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SIGN 130 • Brain injury rehabilitation in adults

A national clinical guideline

March 2013

KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS

LEVELS OF EVIDENCE

1 ⁺⁺	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1 ⁺	Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1 ⁻	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2 ⁺⁺	High quality systematic reviews of case control or cohort studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2 ⁺	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2 ⁻	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, eg case reports, case series
4	Expert opinion

GRADES OF RECOMMENDATION

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A	At least one meta-analysis, systematic review, or RCT rated as 1 ⁺⁺ , and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1 ⁺ , directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2 ⁺⁺ , directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1 ⁺⁺ or 1 ⁺
C	A body of evidence including studies rated as 2 ⁺ , directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2 ⁺⁺
D	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2 ⁺

GOOD PRACTICE POINTS

✓	Recommended best practice based on the clinical experience of the guideline development group
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Scottish Intercollegiate Guidelines Network

**Brain injury
rehabilitation in adults**
A national clinical guideline



March 2013

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1 Introduction

1.1 THE NEED FOR A GUIDELINE

Acquired brain injury (ABI) is a significant cause of morbidity and mortality in Scotland encompassing damage to the brain's physiology caused by an external force or pathophysiological damage resulting from non-degenerative disease states (*see section 1.3*). It is estimated that more than 100 out of every 100,000 people have a traumatic brain injury (TBI) that results in difficulties that persist beyond one year post injury.¹ People who have suffered a brain injury have a higher risk of death than people hospitalised for equal durations due to other injuries or people from the general population. In a case control study which calculated mortality rates following brain injury in Glasgow over a 13 year period, the death rate was more than twice that for the general Scottish population (30.99 versus 13.85 per 1,000 per year).² Traumatic brain injuries challenge entire family/social systems and cause stress and disruption to normal life. The subsequent constellation of difficulties experienced by the person with the injury and their family or carers can have a longer term impact on their ability to return to their previous level of function and quality of life. This includes their ability to attain, or retain, employment or education.

Access to appropriate and timely specialist assessment and rehabilitation can have a positive impact on outcome. Historically, however, services in Scotland for this patient group have been variable. Rehabilitation to manage brain injuries can be provided by individual professionals or specialised teams across a range of settings from primary to tertiary care but a national strategy to coordinate this care has yet to be developed.

1.2 REMIT OF THE GUIDELINE

1.2.1 OVERALL OBJECTIVES

While SIGN 110, Early management of patients with a head injury,³ focused on the management of the patient in the first 72 hours following an acute injury, this SIGN guideline has been developed as a companion document and covers the longer term rehabilitation of adults in the post-acute period. Other SIGN guidelines will also assist practitioners in this area, eg SIGN 107, Diagnosis and management of headache in adults;⁴ SIGN 118, Management of patients with stroke: rehabilitation, prevention and management of complications and discharge planning;⁵ and SIGN 119, Management of patients with stroke: identification and management of dysphagia.⁶

In some people with brain injuries there may be complications that impact on rehabilitation such as pre-existing cognitive impairments or epilepsy. Cognisance should be taken of these issues, however their presence does not preclude the affected individual from rehabilitation. Management of epilepsy is covered in SIGN 70.⁷

The guideline will provide recommendations, where possible, about post-acute assessment for adults over 16 years of age with brain injuries and interventions for cognitive, communicative, emotional, behavioural and physical rehabilitation. Furthermore, evidence will be presented on important questions relevant to patient outcomes such as optimal models and settings of care, the benefits of discharge planning and the applicability of telemedicine. While section 3 focuses specifically on the assessment and treatment of mild traumatic brain injury, the remainder of the guideline is not limited to particular severities of injury.

Although this guideline focuses on the person with a brain injury, professionals working with this group should be aware of the impact the injury and subsequent problems may have on the family and wider social network, including children, siblings, partners and friends.⁸ Children and siblings of the person with the TBI may experience physical, psychological and emotional upheaval. This can have long term effects on relationships within the family unit as well as their own cognitive and emotional development (*see sections 6.1.1 and 10.2.4*).

While this guideline originally aimed to present recommendations for the management of adults and children with brain injuries, after carrying out a systematic literature review it became clear that there was not a sufficiently robust evidence base to support recommendations for the paediatric population. The consequences of a brain injury in a child may be very different to those in adults. The injury may interfere not only with daily functional activity, but also with important stages of physical and cognitive growth and development. In addition, much of the available evidence in adults describes interventions which are tailored for the specific individuals involved. The guideline development group therefore decided it was not reasonable to extrapolate from the evidence for assessment and intervention in adults to a paediatric population.

1.2.2 TARGET USERS OF THE GUIDELINE

This guideline will be of interest to people who have a responsibility for the management of adults with brain injuries in primary, secondary, tertiary or independent health care or the voluntary sector. This includes specialists with an expertise in rehabilitation medicine, nurses, allied health professionals, neurologists, clinical neuropsychologists, neuropsychiatrists, general practitioners and managers of rehabilitation services. It will also be of interest to individuals with personal experience of brain injury, including patients and their carers, members of the voluntary sector and those who are keen to develop research strategies in the area of rehabilitation.

1.3 DEFINITIONS

1.3.1 ACQUIRED BRAIN INJURY

For the purposes of this guideline, the definition of acquired brain injury used is taken from the Scottish Needs Assessment Programme report (2000):⁹

“ABI implies damage to the brain that was sudden in onset and occurred after birth and the neonatal period. It is thus differentiated from birth injuries, congenital abnormalities and progressive or degenerative diseases affecting the central nervous system.”

