association

between the HI groups (HIN and HICC) and clinically significant scores on the HADS scale, X^2 *(1*) = 0, *p* = 1.00.

ii. Self Esteem

When comparing self-esteem (Rosenberg Self-Esteem Scale) and QOL (QOLIBRI) a positive correlation was found in the HICC group, *r* = .904, *p* =< .001, with higher levels of self-esteem being associated with higher levels of QOL. No statistically significant relationship was found in the HIN group.

On the SF-36, higher self-esteem scores were positively associated with higher QOL (emotional role domain) in the HICC group, *r* = .827, *p* = .002. Statistically significant positive relationships with self-esteem were also found on an additional four domains on the SF-36 in the HICC group (General Health, *r* = .734, *p* = .01, Vitality, *r* = .789, *p* = .004, Social functioning, *r* = .775, *p* = .005 and Mental Health, *r* = .849, *p* = .001). No statistically significant relationship was found in the HIN group.

iii. Contact with family and friends

Both HI groups had a high frequency of weekly contact with family and friends; HIN 72.7%, HICC 100% (*Appendix 2.6)*.

The relationship between contact with family and friends and subjective QOL (QOLIBRI, SF-36) was investigated using Spearman rho correlation coefficients. No statistically significant relationships were found between or within the HI groups (Tables 6-7).

To explore whether there was a significant association between the regular contact with family and friends (one visit per week) between the HI groups, a Chi-squared test for independence was carried out. The Chi-squared test for independence (with Yates

Continuity Correction) indicated no significant association between the HI groups (HIN and HICC) and regular contact with family, X^2 *(1)* = .306, *p* = .580 and friends, X^2 *(1)* = .1.650, *p* = .199.

iv. Completion of age/ability related recreational activities

In the HIN, the most frequently completed recreational activities were eating out (45.4%), attending a club (36.4%) or hobby (36.4%). The most frequently completed recreational activities in the HICC group were sports (82%), shopping (82%) and hobbies (64%). Overall, within the HICC group, a greater number of recreational activities (33 activities) were completed weekly compared to the HIN group (15 activities) (*Appendix 2.6*).

The relationship between the frequency of completion of recreational activities and subjective QOL (QOLIBRI, SF-36) was investigated using Spearman's Rank Order Correlation (rho). No statistically significant relationships were found between or within the HI groups.

To explore whether there was a significant association between the completion of regular recreational activities (4 + per week) and living environment, a Chi-squared test for independence was carried out. The Chi-squared test for independence (with Yates Continuity Correction) indicated no significant association between the HI groups and completion of regular recreational activities, X^2 *(1)* = .183, *p* = .669.

<u>Reason for Placement in Nursing Home</u>

Descriptive statistics were used to explore the various reasons for placement in nursing homes (Table 5). Appropriate place (*n* =8) was the most frequently selected reason for a young adult with HI to be placed in a nursing home followed by unavailability of a more suitable place (*n* = 2) and family preference (*n* = 1).

Discussion:

Summary of Main Findings

The present study did not provide support for the hypothesis that QOL is poorer for young adults with HI living in nursing homes when compared to young adults with HI living in the community and a healthy control group. Significant differences in QOL were almost found in physical domains (Physical Functioning and Physical Role) on generic QOL measures suggesting that individuals with HI living in nursing homes may have poorer QOL with regards to their physical functioning compared to healthy peers. The present study provided support for the second hypothesis that there would be a relationship between QOL and a number of psychosocial variables. Subjective measures of QOL (QOLIBRI and SF-36) were associated with Self-Esteem and Depression. When exploring associations of psychosocial variables and QOL; a greater number of significant associations were found in the HI community group. No association was found between frequency of completion of recreational activities and contact with friends/family with objective and subjective QOL. However, individuals with HI living in the community were found to complete a greater number of recreational activities than those living in nursing homes. When exploring reasons for placement in nursing homes; appropriate place was the most frequent reason for placement followed by unavailability of more suitable accommodation and family preference.

Relationship to the evidence base

The lack of support for the primary hypothesis is consistent with the evidence base. Research exploring the impact of HI severity on perceived QOL has yielded mixed results; with individuals with more severe injury rating QOL as higher in some investigations (Kreuter et al, 1998) with other studies reporting a lower perceived QOL in more severe HI participants (Brown and Vandergoot, 1998). The lack of difference found in the current study may be due to differences in injury severity across the HI groups. A greater level of injury

severity may have impacted on individual's insight, ability to complete measures and rate their self-report QOL. Information regarding injury severity was not gathered in the present study and it is worth noting that others have not found that injury severity predicts QOL (Dijkers, 2004).

Despite not being statistically significant; a difference in physical functioning across the groups would be expected given the reasons why individuals require different types of accommodation/support following HI. In a recent study of young adults with acquired brain injury (ABI) living in residential care settings, 44% of the sample required 24 hour care and maximum support (Winkler, 2010). In the present study a majority of the HIN sample required 24 hour care compared to the HICC group. So whilst a difference in physical functioning (as indicated by objective and self-report measures) has been found between groups, it is worth noting that the reasons why individuals with HI require this level of care is not restricted to physical impairments. In the present study a number of participants in the HIN required this level of care due to the cognitive impact of their HI.

When considering the reasons why significant differences were not found between the groups, it is important to highlight the impact that good standard of care currently provided to young adults with HI living in nursing homes may be having on QOL ratings. For example, an interesting finding of the present study was that individuals with HI living in nursing homes had similar recreational activities to those living in the community. This finding is in contrast with previous studies which found that those living in residential care did not access the community as frequently as those living in supportive accommodation or the community (Winkler et al, 2010). In addition to the number of recreational activities offered, many of the participants in the nursing home talked about the value of having the opportunity to regularly socialise with other residents rather than being isolated in the community. Informal discussions with staff also highlighted how concerned nursing homes were to ensure service users achieved their potential and were not isolated by encouraging them to engage in activities they enjoyed and recruiting carers who were young adults.

The type of nursing homes participants were recruited from in the present study may have also impacted on the results. For example, three homes catered specifically for young adults with HI, or physical disabilities. Four other nursing homes provided services for young adults but were part of a larger home that also provided care for older adults with a range of needs. The variation in nursing homes may have had an impact on the number and range of recreational activities offered and QOL ratings.

It has been of interest to explore the impact of psychosocial factors on QOL following HI in order to ensure rehabilitation is focusing on pertinent areas that enhance reintegration into the community and outcome. The significant relationships found between perceived QOL and depression and self-esteem is consistent with previous research (Corrigan et al, 2001 & Steadman et al, 2001). These findings not only add to the limited evidence base but also highlight areas where intervention may be required or targeted. It is also of interest to note the high correlations between measures of depression and self-esteem with the QOLIBRI. Whilst no study has explored the relationship between the Rosenberg Self Esteem Scale and the QOLIBRI; studies have previously indicated a relationship between the HADS and the QOLIBRI (von steinbuchel et al, 2010). The results obtained in the current study are consistent with this previous research suggesting that an individual's emotional state impacts on multiple aspects of QOL. However, as the QOLIBRI is not providing an assessment of depression or self-esteem, a concern may be that the construct being measured in the QOLIBRI is too narrow.

To date, few studies have explored why nursing homes become an option for young adults with HI and the present study has attempted to answer this question. The finding that nursing homes were the most appropriate place for individuals at the time of placement is in contrast to the limited research which suggests that young people are not always placed in nursing homes because they require 24 hour care (Strettles et al, 2005). However, another question that requires investigation relates the lack of transition opportunities for individuals to move from nursing home care to community living.

The QOL measures may also have impacted on the degree to which significant differences in QOL between the HI groups were detected. Concerns have been raised regarding the ability of generic measure of QOL to capture meaningful issues for individuals HI with regards to QOL (Peterson and Bullinger, 2005). A majority of questions on the SF-36 concern the impact of physical and emotional health on daily functioning.

Strengths of the present study

The inclusion of a demographically similar control group is a strength of the study for a number of reasons. Firstly, participants across all three groups were matched in term of age and gender. Controlling for the impact of age and gender reduced the possibility that these variables contributed to the between group differences in QOL ratings. Secondly, as previously mentioned, individuals with HI may judge their QOL on two contextual bases; their current context and their pre-injury context (Brown and Vandergoot, 1998). The inclusion of a control group ensures that there is a baseline rating of QOL which may reflect QOL pre-injury. To date, no study has assessed QOL in young adults with HI in a variety of different settings, therefore this study adds depth to the QOL following HI evidence base.