This definition permits the inclusion of open or closed traumatic head injuries, and non-traumatic causes, such as vascular incidents (eg stroke), infection (eg meningitis), hypoxic injuries (eg cardiorespiratory arrest), or toxic or metabolic insult (eg hypoglycaemia). Although stroke is included in this definition of ABI, specific guidance on stroke rehabilitation can be found in SIGN 118.⁵ Where available, evidence from non-stroke ABI populations has been used in this guideline. In some sections, however, it has been necessary to extrapolate from mixed populations, including those with stroke (*see section 1.4.3 for further discussion of the use of evidence in this guideline*).

1.3.2 TRAUMATIC BRAIN INJURY

Traumatic brain injury may be defined as a traumatically induced structural injury and/or physiological disruption of brain function as a result of an external force that is indicated by new onset or worsening of at least one of the following clinical signs, immediately following the event:

- any period of loss of or a decreased level of consciousness
- any loss of memory for events immediately before or after the injury
- any alteration in mental state at the time of the injury (confusion, disorientation, slowed thinking, etc)
- neurological deficits (weakness, loss of balance, change in vision, praxis, paresis/plegia, sensory loss, aphasia, etc) that may or may not be transient, or
- intracranial lesion.

1.3.3 BRAIN INJURY SEVERITY

Long term prognosis in people with brain injuries correlates to different extents with various factors including levels of consciousness, duration of post-traumatic amnesia, age, gender and pre-injury education and employment. The most widely used index of injury severity is the Glasgow Coma Score (GCS) which classifies injuries into mild, moderate or severe categories based on level of consciousness post injury (*see Table 1*). It should be noted that severity of symptoms associated with an injury may not correlate perfectly with severity of injury as defined by GCS, so that patients with a severe brain injury may experience many of the same symptoms as patients with a mild injury, although these may be longer lasting or result in greater disability.

Table 1: Definition of mild, moderate and severe brain injury by GCS score

Degree of brain injury	GCS score
Mild	13-15
Moderate	9-12
Severe	8 or less

Throughout this guideline definitions of injury severity have been used which match those used in the studies which support each section, therefore, there may be some variation between the characterisation of the terms mild, moderate and severe between different sections.

1.3.4 MULTIDISCIPLINARY AND INTERDISCIPLINARY WORKING

In the evidence reviewed for this guideline, the terms multidisciplinary and interdisciplinary are often used synonymously, although they are not consistently defined. They both imply a holistic approach to patient care, maximising the resources (knowledge, experience, financial and physical) available to work towards a common goal. However, multidisciplinary and interdisciplinary are methods of practice on a continuum ranging from discipline-specific to transdisciplinary. Given the complexity of the cases with which practitioners will be working, the guideline development group recommends that, in the majority of cases, the integrative approaches of interdisciplinary practice across professions and sectors would most benefit patients and their families. It is acknowledged that there are occasions when uni-disciplinary practice is required, but the method of sharing information and goal setting will remain interdisciplinary.

1.3.5 GOAL SETTING

Goal setting in brain injury rehabilitation is used by a range of professionals to maximise patient-centred and therapy-focused goals. Ideally, the patient should be involved in the goal setting at all times and their family or carers included at appropriate points. These goals can also be used to aid communication and to structure planning and decision making. The goals set should be in context for the person involved and should be reviewed and documented regularly. Engaging patients and families in goal setting increases the number of goals set in a wider range of areas and in particular areas that are less common in global outcome measures.¹⁰

A range of tools may be used to assist in the assessment and subsequent setting of goals, for example the Canadian Occupational Performance Measure,¹¹ the Functional Independence Measure/Functional Assessment Measure (FIM/FAM)¹² or the Barthel Index.¹³

1.4 METHODOLOGICAL LIMITATIONS INHERENT IN REHABILITATION LITERATURE

There are inherent difficulties in appraising the quality of rehabilitation studies by traditional evidence based methods. This is particularly true of the complex, experience-based treatments that predominate in rehabilitation over medically-oriented treatments such as pharmacotherapy and surgery.¹⁴ Interventions that involve explicit teaching, behaviour change, and/or environmental manipulations cannot typically be hidden from the patient or the therapist, thus the removal of bias by using standard blinding procedures, such as placebo treatment, is not straightforward. Unlike medical treatments which may be aimed at specific symptoms, rehabilitation interventions usually target multiple or complex outcomes at the levels of activity and participation. Identification of a primary outcome for such treatments may be impossible and even inappropriate. Goals associated with successful treatment will vary across participants, meaning that simple outcome measures may not provide universal and objective metrics of improvement. Moreover, a highly meaningful intervention may appear meaningless if the wrong outcome measure is selected. Rehabilitation interventions are often delivered by members of multiple disciplines working synergistically, complicating the application of quality appraisal standards that do not incorporate such factors.¹⁵

1.4.1 THE CHOICE OF STUDY DESIGN IN REHABILITATION RESEARCH

Randomised controlled trials (RCTs) where patients are randomly assigned to at least two comparison groups are best able to control for threats to the internal validity of studies and ensure pre-treatment equivalence of experimental and control groups, strengthening the basis for statistical inference. Completing an RCT with an adequate sample size, appropriate randomisation techniques to account for variability in the diagnostic conditions and a combination of patient, service and/or system level outcome measures is difficult due to competition for rehabilitation research funding and the individual nature of brain injuries.