Additionally, the assessment of multiple domains of QOL is a further strength of the study design as this ensures a broad range of factors that contribute to QOL are captured. Further to this, the inclusion of a disease specific measure of QOL ensures that factors related to QOL, specifically in HI, were assessed. For example, the inclusion of cognitive domain is a particular strength of the study as many QOL measures do not include this area of functioning which frequently compromised following HI.

Often individuals with HI who do not have the capacity to provide consent are excluded from participating in research studies. Increased vulnerability due to severe disability or impaired cognitive functioning should not in itself exclude an individual; however stringent protocols

and appropriate measures should be utilised to enhance their ability to participate. The use of measures validated in a range of HI severities (mild to severe) and requesting consent from legal guardians enabled individuals to participate in the study which helps to generalise the findings to the HI population as a whole.

Limitations of the present study and future research considerations

The present study had a modest sample size which did not meet the numbers estimated to be required to achieve power and detect statistical significant results. In addition, multiple correlations in the context of a small sample may increase the chance of Type I error. Replication of the study with a larger sample size is required to add weight to and extend the current findings. The required use of non-parametric tests resulted in it not being possible to control for variables such as time since injury. There was a significant variation in time since injury which ranged from 18 to 54 years. The implication of this variation is that the group is not matched with regards to stage in recovery from injury and may have impacted on perceived QOL.

Additionally, the conclusions of the present study should be interpreted tentatively due to multiple comparisons being carried out without a Bonferronni adjustment. As this is a preliminary study, Bonferroni adjustments were not carried out in order to maximise probability that significant effects are found to inform subsequent research directions. Finally, individuals in the nursing home group may have felt pressured not to speak negatively about the homes they lived in. This may have impacted on the accuracy with which they answered questions during the interview.

Future research would benefit from assessing a broader range of QOL domains relevant to HI population as this study focused heavily on health-related domains. As this study was exploratory, the addition of a qualitative methodological design to future research studies would be advantageous as the richness of individual's insight into their QOL would be

captured. The findings of this study provide further evidence of the impact that psychological wellbeing has on an individual's QOL. To date, HI research has predominantly focused on functional outcome and physical and cognitive rehabilitation in comparison to psychological wellbeing following HI. Further investigation into effective psychological interventions for individuals with HI could enhance individual's coping following HI and ultimately improve their QOL.

Conclusions:

The findings of the present study do not suggest that young adults with HI living in nursing homes have poorer QOL compared to young adults with HI living in community and healthy peers. Relationships were found between levels of depression, self-esteem and disability and QOL after HI. These findings have clinical and theoretical implications, however, as the present study is exploratory; replication with a larger sample size and a qualitative methodological design is required to extend and strengthen the results.

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Chapter 3: Advanced Clinical Practice 1

Reflective Critical Account

Amy Best

Doctorate of Clinical Psychology

Title: ‘Psychology is an afterthought’: A reflection on being a trainee in Stroke Clinical Psychology.

Title:

‘Psychology is an afterthought’: A reflection on being a trainee in Stroke Clinical Psychology.

Structured Abstract:

Reflective Practice facilitates individuals learning from experience. This learning can challenge assumptions, biases and personal beliefs which can be difficult to communicate and can subsequently shape an individual’s practice in the future (Bolton, 2010: pg. 3). This reflective account will focus on my experience of being a Trainee Clinical Psychologist in a stroke rehabilitation team. I will reflect on the challenges I feel the profession has encountered in developing a role and professional identity in this area. To structure this reflection I plan to utilise Rolfe’s Framework for Reflexive Practice (2001) which asks three key questions, “What? So What? And Now What?” (Jasper, 2003).

There has been an increased recognition of the importance of including Clinical Psychologists in physical health settings including multi-disciplinary stroke rehabilitation teams. I feel that this has led to a number of challenges particularly in relation to developing clear roles within services. The Development of the National Occupational Standards (NOS) (BPS, 2008) has not only clarified the role of a psychologist but has also highlighted the importance of having clear standards of skills, knowledge and understanding. Of interest in this particular reflective account are the following NOS: Ethics, Communication and Clinical Practice.

I will be focusing on a theme I have encountered throughout my placement with stroke services; “psychology is an afterthought”; analysing my thoughts, feelings and actions which developed in response. The reflection process will not only highlight the key thoughts, emotions and responses that occurred during my time with stroke services, but will also highlight how I have developed as a clinician in addition to areas of my practice I am keen to further and develop in the future.

Chapter 4: Advanced Clinical Practice 2

Reflective Critical Account

Amy Best

Doctorate of Clinical Psychology

Title: ‘Developing Practice’. The role of a Clinical Psychologist in training other professionals in a Physical Health Setting: A Reflective Account

Title:

‘Developing Practice’. The role of a Clinical Psychologist in training other professionals in a Physical Health Setting: A Reflective Account

Structured Abstract:

This reflective account will focus on my experience of being a Trainee Clinical Psychologist in an oncology service. I will reflect on my involvement in a group designed to train other professionals to deliver low intensity psychosocial interventions. I will also describe and reflect on how the group has highlighted areas of my practice I would like to develop (supervision and facilitating reflective practice groups) and areas of practice I feel Clinical Psychologists would benefit from developing within oncology services. To structure this reflection I plan to utilise Rolfe’s Framework for Reflexive Practice (2001) which asks three key questions “What? So What? And Now What?” (Jasper, 2003). The key learning point in this reflective account concerns how the role of Clinical Psychology is changing, with a greater requirement to providing teaching, training and supervision to other professional groups. This account will also highlight areas of my own personal practice requiring development that will subsequently shape my ongoing training as I embark in lifelong learning as an autonomous practitioner.

Systematic Review Appendix Section

Table of Contents

Appendix 1.1: *Description of descriptive data collected from papers*

Description of study participants	Injury Severity
	Number of participants
	Time of assessment
	Definition of quality of life provided
	Target population
Description of instrument characteristics	Number of items
	Number of response options
	Scoring algorithm
	Completion time
	Mode of administration
	Full text of instrument available
	QOL domains instrument is intended to measure
	Instrument available in the public domain
	Administration, scoring and interpretation manual available

Appendix 1.2: *Quality Rating Assessment*

Quality Assessment Checklist	
Authors	
Title of Article	
Title of Journal	
Publication Date	

Methodological Quality Criteria	Rating Classification	Rating
1. Title and Abstract		
1.1 Does the abstract clearly define the population of interest?	Yes (1) No (0)	
1.2 Does the abstract adequately outline the clinimetric property to be assessed?	Yes (1) No (0)	
2. **Introduction and Objectives**		
2.1 Does the introduction clearly outline the background information and link it the rationale of the study?	Yes (1) No (0)	
3. Study Objectives		
3.1 Study addresses an appropriate and clearly defined/focused question	Yes (1) No (0)	
3.2 Settings/Location of data collection stated?	Yes (1) No (0)	
4. Study Design		
4.1 (see score from appropriate COSMIN Box) Clinimetric property assessed: (i) : (ii) : (iii) : (iv) :	 Excellent (4) yes Good (3) Fair (2) Poor (1)	(i) : (ii) : (iii) : (iv) :
5. Study Sample		
5.1 Recruitment	Geographical cohort or random sample (2) Convenience or volunteer sample (1) (i.e. rehabilitation setting) Unclear how sample was obtained (0)	
5.2 Sources/methods of recruitment are clearly stated	Well addressed; includes information on sources and methods (2) Partially addressed; information provided on one (1) Not addressed/reported (0)	
5.3 Inclusion / exclusion criteria clearly defined	Yes (1) No (0)	

5.4 Sample *5.41Injury* (Heterogeneous/homogenous)	Homogenous Injury Type (2) Heterogeneous Injury Type (1) Not Reported (0)	
5.42 Severity	Injury severity defined and diagnosed by appropriate methods (GCS) and a range is used (e.g. mild to severe) (2) One of the above reported (1) Not reported (0)	
5.43 Time of since injury defined	Yes (1) No (0)	
6. Methods and Measures		
6.1 Definition of Quality of Life	Yes (1) No (0)	
6.2 Quality of Life domains assessed	2 + (2) 1 (1) Not reported (0)	
6.3 Clear description of measure (number of items, scoring algorithm, recall period, completion time, mode of administration)	Yes (2) Partial (1) No (0)	
7. Results		
7.1 Demographic characteristics of sample clearly reported?	Yes (1) No (0)	
7.2 Do results relate to the initial hypothesis?	Yes (1) No (0)	
7.3 Statistical Analysis appropriate?	Yes (1) No (0)	
7.4 Data adequately described (means and ranges)	Yes (1) No (0)	
7.5 COSMIN Quality Rating of Statistical Analysis (see Design Rating)	Excellent (4) Good (3) Fair (2) Poor (1)	No score required
8. Discussion		
8.1 Provides summary of key results with reference to the study objectives	Yes (1) No (0)	
8.2 Acknowledges and discusses limitations to the study	Yes (1) No (0)	
8.3 Gives an overall interpretation of results considering objectives,	Full (2) Partial (1)	

limitations, multiplicity of analyses, results from similar studies and other relevant evidence and generalizability of findings	No (0)	
Total Score: Overall Qualify Rating: A – High Quality (>70%+) B – Moderate Quality (40-70%) C – Low Quality (0 - 39%)	/ 33 (1 Clinimetric property) / 37 (2 Clinimetric Properties) /41 (3 Clinimetric properties) /45 (4 Clinimetric Properties)	Percentage:

Appendix 1.3: *Clinimetric Properties of Instruments*

Study and Quality Rating	Objectives	Study Sample Number of Participants Type of Injury Injury severity Time of Assessment Following Injury	Validity	
			Hypothesis Testing	Structural
Chiu et al (2006) WHOQOL-BREF 87.5%	Examine the psychometric properties of the WHOQOL-BREF in persons with TBI Determine the relations of severity indicators of TBI to four WHOQOL-BREF domain scores	199 participants Traumatic Head Injuries Mild to Severe Disability Not reported	Scores for Physical capacity on the WHOQOL-BREF correlated with scores on the Scores on the GOS (r= 0.53, p <0.001) and the Barthel scale r= 0.31, p <0.001). Scores between psychological wellbeing and the CES-D were negatively correlated (r = -0.64, p = <0.001). Scores for psychological wellbeing and the Social Support Survey were correlated (r = 0.52, p <0.001). Scores between social relationships and the social support survey were correlated (r = 0.37, p <0.001). To examine known groups validity of the WHOQOL-BREF, a one way analysis of variance was carried out based on four characteristics (employment independence in ADL's, social support and level of depression) known to influence health profiles among people with TBI. scores in all four domains and the overall QOL and general health facet among subjects who were unemployed, were dependent for daily activities, had weak social support, and indicated having depression were lower than those of their contrasting counterparts. All effect sizes were >0.2 and most of them were >0.5.	
Guilfoyle et al (2010) SF-36 78.4%	Examine whether SF-36 scores are valid and robust for use in assessing outcome following TBI	514 participants TBI Mild to severe disability (GOS-E) 1-24 months following injury	All item-scaled correlations exceeded 0.4 confirming convergent validity. All item-own scale correlations exceed item-other correlations indicating discriminant validity. External validity of the SF-36 domains confirmed by showing an appropriate relationship between scores on the GOS-E F = 19.7-48.8, df = 5, a; p <0.001. Overall the findings suggest that the 8 SF-36 health domains are valid for assessing WOL following HI however the PCS and MCS are not valid in this context	Eigenvalude exceeding unity explained 59.2% variance in the data with the second PC accounting for 9.4% of variance therefore a unidimensional model was accepted rather than PCS and MCS.

			as scores overlapped which indicates that measures of mental and physical health will not be independent of eachother.	
Findler et al (2001) SF-36 66%	Determine whether the Sf-36 is a reliable and valid measure for use with individuals with TBI Determine whether the SF-36 scales can distinguish individuals with TBI from those with no disability	*N* = 597 across three groups: No disability (*n* = 271) Mild TBI (*n* = 98) Moderate-severe TBI (*n* = 228)	Mild TBI group: strong correlations (-0.50 - -0.63) were found between SF-36 scales directly pertaining to physical functioning (GH, PF, PR, BP and V) and the physical symptoms scale of the SCL. Emotional Role and Mental Health scores were more strongly related to psychological factors than physical factors on the SCL. Robust correlations found between BDI-II scores and the SF-36 scales (-0.52 to -0.77). Moderate/Severe TBI group: correlations lower but generally found where expected.	
Hawthorne et al (2011) 85%	Paper reports the preliminary validation study using an Australian sample that was part of an international QOLIBRI project	*N* = 60 participants with TBI , 3-15 years post injury. 48% had a mild injury, 9% moderate and 48% had a severe injury.	Correlations between the Cognition, Self and DLA QOLIBRI subscales were highly correlated as were the Physical Problems with Emotions and Social Relationships (*r* = 0.54-0.75) Correlations of QOLIBRI with other instruments (AQoL, SF-36 &SWLS) ranged between 0.40-0.60 suggesting they had something in common QOLIBRI was sensitive to disability (GOSE), depression (HADS), social isolation.	
Temkin et al (1988) SIP 62.1%	The objective is to determine whether the three modifications improve the SIP as an outcome measure for HI patients	HI group: *n* = 102 Tested 1 month and 1 year following injury Comparison group: *n* = 102 friends of HI group	Correlation varied between *r* = 0.40-0.43 on the GCS and r = 0.24-0.31 on the time to follow commands task. The SIP and modifications were excellent discriminators of the groups however the modified version was not better at classifying subjects into the groups from which they came. The percentage correctly classified (between healthy and HI groups) was deemed the most relevant measure in this analysis and this varied from 91-93% across the standard and modified SIP at one month and 78-80% at one year follow up.	
Alderman et al (2001) 59%	Paper reports the validity of the EuroQOL 5-D with individuals with acquired head injury	*N* = 52 participants with severe and very severe neurological damage 6months to 24 years after injury.	Comparisons revealed no significant differences between groups on either the visual analogue scale (mean self-rating = 66, SD = 23.3, mean others rating = 66, SD = 19.2: *t* = 0.006, n.s) or the five-dimensional Health State (mean self-rating = 0.67, SD = 0.30, mean others rating = 0.66, SD = 0.22: *t* = 0.155, n.s.). Ratings by the clinical team on the DEX were significantly higher (mean = 36.8, SD = 11.7)than patient reported ratings (mean = 23.3, SD = 13.9: *t* = 5.02, *p* < .001).	

			significant correlations were found between the Barthel ADL Index and the health dimension on the EuroQOL - 5D ((r = .48, p < .001) and the visual analogue scale ((r = .33, p = .02). no relationship was found between the DEX and the EuroQOL-5D.	
Von Steinbuchel (2010) (a) 87.5%	Report findings concerning the validity of the QOLIBRI from a large scale international study Consider clinical and research value of the new instrument Examine correlates of QOL after TBI	N = 795 with TBI 3-15 years post injury. 58% were severely injured, 10% had moderate injuries and 32% had mild injuries	Significant relationships found between the GOS-E and QOLIBRI scales, the strongest relationships was with the Daily Life and Autonomy Scale (r = .42). There were systematic relationships between the QOLIBRI scales and emotional state as assessed by the HADS (r = 0.37-0.67). (3): Relationships indicate the QOLIBRI has more in common with MCS than the PCS of the SF-36. Relationship between GOS-E and QOLIBRI was greater (r = 0.39) than the relationships between GOS-E and the MCS (r = 0.20) indicating that the QOLIBRI performs as well as the SF-36 as a measure of HRQoL. Overall the systematic relationships between QOLIBRI scales and the GOS, HADS and sF-36 confirming the validity of the QOLIBRI.	
Von Steinbuchel (2010) (b) 92.5%	Paper reports on the scale development and assesses psychometric properties of the scale	N = 795 participants with mild (32%), moderate (10%) and severe (58%); 1-18 years after injury.		Rasch analysis was carried out on items within each scale and showed that infit was in the required range for all items in each of the scales thus confirming that items have satisfactory fit with their home scales. Rasch analysis was also performed with all items combined to examine whether QOLIBRI items fit a unidimensional scale. The infit values indicated that the majority of QOLIBRI items fitted an overall Rasch dimension. The results of the analysis giver moderate support to a unidimensional model, but also indicate some items have a poor fit with unidimensional model. Exploratory factor analysis (PCA) indicated that items in the first three scales generally have a good fit (loadings >0.6) with a unidimensional HRQoL model descriptive system. The result from the single factor PCA are consistent with the Rasch analysis which indicates that there is an element of unidimensiaonl component in the QOLIBRI which is primarily based on the first three scales (cognitive function, self-perception and independent living). The second PCA highlighted hat all items have the highest loadings on their home scales with relatively little cross loading >0.25.
Teasdale et al (1997)	Aim is the develop and validate a questionnaire	Participants drawn from seven European	A large majority of the individual items in the EBIQ are significantly elevated in the brain injured group	