There are also ethical constraints in using RCTs, particularly with severely affected patients for whom clinicians believe there are no realistic alternative interventions to specialised care. Notably for conditions in which multidisciplinary rehabilitation has become the standard of care without systematic evidence to support it in practice, denying services randomly in order to conduct an RCT could be considered unethical.¹⁶

Few rehabilitation-focused, observational studies control for selection bias. A systematic review of multidisciplinary rehabilitation services in post-acute care across a range of populations concluded that adjusting for case mix when examining the influence of two or more interventions on an outcome does not necessarily sufficiently reduce the selection bias associated with assignment to each intervention group.¹⁶ Adjusting for the probability of receiving the treatment is essential in non-randomised studies of the effectiveness of rehabilitation services.

The majority of studies published describing patients with brain injury use single-case design or are small case series, reflecting the individual nature of rehabilitation interventions, the challenges of using more complex designs and the relative simplicity of conducting single case studies. While RCTs may suffer from problems with applicability of results or heterogeneity of included patients or wider population, "studies of individuals and small case series can be optimal for exploring a new treatment, for titrating therapies, for documenting a promising variation in behavioural therapies, for enhancing knowledge of generalisation of treatment to a new group, and to enhance understanding of why some patients respond to a treatment of known (average) effectiveness whereas others do not, that is, for extending results of an RCT."¹⁴

The disadvantages associated with single case design studies are well reported. These include the difficulty in drawing cause-and-effect conclusions (limited internal validity), possible biases when interpreting outcomes due to observer bias and bias in data collection, and crucially, the problem of generalising findings from a single individual to a group or wider population (limited external validity). While researchers can take steps to attempt to limit the biases associated with this design there remain difficulties in assessing behaviours which do not reverse back to baseline after withdrawal of treatment, indicating that the treatment may not have been the key variable affecting change. Single case studies are usually ranked at the bottom of the traditional hierarchy of evidence.¹⁷

Functional therapies tend to be safe, and due to their context-dependent nature, their effectiveness may be better examined using observational techniques which permit natural heterogeneity. Similarly, vocational rehabilitation interventions by definition are contextual, depending on the nature of the specific job, employment sector, country etc.

Meta-analysis can be undertaken only if the study populations, interventions, outcomes, and study designs are agreed to be sufficiently consistent to allow pooling of data. This has tended to limit the use of the technique to binary outcomes from RCTs. One systematic review notes that “while dichotomous data (for example return to work) might reasonably be pooled, most outcome instruments which are commonly used to assess activity and participation are in the form of ‘long ordinal’ scales. There are significant concerns about the validity of either treating these as continuous data or reducing them to binary outcomes. We expected that there would be too much clinical heterogeneity among the studies, particularly with regard to outcome measures (diversity of assessment tools, timing of measurements, presentation of results) to make quantitative analysis possible.”¹⁸ Nevertheless, some authors have pooled data using a range of study designs and making a range of assumptions about the quality of the data. In such cases, individual decisions were made by the guideline development group about grading of these meta-analyses based on the volume of included evidence with different study designs and attempts to maximise validity and reduce sources of methodological bias.

1.4.2 SPECIFIC PROBLEMS OF BRAIN INJURY POPULATIONS

The evidence base in specific areas is small, for example in the management of challenging behaviour. Reasons for this may be that staff are understandably not tolerant of aggression and fear entry into a trial will delay treatment, the patients are not usually in a position to give informed consent, symptoms of agitation and aggression fluctuate and the population of patients with ABI is very heterogeneous.¹⁹

Psychosocial, behavioural, exercise and/or educational interventions are fundamentally different from pharmacological therapies as they are a function of the attention and activity of the individual rather than the action of an external agent. Interventions tend to be multifactorial, context-dependent and vary according to the motivations, values, thoughts and environmental situation of the patient. The conduct of interpersonal therapeutic interventions can often depend on the development of a complex relationship between patient and therapist, which can make distinguishing treatment efficacy from the characteristics of those delivering it challenging.

The various challenges to conducting valid research which is sufficiently powered to establish clinical effectiveness across a diverse population are outlined in the previous sections. These partially account for the paucity of high quality evidence in the field of brain injury rehabilitation. It should be pointed out that, while a lack of evidence is not synonymous with evidence for no clinical effect, in many cases the evidence base to make firm recommendations either in support or contrary to an intervention is not available. While this situation may be frustrating to therapists who have anecdotal daily demonstrations of effective rehabilitation practices, it does not allow these to be recorded in an evidence based guideline which is reliant on objective, repeatable measures of benefit.

1.4.3 SELECTION OF EVIDENCE IN THIS GUIDELINE

Evidence was identified in accordance with standard SIGN methodology, which matches the results of systematic literature searches to a model for each key question that specifies the populations, interventions, comparisons and outcomes (PICO) of interest to each question (*see Annex 1*). In this way, evidence which included only individuals with brain injuries was identified and assessed for inclusion in the guideline. Due to the paucity of direct evidence, the guideline development group also agreed to consider evidence which included mixed populations of patients as long as they included some with brain injuries. Thus, for some sections of the guideline, there is evidence cited which may include patients with other diagnoses, such as stroke or multiple sclerosis.

While the volume of evidence available describing rehabilitation of patients following stroke far outnumbers that in non-stroke brain injury, the guideline development group noted that these two etiologies are likely to lead to different patterns of impairments that may be differentially receptive to rehabilitation during treatment post injury. Therefore, it was decided not to use evidence in this guideline which described only stroke patients in the absence of any other diagnoses.

1.5 STATEMENT OF INTENT

This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is advised, however, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

1.5.1 PRESCRIBING OF LICENSED MEDICINES OUTWITH THEIR MARKETING AUTHORISATION

Recommendations within this guideline are based on the best clinical evidence. Some recommendations may be for medicines prescribed outwith the marketing authorisation (MA) also known as product licence. This is known as 'off label' use.