EBIQ 62.2%	specifically designed for use with brain injured populations Aim to explore the construct validity of the EBIQ questionnaire and the derived scales.	Countries. *N* = 905 (*n* = 63 CVA, *n* = 29 TBI and *n* = 8 Other). Months since injury = 1-278) Controls (*N* = 203) drawn from France and Brazil	compared to the control group with regard to self-report. (Mann-Whitney U test, p <0.05). There was also a high level of agreement between the brain-injured patients and their relatives (Wilcoxon signed-rank . test, *p*, <0.01)	
Bateman et al (2009) EBIQ 72.7%	The aim of the study was to establish baseline item response characteristics for the EBIQ questionnaire.	*N* = 226 with acquired brain injury (77% TBI, 8% stroke, 6% anoxia, 3% open head injury, 6% other conditions) 1-10 years post injury.		In the overall EBIQ scale, a person separation index of 0.94 was found indicating that there is good separation of items along the construct and sufficient power to discriminate between four class interval groups of respondents. The overall EBIQ scale should good fir to the Rasch model (*M* = 0.048, *SD* = 0.977). Item trait interaction was significant (*X2* = 322.0, *p* < .0001) suggesting that the scale as a whole is deviating significantly from the model's expectations and lacks invariance across the construct of "total distress" caused by brain injury. Some items (17) did not meet the expectations of the Rasch model and were removed. The overall fir to the Rasch model was recalculated (item fit mean = 0.00, *SD* = 0.63; *X*2 = 159.7, *p* = .10). After removal of items it was possible to validate the six subscales from previously published subscales (Cognitive, impulsivity, somatic, depression, communication and difficulties in social interaction).
Caracuel et al (2001) EBIQ	To explore the factor structure and overall psychometric properties of the items on the EBIQ in a sample from three different cultures To perform a cross-cultural validity assessment.	*N* = 366 with ABI (66% diagnosis of TBI, 34% stroke). Mean time (months) since injury = 21.16 (SD = 19.45).		Exploratory factor analysis was used to determine the structure of the EBIQ. Separate Rasch analyses of the 3 subscales (Depressive mood, Cognitive dysfunction and poor social and emotional self-regulation) were conducted to determine unidimensionality and overall fit of the subscales to the Rasch model, individual item fit, targeting of the subscales to the severity of participants, functioning of response categories and the presence of DIF by age, gender etiology, time since injury and country.

Study and Quality Rating	Test-retest Reliability	Internal Consistency
Chiu et al (2006) WHOQOL-BREF 87.5%	The intraclass coefficients varied from 0.74-0.95	Cronbach's alpha coefficients varied between 0.75-0.89.
Guilfoyle et al (2010) SF-36 78.4%		Alpha coefficients for the eight domains ranged from 0.82-0.95 and were substantially greater than the correlations between domains.
Findler et al (2001) SF-36 66%		
Hawthorne et al (2011) SF-36 85%	Four scales (Cognition, Self, Social and Physical Problems) exceeded the test re-test criterion (ICC 0.75); DLA and Emotions were just below this	Cronbach's α ranged from 0.47 -0.90 for self-ratings It was concluded that the questionnaire has an acceptable reliability and validity, but that it will be necessary to obtain culturally relevant non-brain injured control data when employing it in different countries.
Van Baalen (2006) Sf-36 60.6%	ICC varied between 0.44 (Mental Health) to 0.94 (Role Emotion)	
Van Baalen (2006) SIP 60.6%	ICC = 0.87.	
Alderman et al (2010) 59%	Due to small sample size on follow-up (n = 11) test –retest reliability was demonstrated using means and standard deviations of participant and staff ratings on all scales (five dimension health state (EuroQOL- 5D) Visual analogue scale (EuroQOL- 5D), DEX and The Barthel ADL Index. No difference between staff and participants ratings on the visual analogue scale from EuroQOL- 5D was apparent or the staff test-re-test ratings on the five dimension health state. However, in comparison, test re-test ratings by participants indicated that there was a difference in the five dimension health state (t = 1.9, p = .43). No differences were found in ratings on the Barthel ADL index. However in	Cronbach's *a* ranged from 0.75 ("Physical Problems") to 0.89 ("Cognition" and "Self"). The individual scales fulfil criteria for use in research studies and the totally QOLIBRI scores provides reliable assessment at the level of the individual with Cronbach's *a* ranging from 0.92 (French; n = 147) to 0.97 (English; n = 96). The results indicate that the QOLIBRI scales generally have good internal consistency.

	the DEX, clinical staff reported fewer difficulties on re-test (t = 1.78, p = .050) indicating that difficulties were less prevalent on follow-up. This difference was also reflected within those ratings made by patients regarding themselves (t = 1.91, p = .042).	
Von Steinbuchel (2010) (b) 92.5%	ICC in sample of participants after two weeks ranged from 0.78 ("Emotions") to 0.85 ("Physical Problems") indicating that all scales show good test-retest reliability.	Due skewed data, internal consistency was assessed with Mokken ρ (rho). All scales met the reliability criteria (ρ > 0.80) except for physical problems (ρ > 0.78)
Soprena et al (2007) EBIQ 69.7%	Reliabilities were significant ranging from between 0.55-0.90 with a median value of 0.76.	Cronbach's reliability coefficient alpha was used to assess internal consistency. This quantity could not be calculated when a modification involve disregarding irrelevant items since, in that modification, each individual responded to different questions. Pearson's correlation coefficient was used. Reliability was essentially identical for SIP and all modification ranging from r=0.93-0.96

Appendix 1.4: *Methodological quality of each study per measurement property and questionnaire*

Study	Validity: Hypothesis Testing	Validity: Structural	Reliability: Interrater	Reliability: Test-retest	Internal Consistency
Generic Measures					
SF36					
Guilfoyle et al (2010)	Good	Excellent			Good
Findler et al (2001)	Fair				Fair
Van Baalen				Poor	
WHOQOL-BREF					
Chiu et al (2006)	Good			Good	Good
Sickness Impact Profile (SIP)					
Temkin et al (1988)	Fair			Fair	Poor
Van Baalen				Poor	
EuroQOL-5D					
Alderman et al (2001)	Poor			Poor	
Disease Specific Measures					
QOLIBRI					
Von Steinbuchel et al (2010 a)	Fair				
Von Steinbuchel et al (2010 b)		Excellent		Good	Excellent
Hawthorne (2011)	Fair			Good	Fair
EBIQ					
Teasdale et al (1997)	Fair				Good
Bateman et al (2009)		Good			
Caracuel et al (2001)		Fair			
Sopena et al (2007)				Fair	

Appendix 1.5 – Author guidelines for submitting to Journal of Neurotrauma

Guidelines for submission to Journal of Neurotrauma on Thursday 28th June 2012:

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Bearn, A.G. (1972a). Wilson's disease, in: *The Metabolic Basis of Inherited Disease.* J.B. Stanbury, J.B. Wyngaarden, and D.S. Frederickson (eds). McGraw-Hill: NY, pps. 1033-1050.

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TABLE AND ILLUSTRATIONS

Type tables double-spaced in a separate file, number tables with Arabic numerals, and provide a legend for each table. Tabular data should not be duplicated in figures.

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Major Research Project Appendix Section

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Appendix 2.1 – Major Research Proposal

Quality of life in young adults with head injury living in nursing homes: a comparative study

Amy Best

Dr Tom McMillan

8th July 2011

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(4694 with references)

Re-Submission 1

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Quality of life in young adults with head injury living in nursing homes: a comparative study

Word count: 3800 (excluding references)
(4694 with references)

Background: The impact of Head Injury (HI) on quality of life (QOL) is increasingly being used as a measure of outcome in rehabilitation research. Studies, however, have focused primarily on individuals who live in the community following HI or have recently experienced a head injury. Little is known about the long-term outcomes of young adults who reside in nursing homes following a head injury and the degree to which living environment impacts on QOL.

Aims: The study aims to document why young adults with HI are placed in nursing homes, to compare QOL of young adults living in nursing homes, with young adults with HI living in the community and the general population and whether this rating is associated with a number of psychosocial variables.

Methods: Participants aged 18+ with a HI living in nursing homes and in the community with care packages and the general population will be invited to take part in an interview where a number of structured assessment measures will be completed. A carer will also be invited to complete a number of objective assessment measures in an interview format.

Applications: The purpose of the study will be to generate more information regarding young adults with HI living in nursing homes in comparison to those living in the community and whether nursing homes meet the needs of this under researched group of the HI population.