Medicines may be prescribed off label in the following circumstances:

- for an indication not specified within the marketing authorisation
- for administration via a different route
- for administration of a different dose
- for a different patient population.

An unlicensed medicine is a medicine which does not have MA for medicinal use in humans.

Generally the off label use of medicines becomes necessary if the clinical need cannot be met by licensed medicines within the marketing authorisation. Such use should be supported by appropriate evidence and experience.²⁰

"Prescribing medicines outside the conditions of their marketing authorisation alters (and probably increases) the prescribers' professional responsibility and potential liability".²⁰

The General Medical Council (GMC) recommends that when prescribing a medicine off-label, doctors should:

- be satisfied that such use would better serve the patient's needs than an authorised alternative (if one exists)
- be satisfied that there is sufficient evidence/experience of using the medicines to show its safety and efficacy, seeking the necessary information from appropriate sources
- record in the patient's clinical notes the medicine prescribed and, when not following common practice, the reasons for the choice
- take responsibility for prescribing the medicine and for overseeing the patient's care, including the monitoring the effects of the medicine.

Non-medical prescribers should ensure that they are familiar with the legislative framework and their own professional prescribing standards.

Prior to any prescribing, the licensing status of a medication should be checked in the current version of the British National Formulary (BNF).²⁰ The prescriber must be competent, operate within the professional code of ethics of their statutory bodies and the prescribing practices of their employers.²¹

1.5.2 ADDITIONAL ADVICE TO NHSSCOTLAND FROM HEALTHCARE IMPROVEMENT SCOTLAND AND THE SCOTTISH MEDICINES CONSORTIUM

Healthcare Improvement Scotland processes multiple technology appraisals (MTAs) for NHSScotland that have been produced by the National Institute for Health and Clinical Excellence (NICE) in England and Wales.

The Scottish Medicines Consortium (SMC) provides advice to NHS Boards and their Area Drug and Therapeutics Committees about the status of all newly licensed medicines and any major new indications for established products.

SMC advice relevant to this guideline is summarised in section 12.4.

2 Key recommendations

The following recommendations were highlighted by the guideline development group as the key clinical recommendations that should be prioritised for implementation. The grade of recommendation relates to the strength of the supporting evidence on which the evidence is based. It does not reflect the clinical importance of the recommendation.

2.1 ASSESSMENT AND TREATMENT OF MILD BRAIN INJURY

B Patients presenting with non-specific symptoms following mild traumatic brain injury should be reassured that the symptoms are benign and likely to settle within three months.

2.2 COGNITIVE REHABILITATION

D Patients with memory impairment after TBI should be trained in the use of compensatory memory strategies with a clear focus on improving everyday functioning rather than underlying memory impairment.

- For patients with mild-moderate memory impairment both external aids and internal strategies (eg use of visual imagery) may be used.
- For those with severe memory impairment external compensations with a clear focus on functional activities is recommended.

D In the post-acute setting interventions for cognitive deficits should be applied in the context of a comprehensive/holistic neuropsychological rehabilitation programme. This would involve an interdisciplinary team using a goal-focused programme which has the capacity to address cognitive, emotional and behavioural difficulties with the aim of improving functioning in meaningful everyday activities.

2.3 SERVICE DELIVERY

B For optimal outcomes, higher intensity rehabilitation featuring early intervention should be delivered by specialist multidisciplinary teams.

D Planned discharge from inpatient rehabilitation to home for patients who have experienced an ABI provides beneficial outcomes and should be an integrated part of treatment programmes.

3 Assessment and treatment of mild brain injury

This section describes the post-acute assessment of patients who later present to primary care services complaining of ongoing symptoms in the aftermath of mild traumatic brain injury (MTBI).

3.1 EPIDEMIOLOGY AND DEFINITIONS

The incidence rate of mild brain injury varies substantially depending on the specific definition used and the population studied. The point at which the minimum criteria are set for distinguishing between brain injury, as opposed to a head injury in which the brain was unaffected, will have a significant effect on the incidence rate as milder injuries are much more common. Worldwide, the incidence rates for MTBI are between 100-300 per 100,000 population with mild injuries accounting for between 70-90% of all TBIs.²² Incidence figures from Scotland are consistently at the upper end of this range.^{1, 23-25}

The definition of what constitutes an MTBI varies. Differing criteria including measures of GCS, duration of total loss of consciousness and duration of post-traumatic amnesia have been recommended and adopted in different settings. Following comprehensive review of the scientific literature the World Health Organisation (WHO) recommended the following definition:²⁶

“Mild traumatic brain injury is an acute brain injury resulting from mechanical energy to the head from external force. Operational criteria for clinical identification include:

- (i). One or more of the following: confusion or disorientation, loss of consciousness for 30 minutes or less, post-traumatic amnesia for less than 24 hours, and/or other transient neurological abnormalities such as focal signs, seizure, and intracranial lesion not requiring surgery;

AND

- (ii). GCS score of 13-15 after 30 minutes post head injury or later upon presentation for health care. These manifestations of MTBI must not be due to drugs, alcohol, medications, caused by other injuries or treatment for other injuries (eg systemic injuries, facial injuries or intubation), caused by other problems (eg psychological trauma, language barrier or coexisting medical conditions) or caused by penetrating craniocerebral injury”.

Clinicians need to be aware that this imposes a categorical definition for convenience of clinical decision making on a dimension of severity. Whilst the vast majority of injuries will be easily classified within this definition there will be injuries which lie at the cusp of the definition which may require separate consideration to the general guidance contained below; in particular, injuries where there is skull fracture, or substantive haematoma (this is sometimes referred to as complicated mild brain injury), are not generally considered as mild.