Introduction:

Head injury (HI) is one of the leading causes of death and disability and has been defined as "a blow to the head or the presence of a scalp wound or those with evidence of altered consciousness after a relevant injury" (Jennett and MacMillan, 1981). The incidence of HI requiring admission to hospital is around 100-150 per 100,000 of the UK population each year and incidence rates vary between different age groups with the highest frequency occurring in males between 15-24 and >75 years of age (Thornhill, Teasdale, Murray, McEwen, Roy and Penny, 2000 & Barnes, Eames, Evans C Iannotti Jessop et al ,1998).

Memory impairment, language deficits and difficulties with attention are all common cognitive consequences of HI (Buchanan et al ,2003) along with a range of emotional and behavioural difficulties including; physical aggression, social disinhibition, impulsivity and depression (Buchanan et al , 2003). These physical, cognitive, behavioural and emotional difficulties can severely limit a person's ability to complete daily life activities, function independently in the community and ultimately their quality of life (QOL) (Truelle et al, 2010).

The assessment of QOL is increasingly used to compliment traditional medical and psychological outcome measures in neurological rehabilitation settings including stroke, HI and degenerative conditions (Meyers et al, 2000). The ultimate goal in rehabilitation settings is to return the individual to as high a level of functioning/QOL as possible (Koskinen, 1998). Therefore the inclusion of subjective QOL measures ensures that the patients' perspective of QOL can be captured in addition to other outcome measurements to inform treatment and subsequent care.

The definition of QOL adopted for this project is from the World Health Organisation (WHO): 'an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns' (WHOQOL Group, 1993, P153).

The measurement of QOL within rehabilitation populations has faced a number of challenges due to the lack of consistent definition amongst researchers, the impact of societal, cultural and religious views on subjective QOL as well as the large number of QOL measurements that do not clearly indicate which definition is being utilised (Kalpakijan et al, 2004, McMillan and Herbert, 2004). Within the HI population specifically; profiles of QOL are lacking as few studies have explored QOL after HI (Brown and Gordon, 1999 & Emanuelson and colleagues, 2003).

Of the research that has been carried a range of QOL after HI is reported. Kalpakijan et al (2004) carried out a cross-sectional study to describe the QOL and psychosocial outcomes in a sample of 50 people with HI living in the community and found mean QOL ratings were lower (M = 1.6, SD = 2.18) than in a non-injured comparison group (M = 2.6, SD = 1.3; t (846) = -5.02, p = <0.01). The near even distribution of scores across all of the rating options on the QOL measure suggests QOL can vary in individuals with HI. However, Emanuelson and colleagues (2003) carried out a comparison study of QOL of individuals with HI at 3 weeks (n=107) and 3 months (n=101) post injury with a normative control group using a standardised measure of QOL; the SF-36 and found QOL was significantly impaired in the HI groups compared to the normative control group on all subscales.

The inconsistent results regarding perceived QOL in individuals with HI may be due to the different variables investigated in studies. Demographic variables such as age, injury severity have yielded a weak relationship with perceived QOL (Kalpakijan et al, 2004) whereas psychosocial variables such as depression have been consistently related to poorer ratings of QOL and positive self-esteem and employment have been consistently related to higher ratings of QOL (Corrigan et al, 2001, Trezesniewski, 2003, Steadman et al, 2001 & O'Neil et al, 1998). Brown and Vandergoot (1998) have also highlighted that the contextual base for an individual with HI may be very different compared to an individual without a HI due to individuals with HI having two contexts for judging their QOL; their current context after experiencing a HI and the context they remember from before their HI.

Much of the previous research on QOL after HI has focussed on those living in the community or who have been recently injured (Brown and Vandergoot, 1998). There has been little work on people who are discharged to a nursing home and why nursing homes become an option. McMillan and Laurie (2004) carried out a survey of all adults with HI living in nursing homes in Glasgow and reported that 92 individuals with HI under the age of 65 resided in nursing homes. Concerns regarding the appropriateness of nursing homes for young people with HI compared to a community placement with a package of care have been expressed due to a number of reasons. Firstly, 'nursing homes which have a primary focus on supporting elderly people' have 'limited capacity to support the complex social and rehabilitation needs of young people with disabilities' (Stringer, 1999). The potential limits in providing rehabilitation needs is concerning in light of the evidence provided by McMillan and Herbert (2004) which suggests that with continued support and review, functionally significant improvements can be made up to ten years post injury. More recently in Australian study Winkler and colleagues (2011) demonstrated that nursing homes accommodating young adults with HI did not foster an environment that encouraged an

increase in independence compared to community living. Secondly, Gething (2001) reports that nursing homes do not provide age-appropriate activities for younger people. The Mental Health Welfare Commission (2010) highlighted the importance of individuals with HI being given the opportunity to participate recreational activities and being supported to stay in touch with family and friends which contribute to QOL. This review highlighted that suitable programmes of social and recreational activities were found less frequently in nursing homes when compared to those living in the community and that involvement with family and friends was variable.

To date studies into QOL within HI populations have found that, adults with HI living in the community have poorer QOL than in the general population; it has also been shown that QOL varies widely in these adults. At present, there is no research into the QOL of young adults with HI living in nursing homes. However, given recent findings showing that adults with HI living within nursing homes have limited social activities and contact with family and friends, we may predict that they would have poorer QOL, than adults with HI living within the community and the general population.

Measures of QOL can help create a picture of the impact of the multiple consequences of HI for individuals including those discharged to nursing homes and potential inform services as to areas of care which require modification changes. Therefore in the current study it is of interest to explore the following:

Aims:

- To explore QOL of individuals with HI of individuals living in nursing homes and compare whether these ratings differ with individuals with HI living in the community and a healthy control group who have not experienced a HI.
- In order to develop a greater understanding of the factors associated with QOL in the HI population it is also of interest to explore whether subjective QOL is associated with a number of psychosocial variables.
- Finally, given the potential impact nursing homes can have on long term rehabilitation and QOL it is of interest to identify why nursing homes becomes an option for young adults with HI.

Hypotheses:

3. Objective and self-ratings of QOL of individuals with HI living in nursing homes are poorer than in individuals with HI living in the community and the general population.

4. QOL is associated with Disability, Depression, Self Esteem, Contact with family and peers and Completion of age/ability-related recreational activities.
    - Greater disability will be associated with poorer QOL
    - Increase in depression scores associated with poorer QOL
    - Positive self-esteem will be associated with increased QOL
    - Limited contact with family and friends will be negatively associated with QOL
    - A low frequency of appropriate recreational activities completed each month will be associated with poorer QOL

Plan of Investigation

Participants: There will be three groups: HI Nursing Home (HIN), HI Community Care Package (HICC) and a Healthy Control group. Participants will be matched by Age, Gender, Education and Relationship Status.

Inclusion Criteria:

3. Participants in the HI groups will be aged 18 years or over at time of HI and living either in a nursing home (HIN) or in the community (HICC).
4. Participants in the Healthy Control Group will aged 18 years or over.

Exclusion Criteria:

6. Participants will be excluded if first language is not English individuals as modifications of measures would be required which may invalidate measures.
7. Participants with profound motor, cognitive and communication problems will be excluded if unable to provide self-report details, complete measures and ability to attend to information during assessment.
8. Participants who display severe challenging behaviour will be excluded to ensure safety of the participant and researcher.
9. Participants currently undergoing rehabilitation will be excluded as ongoing rehabilitation may impact on perceived QOL.

10. Participants who have a current or history of alcohol and/or drug related dependency will not be invited to take part in this study due to impact substance misuse may have on QOL.
11. Participants will be excluded from the healthy control group if there is a history of HI.

Recruitment Procedures: The sample for the HIN group will be recruited by approaching nursing homes with young adults with HI in Greater Glasgow. Consent will be gained from managers to approach potential participants. The Trainee will liaise with Social Work, Public Health and community brain injury teams to recruit the HICC group. The following have been identified as possible recruitment methods: poster and/or presentation at the Brain Injury Rehabilitation Unit and a local brain injury charity. Participants will also be recruited via the NHS GGC extra contractual referral data base for rehabilitation of people with HI. The Healthy Control Group will be recruited from families of HI participants (to minimise impact of socio-demographic status), using posters in community centres, adult education centres, sports facilities, newspaper advertisements and partners of colleagues. Those who express an interest will be sent an information sheet outlining the aims of the study and a consent form. Participants will be invited to return this form indicating that they consent to participate in the study. If assessed as suitable according the inclusion/exclusion criteria, participants will then be sent a letter inviting them to meet the main researcher at a local clinical setting or the nursing home they are currently residing in. This letter will be followed up by a telephone call to confirm attendance and to check for any special requirements and answer any questions which will inform their choice to participate.

Measures:

Demographic Measures: Age (at time of interview), Gender (Male / Female), Education (Primary / High / trade / certificate / diploma or degree) and Relationship Status (single/ married/ separated/ divorced/widowed).