The description of acute assessment of severity is described within SIGN guideline 110.³ The criteria will require to be applied retrospectively when reviewing patients after the acute phase. The assessment of post-traumatic amnesia can be made retrospectively but may, in some circumstances, be less reliable. Review of emergency department (ED) records (or discharge letter) may be required, as may supplementary questions about patients' behaviour during any putative amnesic period; for example, to determine if they had shown evidence of goal-directed behaviour that would indicate the presence of intact cognitive function, such as managing to go to work.

B The diagnosis of mild traumatic brain injury should be made according to WHO task force operational criteria, subject to clinical judgement when complicating factors are present, eg skull fracture, seizures, or a haematoma.

2++

3.2 NON-SPECIFIC SYMPTOMS

Almost all patients experiencing an MTBI will report any of a wide range of symptoms in the aftermath. These typically consist of headache, fatigue, sleep disturbance, irritability, dizziness, subjective cognitive impairments, sensitivity to light and noise, nausea and depersonalisation.

Such symptoms are non-specific in nature and occur at similar rates after other forms of physical trauma. There is no consistent picture as to their causality. In particular, currently available evidence does not support neuronal damage as the main underlying mechanism but a range of other factors, including pain and distress, may be involved.²⁷

Such symptoms are often referred to as 'post-concussional syndrome' (PCS) and there are definitions for this condition in the International Classification of Diseases (ICD-10) and Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). However, the definitions vary and causal implications of the term post-concussional syndrome are not supported by evidence as there is no specificity to the syndrome which is found in a range of conditions including other physical trauma, chronic pain disorders, chronic fatigue syndrome and mood disorders.

- ✓ Using 'post-concussional syndrome' as a diagnostic term may imply a mechanism of neuronal damage that is not supported by the available evidence. A wider formulation of all relevant factors to the patient's symptoms is more appropriate.

2⁺⁺

3.3 PROGNOSTIC FACTORS IN ADULTS

In the overwhelming majority of cases symptoms will remit within two to three months of injury.²⁷ In a small minority, symptoms may be more prolonged but in such cases the determinants of disability appear to be personal and social factors and not related to the brain injury. Litigation has been consistently identified as a poor prognostic factor (*see section 3.3.2*).²⁷ Recall bias is a common problem and pre-existing symptoms may be subsequently misattributed to MTBI.²⁷

2⁺⁺

3.3.1 NON-SPECIFIC SYMPTOMS

Persistent physical illness, prior neurological disease, prior head injuries, mood and anxiety disorders, being a student, sustaining the injury in a motor vehicle accident and age over 40 years have been cited as predictive of poor prognosis.^{1,27} In general, the nature of the MTBI itself is not predictive of outcome except for those MTBIs which are complicated or on the cusp of being graded as moderate (*see section 3.3.2*). A limited number of studies in the elderly (aged over 70 years) suggest poorer outcome.²⁷

2⁺⁺
3

- B Patients presenting with non-specific symptoms following mild traumatic brain injury should be reassured that the symptoms are benign and likely to settle within three months.**

- ✓ Consideration should be given to alternate diagnostic explanations for ongoing symptoms post MTBI, eg coincidental mood disorder or thyroid disease, and further investigation may be warranted. Other secondary pathologies which are consequences of the original injury but not associated with, or dependent on, any brain injury may occur in the context of a head injury, eg benign positional paroxysmal vertigo, and should be treated accordingly.

3.3.2 COGNITIVE DEFICITS

In adults, evidence consistently suggests there are no MTBI-attributable cognitive deficits beyond three months after injury. However, those with complicated MTBI, ie with associated skull fractures or intracranial lesions may have significant cognitive deficits.^{27,28}

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2⁺

False positives on cognitive testing can be a problem. Effort tests have been developed for use in psychometric examinations which evaluate whether a patient's poor score on cognitive testing is likely to represent a false positive due to poor effort. A number of such tests have been developed but no recommendation can be made on the superiority of one test over another. The British Psychological Society has discussed this in greater detail.²⁹ A systematic review, which identified seven studies using tools to assess malingering and incomplete effort, showed that litigation was the only consistently identified poor prognostic factor.²⁷ It is not possible to distinguish between malingering and poor effort for valid reasons using such tests.

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B Referral for cognitive (psychometric) assessment is not routinely recommended after MTBI.

✓ If a cognitive assessment has been conducted clinicians should be aware that false positives can occur and that results may be unreliable in the absence of effort testing.

3.3.3 MOOD AND ANXIETY DISORDERS

Cohort studies have consistently identified post-traumatic stress disorder (PTSD) and other psychiatric disorders as contributing to the disability present in both military and civilian cohorts following reported MTBI.³⁰⁻³⁵ These studies support the view that while an incident that causes an MTBI (eg motor vehicle accident or assault) may result in some short term symptoms, these usually resolve over time. It is argued that such an incident, rather than the MTBI, is the main factor resulting in the development of longer term PTSD symptoms. The evidence suggests that any resulting association between MTBI and PTSD symptoms is therefore not causal.

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C As PTSD and other psychiatric disorders may contribute to the overall burden of symptoms in some individuals following MTBI, particularly where problems persist for more than three months, mental state should be routinely examined with an emphasis on symptoms of phobic avoidance, traumatic re-experiencing phenomena (eg flashbacks and nightmares) and low mood.

3.3.4 NEUROLOGICAL DISORDERS

In a well conducted Scottish cohort study which followed up 549 patients admitted to hospital following a head injury (two thirds of which had mild injury), pre-existing brain illness was present in 28% of patients, 30% had a previous head injury and 28% had physical limitations at time of injury.¹

3

3.3.5 SUBSTANCE MISUSE

In the Scottish cohort study described in section 3.3.4, excessive alcohol consumption was a clinical problem at the time of injury in 39% of patients.¹ (*SIGN 74, The management of harmful drinking and alcohol dependence in primary care makes recommendations on screening and detection*).³⁶

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D Assessment and consideration of pre-existing health variables such as previous neurological disorders and substance misuse should be carried out for all patients with MTBI.

3.3.6 INTRACRANIAL PATHOLOGY

Delayed presentation of intracranial pathology is rare after MTBI. When such deterioration happens it normally occurs within 24 hours of injury, deterioration after 21 days post injury is exceptionally rare (0.1% of cases).³⁷

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Nevertheless, MTBI is a very common occurrence and, in a very few patients, will be the result of a developing neurological condition. For example, a developing brain tumour may cause loss of balance and predispose to a fall. Clinicians should be vigilant to such alternative diagnoses because of the potentially serious implications of missing them. New-onset focal neurological signs or deteriorating consciousness should be an indication for further appropriate investigation.

B Cranial imaging is not routinely recommended for the assessment of post-acute mild brain injury, but should be considered in an atypical case.

3.3.7 BLOOD MARKERS

One systematic review identified no evidence to support use of any specific blood chemistry markers as a prognostic tool for the assessment of individuals with mild brain injury.²⁷

2⁺⁺

3.4 TREATMENT OF MILD TRAUMATIC BRAIN INJURY

No evidence was identified that uncomplicated symptoms should be treated differently in the MTBI population from the general population. For example, SIGN guideline 107 makes recommendations on diagnosis and management of headache in adults.⁴

3.4.1 EDUCATIONAL INTERVENTIONS

A systematic review did not find strong evidence that any non-surgical treatment has a clinically important effect on symptoms or disability after MTBI.³⁸ The review identified a small number of studies on early intervention which provided some evidence that early, limited, educational intervention and providing reassurance about the lack of brain damage and the high probability of a good recovery, coupled with advice and encouragement on gradual return to regular activities, reduce long term complaints. Routine provision of intensive assessment and treatment is not additionally beneficial.

1⁺⁺

Another two systematic reviews which considered some of the same evidence noted that of 10 RCTs identified concerning educational interventions, six showed no benefit and only three showed improvement in symptoms. These trials were generally of poor quality and the authors note that the effectiveness of such interventions has been previously overstated. Nevertheless, non-randomised studies also included in the reviews supported a potential benefit for information provision, reassurance and educational approaches.^{39,40}

1⁺⁺

C All patients should be offered reassurance about the nature of their symptoms and advice on gradual return to normal activities after uncomplicated mild traumatic brain injury.

3.4.2 PHARMACOLOGICAL INTERVENTIONS

One systematic review identified eight studies of pharmacological interventions in patients with MTBI.⁴¹ The indications for pharmacotherapy were diverse including headache, cognitive dysfunction and post-MTBI depression. Four involved amitriptyline and two included sertraline. Three of the four studies involving amitriptyline showed either no benefit in the symptoms of patients with MTBI, or poorer performance than patients without MTBI. In two studies patients without MTBI exhibited greater improvement of depressive symptoms than patients with MTBI.^{42,43} In an evaluation of amitriptyline as a treatment for headaches associated with depression 100% of patients in the depressed group without MTBI reported headache improvement following four weeks of amitriptyline while none of the patients in the group with depression and MTBI improved ($p < 0.001$).⁴⁴ Only one study found headache symptoms decreased substantially for patients with MTBI treated with amitriptyline.⁴⁵ In contrast, sertraline was associated with significant improvement in depression, anger, aggression, functional disability, PCS and cognition in MTBI patients. It should be noted that the studies reporting positive results in MTBI patients used a 'pre-post' design rather than RCT and may therefore be overestimating the effectiveness.

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C Antidepressants may be considered for symptom relief after MTBI.

3.4.3 PSYCHOLOGICAL INTERVENTIONS

A systematic review of psychological treatments found 10 studies of cognitive behavioural therapies (CBT), including three RCTs. The studies, in general, were small and had short duration of follow up, so although robust conclusions could not be drawn the authors concluded there was some evidence that CBT may be effective in the treatment of persistent symptoms (beyond three months duration) after MTBI.⁴⁰

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Another systematic review identified nine studies which assessed the effects of neuropsychological rehabilitation in patients with MTBI, although only two studies were RCTs.⁴⁶ Interventions, methods and evaluation tools varied in every study making it difficult to integrate results. The authors concluded that the quantity and quality of evidence was too limited to allow specific recommendations to be formed on neuropsychological rehabilitation for patients with MTBI. The review identified five RCTs which demonstrated the effectiveness of educational programmes for patients with MTBI and their family members in reducing or preventing symptoms, but not necessarily improving neuropsychological function. The authors suggested that educational programmes should start as soon as possible following injury, be simple precise and adaptable to the individual and where possible, be presented in written form.

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C Referral for cognitive behavioural therapy following MTBI may be considered in patients with persistent symptoms who fail to respond to reassurance and encouragement from a general practitioner after three months.