Subjective Quality of Life (i)**:** The Medical Outcome Study Short-Form-36 Health Survey (SF-36) is a generic instrument for the assessment of health related QOL. This survey consists of 36 items across 8 domains; four of the domains relate to functional health (physical functioning, social functioning, physical role and emotional role), three domains related to wellbeing (mental health, vitality and bodily pain) and the overall evaluation of health is based on the general health domain. Scores range from 0 (worst possible functioning) to 100 (best possible functioning). This scale has been shown to be a valid and reliable measure in the HI population (Findler and colleagues, 2001) and will be used to compare QOL in the HI groups and the healthy control group.

Subjective Quality of Life (ii)**:** The Quality of Life after traumatic brain injury (QOLBRI-TBI) scale (Von Steinbüchel, Peterson, Bullinger and the QOLIBRI Group, 2005). This is a 37 item self-report disease specific measure of Quality of Life across four satisfaction domains: cognition, self, daily life and autonomy, and social relationships and two bothered domains; Emotions and Physical Problems. Internal consistency and test-retest reliability of the QOLIBRI have been found to be acceptable to good (Von Steinbüchel and colleagues, 2010). The QOLIBRI will be used to detect differences in ratings of QOL between the HIN and HICC groups in addition to SF-36.

Objective Quality of Life (Functional Impairment): The Barthel ADL Index (Mahoney and Barthel, 1965) is used to measure performance on basic activities of daily living. A score on the Barthel Scale varies between zero to 20; higher scores indicating increased independent functioning.

Disability following TBI**:** Glasgow Outcome Scale-Extended (GOS-E: Wilson and colleagues, 1998). The GOS-E is a structured clinician administered outcome measure that assesses functional and social disability following HI.

Self Esteem**:** Rosenberg Self-Esteem Scale (Rosenberg, 1965) is a 10 item questionnaire measuring self-esteem. Responses are selected from a 4 point likert scale and scores range from 0-30 with higher scores indicating greater self-esteem.

Depression and Anxiety: Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983) is a self-report questionnaire used to assess the presence of symptoms indicative of anxiety and/or depression. Participant's rate symptoms experienced over the past week on a 3 point scale and total scores indicate the following; 8-10 identify mild cases, 11-15 moderate cases and 16+ identify severe cases of anxiety and/or depression.

Participation in recreational activities: Participants will be asked whether they participate in a range of recreational activities (*sports activity, eating out, shopping, club, hobbies, and contact with friends/family)* and the frequency of participation (Weekly/ monthly). This information will be used to investigate whether the activities provided by different living settings and frequency of completion is associated with QOL.

Contact with family and friends: The level of contact with family and friends will be recorded to determine whether there is an association between level of contact and QOL.

Level of contact will be defined as:

- Birthday/Christmas card and occasional phone call
- Phone call/letter once a month
- Visits two times a year
- Visits at least once a month
- Visits at least once a week
- No contact/unknown

Reason for Placement: Information regarding why nursing homes becomes an option for living accommodation will be gathered from participant's social work and nursing home files. The possible reasons for placement used in this study will be drawn from previous studies investigating reasons for adults with learning disabilities being placed in generic residential services for older people (Thompson and Colleagues, 2004). For example:

- Appropriate place
- Family Preference
- Unavailability of a more appropriate service
- Person's own choice

Design: This study employs a between subjects design comprising individuals with HI living in nursing homes, in the community and a health control group. The relationship between QOL will be explored between the three groups as well as the impact of a number of psychosocial variables on perceived QOL.

Justification of sample size: To date no study has compared QOL in individuals with HI living in different settings and a control group. Power was calculated for the primary hypothesis that individuals with HI would have a poorer quality of life as rated by the SF-36 and the QOLIBRI. To establish the necessary sample size to test this hypothesis a power calculation was performed using data by Findler et al (2001). This study validated the use of the SF-36 in a HI population (n=229) and was chosen as participant means and standard deviation scores were reported for individuals with HI and healthy controls. The existence of a number of domains in QOL measurements (SF36 and QOLIBRI) reflects the assumption that QOL are multi-dimensional. Walters (2004) states that one of the dimensions can be used as the primary endpoint and the sample size can be calculated from this. In the current study the data from the 'emotional role' dimension was used to calculate the sample size for the mild HI group (M = 55, SD = 43) and the moderate to severe HI group (M = 74, SD = 37). A total of 45 participants (as determined by a priori power analysis aiming for an 80% medium effect size, 0.48) are required for this study (15 participants in each group). A power

calculation has also been carried out using data from a validation study of the QOLIBRI in a large clinical population (*n*=795) (Truelle and colleagues, 2010). Overall QOL scores for participants with HI living in independent accommodation (*M* = 68.32, *SD* = 17.39) and those living in sheltered accommodation (*M* = 63.06, *SD* = 17.67) were used to calculate a sample size. A total of 32 participants (as determined by a priori power analysis aiming for an 80% medium effect size, 0.5) are required for this study (16 participants in each group). Therefore in the current study 16 participants in each group will be recruited.

Data Analysis: Data will be analysed using SPSS 18. Descriptive statistics and graphs will display the demographic variables. Reasons for placement in nursing home will be explored using chi-squared tests and post hoc analyses will be carried out if significant differences are found in the patient journey to nursing homes. In order to investigate whether the predicted differences exist between the three groups; inferential statistical analyses will be carried out to look at the variance between the groups in terms of differences in performance on dependent variable measures. Non parametric tests of statistical significance will only be chosen when assumptions of normal distribution and homogeneity of variance are violated.

Primary Analysis:

- Hypothesis 1: Objective (Barthel ADL Scale) and Subjective (SF-36) ratings of QOL (SF-36) across the three groups (Nursing home, Community and Control group) and Subjective QOL (QOLBRI) between the HI groups will be analysed using One- Way ANOVA's. Post Hoc analyses will be completed if a significant difference in mean QOL scores differs across the three groups.
-

Secondary Analysis:

- Hypothesis 2: QOL is associated with the following variables (Disability, Depression, Self-Esteem, Contact with friends and family and completion of age/ability related recreational tasks) - will be analysed using correlation coefficients (QOL and each variable). This will be investigated overall and between the three groups.

Health and Safety Issues:

Researcher and Participant Safety Issues: The researcher will conduct interviews in a hospital/residential setting and all appointments will take place between normal working

hours (9am-5pm) or when a member of staff is on the premises. The health and safety protocols of the premises will be followed at all times to ensure the safety of the participant if an emergency were to occur (e.g. fire evacuation procedures).

Ethical Issues: There are a number of ethical issues that need to be addressed in order to ensure participant safety and comfort during the study. At present there are no guidelines that are universally accepted that assess the capacity to consent. There is also a lack of clear procedures which can be used when assessing capacity to consent in the HI population (Windsdale et al, 2004). To ensure that participants are able to provide informed consent, each participant will be asked to explain their understanding of the consent form via the use of probing questions. For those participants who are deemed unable to provide informed consent; consent will be obtained from a Legally Authorised Representative (LAR). According to Johnson-Greene et al (2010) this approach is the standard practice of gaining consent when the risk involved in participating is minimal and benefit of the knowledge to be acquired by the research is acceptable. Fatigue and/or discomfort will be monitored by the assessor (Trainee Clinical Psychologist) and regular breaks will be offered as required. The participant will have the opportunity to discuss any distress experienced when discussing QOL and unmet needs during the debrief session. Guidance detailing the action to be taken if a HADS score indicates that the participant is experiencing symptoms indicative of severe depression or anxiety will be required; e.g. GP informed and referral to be made to the appropriate service at their discretion with supervision from Professor Tom McMillan.

Ethical approval will be sought from West of Scotland NHS Research Ethics committee. Participants will be asked to provide written consent to participate in the study and will have the opportunity to withdraw consent at any time. Data will be handled in accordance with The Data Protection Act (1998), The Freedom of Information Act (2000) and the NHS Confidentiality Code of Practice Guidelines (2003). All identifying information will be removed to preserve anonymity and data will be stored and analysed on an encrypted laptop.

Financial Issues: Costs will be incurred for questionnaires, advertisements and stationary only and travel to and from the settings that the interviews will be taking place in.

Timetable:

- May 2011: Proposal submitted to University
- August/September 2011: Apply for ethical approval

- November-April 2012: Recruitment
- May: Analysis of data
- June-August: Write up and submission

Practical applications: If a significant difference is found i.e. QOL is poorer in individuals with HI who reside in nursing homes; this finding will provide further evidence to the growing need for appropriate accommodation for young people with HI. The results will indicate areas of unmet need which require service improvement and why nursing homes become an option for young adults with HI.