4 Physical rehabilitation and management

Few data are available on the long term physical consequences of moderate to severe TBI. People who have suffered a brain injury have a higher risk of death than people hospitalised for equal durations due to other injuries or people from the general population² and there is a high prevalence of residual disability arising from brain injury.⁴⁷ It has been reported that 90% of people with TBI admitted for rehabilitation will experience one or more problems in the areas of physical functioning and community integration.⁴⁸ Physical deficits such as altered muscle tone, impaired balance, impaired coordination, impaired sensation, muscle weakness and impaired motor control impact on activity and participation. At two years post TBI these problems reduce only slightly, with 84% and 77% still experiencing problems with physical function and community integration respectively.⁴⁸ However, rehabilitation can be effective in this population with studies reporting a significant majority achieving independent ambulation at five months post severe TBI.⁴⁹

4.1 GAIT, BALANCE AND MOBILITY

A key goal, both for people with TBI and members of the multidisciplinary rehabilitation team, will be the recovery of mobility and there are a number of strategies used to address this goal. In general, there is a paucity of research relating solely to the TBI population and therefore some recommendations have been derived from evidence which included mixed diagnostic groups, such as stroke, multiple sclerosis, cerebral palsy and other central nervous system (CNS) disorders.

4.1.1 TREADMILL TRAINING AND GAIT

Treadmill training (TT) is a form of task specific gait re-training that allows the patient to practise walking at different speeds, at various inclines and with the potential for partial support of body weight by use of a harness. While TT for people with neurological impairments has received considerable attention in the past 20 years, on a practical level it can be challenging and labour intensive to deliver this intervention.

No systematic reviews were found that solely looked at TT for people with TBI. Two systematic reviews which included heterogeneous populations showed that partial body weight supported TT gave no added benefit over conventional gait training.^{50,51} 2+
3

One small study investigated body weight supported TT compared to conventional gait training in people with TBI and found that conventional training was more effective in improving gait symmetry than TT.⁵² 1-

A small RCT compared the Lokohelp electromechanical gait device to overground walking in 16 people of whom 12 had a TBI.⁵³ Both interventions resulted in improved gait ability and gait velocity. However, significantly fewer therapists were required with Lokohelp than for overground walking. 1+

C

Patients with TBI receiving gait training should not undergo treadmill training in preference to conventional overground training.

4.1.2 ORTHOSES AND GAIT

Orthoses may be off-the-shelf or custom made to improve ankle-foot alignment and other physical impairments that have a negative impact on gait ability. Ankle foot orthoses (AFOs) are the most commonly prescribed devices to improve gait for people with TBI.

A systematic review of studies in people with hemiplegia found that an AFO might result in immediate kinematic and spatiotemporal improvements in gait (velocity, stride length, gait pattern and walking efficiency), but there was inconclusive evidence relating to the effects of AFO use on muscle activity.⁵⁴ Two of the included studies reported significant reductions in plantarflexion during swing phase and increased dorsiflexion at heel strike. One study demonstrated less foot inversion at heel strike. 2+

4.1.3 TASK-SPECIFIC AND REPETITIVE TASK TRAINING

Task-specific training refers to interventions designed to improve specific tasks: these interventions may or may not be intensive in nature. Repetitive task training is often used to describe an intervention that is both task-specific and intensive and repetitive in nature.

A systematic review identified moderate evidence from one RCT (n=45) to support fine motor control retraining, including functional tasks, resulting in improved fine motor coordination.⁵⁰ The review also included a small RCT (n=22) which showed that sit-to-stand retraining improved the functional ability of this task but had no effect on exercise capacity. | 1+

A small RCT found that repetitive task training using an electromechanical gait training device was beneficial for improving walking ability for people with TBI or stroke.⁵³ | 1+

A systematic review identified five studies of mixed quality that investigated the effects of intensity of rehabilitation for people with TBI and found that there were medium term benefits in terms of improvement of functional skills for people receiving more intensive rehabilitation.⁵⁵ | 1++

B Repetitive task-oriented activities are recommended for improving functional ability, such as sit-to-stand or fine motor control.

4.1.4 PHYSICAL FITNESS TRAINING

Regular fitness training is a relatively recent addition to the therapies available for people with TBI. While physical fitness training can be regarded as safe and acceptable, historically some therapists may have avoided this form of intervention for fear of inducing unwanted negative effects relating to muscle tone and spasticity. Three systematic reviews provide evidence for physical fitness training in TBI patients.

One systematic review identified six RCTs investigating fitness training mostly in patients with TBI meeting their quality criteria. These studies included 303 patients but were clinically diverse with regard to the interventions, time post injury and the outcome measures used. Only one study showed an improvement in fitness. No meaningful improvements in any other motor parameter were noted.⁵⁶ | 1++

Another systematic review of 14 studies included four exclusively in patients with TBI. Benefits in cardiovascular fitness following fitness or aerobic training for people with moderate-severe TBI were noted. However, these benefits did not translate to improved activity or participation levels. A reduction in depression was also noted.⁵⁵ | 1++

A third systematic review identified eight studies investigating the effects of aerobic training on aerobic capacity post TBI and reported that all studies identified at least one positive outcome.⁵¹ An RCT included in this review (n=157) compared a 12 week exercise programme against a 12 week relaxation programme and demonstrated a significant increase in work rate by the exercise group. This increase in work rate did not translate to improved functional ability. | 3

Benefits of fitness training have not shown specific effects on impairments of motor function or spasticity but it has been suggested that regular fitness training, of a sufficient intensity will improve some of the common physical and psychosocial sequelae of TBI.^{56, 57}

4.1.5 VIRTUAL REALITY TRAINING

Virtual reality training is an emerging area in rehabilitation enhanced by the development and popularity of commercially available, interactive computer gaming devices. As such, there is limited evidence relating to this therapy.