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Appendix 2.2 – Ethics Committee Approval Letter

Scotland A Research Ethics Committee

Secretariat
2nd Floor Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone: 0131 465 5680
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www.nres.nhs.uk

NHS SCOTLAND

Professor Thomas McMillan
Academic Unit of Mental Health and Wellbeing
University of Glasgow
Academic Centre, Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Date: 26 September 2011
Your Ref.:
Our Ref.: 11/SS/0047
Enquiries to: Walter Hunter
Extension: 35680
Direct Line: 0131 465 5680
Email: walter.hunter@nhslothian.scot.nhs.uk

Dear Professor McMillan

Study title: **Quality of life in young adults with head injury in nursing homes: a comparative study**

REC reference: **11/SS/0047**

The Scotland A Research Ethics Committee reviewed the above application at the meeting held on 22 September 2011. The Committee was grateful for Miss Best's attendance to discuss the study.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
REC application: IRAS Form	3.1	26 August 2011
Protocol: Resubmission 1	2	08 July 2011
Investigator CV: Amy Best		08 July 2011
Investigator CV: Tom McMillan		
Letter of invitation to participant: Relative/Welfare Guardian	1	02 August 2011
Participant Information Sheet: Participant	1	01 August 2011
Participant Consent Form: Participant	1	11 July 2011
Participant Information Sheet: Control	1	01 August 2011
Participant Consent Form: Control	1	23 August 2011

Chairman Dr Ian Zealley
Vice-Chairman Dr Colin Selby

NHS SCOTLAND

Participant Information Sheet: Relative/Welfare Guardian	1	17 August 2011
Participant Consent Form: Relative/Welfare Guardian	1	11 July 2011
Participant Information Sheet: Carer/Staff	1	17 August 2011
Participant Consent Form: Carer/Staff	1	17 August 2011
GP/Consultant Information Sheets	1	01 August 2011
Flowchart: Nursing Home Group	1	05 August 2011
Flowchart: Community Group	1	05 August 2011
Flowchart: Control Group	1	05 August 2011
Nursing Home Manager Cover Letter	1	02 August 2011
Data Collection Forms	1	01 August 2011
Questionnaire: Rosenberg Self-Esteem		
Questionnaire: SF36™ Health Survey		
Questionnaire: Quality of Life after Brain Injury		
Questionnaire: Barthel Index		
Questionnaire: Glasgow Outcome Scale-Extended		
Questionnaire: Hospital and Anxiety Depression Scale		

The Committee noted that the study methodology was intended to answer the question as to whether there was a difference in the quality of life of young adults with a head injury living in a nursing home, compared to the quality of life of young adults with a head injury living in the community. The Committee had no major ethical concerns and was satisfied that the inclusion of adults lacking capacity was justified but did identify some minor concerns that required to be clarified. These included:

- would adults lacking capacity have the ability to complete the various self reports and give valid responses to the questionnaires and assessments
- clarification was needed in relation to initial identification and approach to potential participants; Dr Laurie was said to involved in the care of all theses individuals whose names were held on the database for rehabilitation of HI patients
- what proportion of participants were expected to lack capacity to give consent
- some of the responses in Section B of the application form related to the Mental Capacity Act which had no jurisdiction in Scotland
- information sheets and consent forms for welfare guardians/relatives appeared to be coercive in parts and needed to be more invitational
- a definition was needed of what care settings were meant by those in the 'community'.

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6. The relatives information sheet should:
   1. be more invitational and not suggest there was a requirement to give consent
   2. to make clear it was not them participating in the study.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact Dr Alex Bailey (telephone 0131 465 5679.

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

If the Ccommittee has asked for clarification or changes to any answers given in the application form, please do not submit a revised copy of the application form; these can be addressed in a covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 24 January 2012.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

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.

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Miss Best attended to discuss the study. In response to being asked about the initial approach to potential participants Miss Best explained that initially participants would be identified from a database, which held their names. These individuals would be approached by Dr Laurie, who has been involved in their care, to establish if they would be interested in participating in the study. Miss Best was asked about the ability of adults lacking capacity to complete the questionnaires. She accepted this could be a problem but she considered that it was important that they be given the opportunity to participate in the study. When asked about the potential for bias due to confounding factors she accepted there was the potential for this to happen. Miss Best was asked where the controls would come from and indicated that these would be from a community setting. Miss Best mentioned that all the interviews would be undertaken at an environment where the participants were comfortable. In response to being asked about the anticipated proportion of adults who would lack capacity to give consent Miss Best was unable to say but this would become clearer once the study progressed. On being asked about the definition of 'community' Miss Best indicated anyone not living in a nursing home and most likely to be in family home.

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

The Committee delegated authority to confirm its final opinion on the application to A meeting of the sub-committee of the REC.

Further information or clarification required

1. Section B of the application form should reflect the requirements of the Adults with Incapacity (Scotland) Act 2000 and not the Mental Capacity Act 2006.
2. Provide a letter to the GP informing them of their patient's participation in the study.
3. Clarify if expenses would be available to participants and carers attending for interview and if so mention in the information sheets.
4. The information sheets should:
    1. mention the involvement of carer/staff member and explain that the HI participant must consent to their being invited to take part
    2. exclude mention of the 'research team' unless there were no additional members in which case it should indicate who they were.
5. The control information sheet should:
    1. explain the 'why, what and how' of needing a control group.

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Scotland A REC

Attendance at Committee meeting on 22 September 2011

Committee Members:

Name	Profession	Present	Notes
Professor Richard Anderson	Professor of Clinical Reproductive Science	No	
Dr Susan Gregory	Social Scientist (retired)	No	
Dr Bridget Harris	Clinical Nurse Researcher	No	
Mrs Fiona Mack	Clinical Pharmacist	Yes	
Dr Mary J Macleod		Yes	
Mrs Angela Macpherson	Retired	Yes	
Mrs Margaret McDonald	Retired Civil Servant	No	
Mrs Katherine McGuigan	Nurse	No	
Canon Matt McManus	Parish Priest	Yes	
Dr Craig Melville	Senior Lecturer in Learning Disabilities	No	
Mrs Wendy Nganasurian	Retired	No	
Dr Richard Quigley	General Practitioner	Yes	
Dr Colin Selby	Consultant Physician	Yes	
Dr Rachel Smith	Project Manager	No	
Mrs Mary Sweetland	Statistician	Yes	
Mrs Margaret Thomson	Retired	Yes	
Professor Nigel R Webster	Professor of Anaesthesia and Intensive Care	No	
Dr Ian Zealley	Consultant	Yes	

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Also in attendance:

Name	Position (or reason for attending)
Dr Alex Bailey	Scientific Officer
Mr Walter Hunter	Committee Coordinator

Written comments received from:

Name	Position
Dr Craig Melville	Senior Lecturer in Learning Disabilities

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SCOTLAND

REC reference number: 11/SS/0047-Please quote this number on all correspondence

Yours sincerely

Dr Ian Zealley
Committee Chairman
cc: Miss Amy Best
Academic Unit of Mental Health and Wellbeing
Academic Centre, Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Scotland A Research Ethics Committee

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2nd Floor Waverley Gate
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NHS SCOTLAND

Miss Amy Best
Academic Unit of Mental Health and Wellbeing
Academic Centre, Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Date: 9 November 2011
Your Ref.:
Our Ref.: 11/SS/0047
Enquiries to: Walter Hunter
Extension: 35680
Direct Line: 0131 465 5680
Email: walter.hunter@nhslothian.scot.nhs.uk

Dear Miss Best

Study title: **Quality of life in young adults with head injury in nursing homes: a comparative study**

REC reference: **11/SS/0047**

Thank you for sending the document listed below as evidence of compliance with the approval conditions detailed in our letter dated 11 October 2011. Please note these documents are for information only and have not been reviewed by the Committee.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant Information Sheet: Relative/Guardian	3	09 November 2011

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

REC reference number: 11/SS/0047-Please quote this number on all correspondence

Yours sincerely

WALTER HUNTER
Committee Coordinator

Chairman Dr Ian Zealley
Vice-Chairman Dr Colin Selby

Appendix 2.3 – Participant Information Sheet

Academic Unit of Mental Health and Wellbeing
Academic Centre,
Gartnavel Royal Hospital
1055 Great Western Road,
G12 0XH

Quality of life in young adults with head injury living in nursing homes: a comparative study

Participant Information Sheet

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask if there is anything that is not clear or if you would like more information.

Who is conducting the research?

The research is being carried out by Amy Best, Trainee Clinical Psychologist from the University of Glasgow Institute for Health and Well Being, Gartnavel Royal Hospital.

Why is the study being carried out?

The study is being carried out as part of the requirements of the Doctorate in Clinical Psychology training course at the University of Glasgow. The study will investigate whether quality of life differs for young adults (18-65 years) who have a head injury living in a nursing home compared to young adults with a head injury living in the community.

Why have I been invited?

You have been invited to take part in this study as you are aged between 18 and 65 years, have sustained a head injury and are currently live in a nursing home or in the community with a care package.

Do I have to take part?

It is up to you to decide. Amy Best (Trainee Clinical Psychologist) will describe the study and go through this information sheet which you can keep. You will be asked to sign a consent form to show that you have agreed to take part. You are free to withdraw at any time, without giving reason. This would not affect the standard of care you receive or your future treatment.

What does taking part involve?

You will be contacted by Amy Best by telephone to arrange a suitable day and time to attend for an interview. The interview will last around 15 minutes and you will have an opportunity to discuss the information in this sheet. If you decide to participate in the study Amy Best will arrange another suitable day and time to attend for a further interview. This interview will last around 45 minutes. During the interview you will be asked a number of questions about how you have been getting on recently and about your daily life. Please note no expenses will be available to participants or carers attending for interview.

What happens to the information?

Your identity and personal information will be completely confidential and known only to the researcher. The information obtained will remain confidential and will be stored within a locked cabinet. The data will be anonymised and held in accordance with the Data Protection Act, which means that we keep it safely and cannot reveal it to other people, without your permission. If at any point during the research process the research team is concerned about your emotional wellbeing this information may be passed on to your general practitioner and staff to ensure that you receive appropriate support. The research team will endeavour to discuss this with you prior to contacting staff/general practitioner. A member of your family or care team may be interviewed by Amy Best to obtain information relevant to the study. Participants will be asked to provide consent before family members/care team will be contacted by the researcher.

What are the possible disadvantages and risks of taking part?

There are no known risks or disadvantages associated with taking part in the study and participating in the interview process should not cause distress. In the event that you do experience distress the interview can be terminated by you or the researcher at any time. The researcher may also inform the care/support staff team in the event that you become distressed to ensure that you receive the support needed once the interview is completed.

What are the possible benefits of taking part?

It is hoped that by taking part in this research, you will be providing valuable information about ongoing quality of life in young adults with head injury in different accommodation settings. This information may be used in the future to inform service development for young adults with head injury.

Who has reviewed the study?

The study has been reviewed by the NHS Scotland A Research Ethics Committee and the University of Glasgow.

If you have any further questions?

We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and want to speak to someone please contact:

Professor Tom McMillan
Academic Unit of Mental Health and Wellbeing
Academic Centre, Gartnavel Royal Hospital
1055 Great Western Road, G12 0XH
Tel: 0141 2113920
thomas.mcmillan@glasgow.ac.uk

Researcher Contact Details:

Amy Best, Trainee Clinical Psychologist
Academic Unit of Mental Health and Wellbeing
Academic Centre, Gartnavel Royal Hospital
1055 Great Western Road, G12 0XH
Tel: 0141 2113920
a.best.1@research.gla.ac.uk

What if you have a complaint about any aspect of the study?

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint mechanism is also available to you.

Thank-you for your time and co-operation

Appendix 2.4 – Participant Consent Form

Academic Unit of Mental Health and Wellbeing
Academic Centre,
Gartnavel Royal Hospital
1055 Great Western Road,
G12 0XH

Quality of life in young adults with head injury living in nursing homes: a comparative study

Participant Consent Form

Please initial the box

I confirm that I have read and understand the information sheet dated (date) (version number) for the above study and have had the opportunity to ask questions.	☐
I understand that my participation is voluntary and that I am free to withdraw at anytime, without giving any reason, without my medical care or legal rights being affected.	☐
I understand that the research team may interview my care staff/ family members to obtain information relevant to this study.	☐
I understand that sections of my medical notes may be looked at by the research team where it is relevant to my taking part in the research. I give my permission for the research team to have access to my records.	☐
I give my permission for the research team to have access to medical records.	☐
I understand that my General Practitioner will be informed of my participation in the study.	☐
I agree to take part in the above study.	☐

Signed: ..... Researcher: .....

Name: .....Name: ....

Date: .....Date: .....

(1 copy to participant, 1 copy to the researcher and 1 original copy for participant medical notes)

Appendix 2.5 - Demographic Activities and Family/Friends Contact Data Collection Form

Participant Demographic Information

Participant Number:	
Name	
Age	
Gender	
Education Attainment (Circle)	**Primary** **Secondary** **Trade** **Certificate** **diploma** **University**
Relationship Status (Circle)	**Single** **Married** **Separated** **Divorced** **Widowed**
Reason for placement in care home (Care home group only) (Circle)	**Appropriate place** **Family preference** **Unavailability of a more appropriate service** **Person's own choice**

Participation in Recreational Activities

Recreational Activity	Yes/No/Declined	Weekly	Monthly
Sport's activity			
Eating Out			
Club			
Hobby			
Shopping			
Contact with family/friends			
Other:			
Other:			

Contact with Family and friends

Level of contact	Family	Friends
Birthday/Christmas card and occasional phone call		
Phone call/letter once a month		
Visit 2 times a year		
Visits at least once a month		
Visits at least once a week		
No contact/unknown		

Appendix 2.6 – Frequency of contact with family, friends and completion of recreation activities

	HIN			HICC		
Recreational Activities	**Weekly N (%)**	**Monthly N (%)**	**Not at all N (%)**	**Weekly N (%)**	**Monthly N (%)**	**Not at all N (%)**
Sports activity	2 (18.2)	1 (9.1)	8 (72.7)	9 (81.8)	1 (9.1)	1 (9.1)
Eating out	8 (72.7)	4 (36.4)	2 (18.2)	3 (27.3)	2 (18.2)	6 (54.5)
Shopping	0	11 (100)	0	9 (81.8)	1 (9.1)	1 (9.1)
Club	5 (45.4)	1 (9.1)	6 (54.5)	5 (45.4)	0	6 (54.5)
Hobbies	4 (36.4)	0	7 (63.6)	7 (63.6)	2 (18.2)	2 (18.2)
Contact with Family /Friends						
No Contact	1 (*n* =1 Friends)					
Birthday/Christmas card	0			0		
Occasional Phone call	0			1 (*n* = 1 Family)		
Monthly Phone call	2 (*n* = 1 Family, *n* = 1 friends)			2 (*n* = 2 Friends)		
Visit x 2 a year	2 (*n* = 2 Friends)			1 (*n* = 1 Family)		
Visit x monthly	3 (*n* = 3 Family)			1 (*n* = 1 Family)		
Visit x weekly	8 (*n* = 4 Family, *n* = 4 (friends and family)			11 (*n* = 3 Family, *n* = 1 Friends and *n* = 7 Friends and family)		

Appendix 2.7 - Correlations coefficients for SF-36 domains and psychosocial variables

HIN Group:	**SF-36**							
	Physical Functioning	**Physical Role**	**Bodily Pain**	**General Health Vitality**	**Vitality**	**Social Functioning**	**Emotional role**	**Mental Health**
Depression	-.097	-.596	-.521	-.854*	-.461	-.727*	-.559	-.577
Self-esteem	-.167	-.110	.199	.361	.375	.070	.257	.592
Recreational Activities	.322	.035	.227	.039	-.239	.237	-.202	-.072
Contact with family	-.166	-.264	.132	-.260	.162	0	.067	.259
Contact with Friends	-.183	-.233	-.142	.164	-.051	.173	-.018	-.212

HICC Group	SF-36							
	Physical Functioning	**Physical Role**	**Bodily Pain**	**General Health Vitality**	**Vitality**	**Social Functioning**	**Emotional role**	**Mental Health**
Depression	.338	-.429	-.333	-.473	-.651*	-.502	-.605*	-.677*
Self-esteem	.068	.578	.571	.734*	.789*	.775*	.827*	.849*
Recreational Activities	.269	.104	.381	.051	.067	.367	.063	.146
Contact with family	-.307	-.201	.202	.202	.453	.152	.327	. 301
Contact with Friends	-.393	-.054	-.237	-.399	-.097	-.065	-.070	-.161

Appendix 2.8 – Author guidelines for submitting to Journal of Neurotrauma

Guidelines for submission to Journal of Neurotrauma on Thursday 28th June 2012:

http://www.liebertpub.com/manuscript/journal-of-neurotrauma/39/

For the full guidelines Please see Appendix 1.5