A systematic review conducted mostly in stroke patients found that there was insufficient robust evidence to support virtual reality interventions in acquired brain injury rehabilitation.⁵⁸ | 3

One study (n=20) included a small number of people with TBI and found that both conventional balance retraining and balance retraining incorporating the use of a Wii™ Balance Board showed improvements over time with no significant differences between the groups. | 1-

4.1.6 WALKING AIDS

No evidence was identified relating to use of walking aids and recovery of mobility post TBI. Similar to guidance for people with stroke in SIGN 118,⁵ it is suggested that individual patients with TBI may benefit from using a walking aid. If walking aids improve confidence, gait efficiency, balance, functional independence, and safety, they could provide a cost-effective intervention. However, walking aids may have adverse effects on gait pattern, safety and the achievement of independent walking (without an aid). At present there is insufficient evidence to assess the size of these potential impacts.

✓ Walking aids should be considered only after a full assessment of the potential benefits and harms of the walking aid in relation to the individual patient's physical status and cognitive ability.

4.2 SPASTICITY AND MUSCLE TONE

Data regarding the prevalence of spasticity post TBI are limited, however incidence rates of up to 75% in people with severe TBI have been reported.⁵⁹

There are other motor disorders associated with TBI ranging from non-specific walking and balancing difficulties through to severe problems affecting cerebellar or extra-pyramidal pathways. Spasticity does not always require treatment, for example some patients with lower limb spasticity develop adaptive gait patterns which rely upon spasticity for postural stability. When it is a problem, spasticity in TBI can be both severe and difficult to manage, requiring multifocal interventions arising from multidisciplinary collaboration.

In TBI spasticity has similar pathophysiology to that found in certain diseases which cause the upper motor neurone syndrome, such as stroke. It is less similar to that found in spinal cord diseases and in multiple sclerosis. Cognitive considerations also impact on physical therapy treatments. These differences are reflected in the individualised approach to the patient's problems.

The multidisciplinary team in spasticity management will include input from nursing, physiotherapy, occupational therapy, orthotists, pharmacy and surgical and medical staff and many patients will receive multiple treatment modalities. Control of pain and review of posture and seating are vital first considerations in spasticity management. Further details are contained in the British Society of Rehabilitation Medicine guideline for specialised wheelchair seating.⁶⁰

4.2.1 SPLINTS, CASTS, STRETCHES AND ORTHOSES

Splints are generally fashioned from plastic or metal and are removable. Casts encase a limb and are made of resin or plaster. Both casts and splints, together with regular passive stretching are employed in management of spasticity and in the mitigation of resulting deformities.

Five systematic reviews of different stretching treatments were identified.^{50,55,61-63} The quality of reviews was good, however the quality of the studies examined in these reviews was highly variable as were the interventions and target populations. The evidence shows that whilst clinically significant improvements are made in short term outcome measures at some joints using each of these types of treatment these benefits are quickly lost once treatment is discontinued.

Further evidence has reinforced that beneficial effects of physical rehabilitation interventions for spasticity are often not preserved in the medium or long term. One trial (n=26) showed that casting reduced elbow flexion contracture by an average of 22 degrees (95% confidence interval (CI) 13 to 31 degrees; p<0.001) compared with the positioning (control) group. One day later this effect had decreased to 11 degrees (95% CI, 0 to 21 degrees; p=0.052). The effect had almost completely disappeared at the four-week follow up (mean 2 degrees, 95% CI -13 to 17 degrees; p=0.782).⁶⁴

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One further RCT (n=35) compared two interventions, lower leg casting plus injections with either saline or botulinum toxin, to controls receiving usual care.⁶⁵ Casting with or without botulinum neurotoxin therapy (BoNT) was more effective in reducing spasticity and plantigrade contracture at the ankle than usual care alone. Outcomes were assessed immediately at the end of the period of treatment but long term outcomes were not reported.

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Hand splinting has been reported to be ineffective.^{50,55}

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C Casts, splints and passive stretching may be considered in cases where contracture and deformity are progressive.

4.2.2 BOTULINUM NEUROTOXIN THERAPY

Botulinum neurotoxin therapy is a widely adopted treatment for focal spasticity. Most of the evidence to support its use derives from before and after studies in various populations, including patients with TBI. Whether the improvements in joint position or spasticity scores seen are clinically important or cost effective have not been addressed in clinical trials. Much use remains outwith the product licence and is customised in a multidisciplinary team (MDT) setting to the needs of the individual.

One RCT (n=15) reported gait improvement following treatment of elbow flexion deformities in TBI patients.⁶⁶ The BoNT group demonstrated a statistically significant increase in walking velocity after treatment (p=0.037) and mean modified Ashworth score was significantly reduced from 2.6 before treatment to 1.4 after treatment (p=0.00003).

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One RCT randomised 40 patients with brain injury or stroke to receive either rehabilitative motor therapy alone (control) or motor therapy plus BoNT (intervention).⁶⁷ Fugl-Mayer Assessment scores (measuring physical ability) were higher in the intervention group at one and three months post injection (mean \pm standard deviation) (23.36 \pm 10.69 and 35.36 \pm 11.36) than the control group (20.55 \pm 10.22 and 30.33 \pm 10.96; p<0.01) Modified Ashworth, and Barthel scores also improved following BoNT. Some of the details of the conduct of this study were not described.

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In one RCT (n=60) where most of the participants were stroke patients BoNT was safer and more effective than tizanidine in reducing tone and deformity in wrist spasticity.⁶⁸

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B BoNT may be considered to reduce tone and deformity in patients with focal spasticity.

✓ BoNT should be used in a multidisciplinary setting with physiotherapist/occupational therapist and orthotic inputs where appropriate.

A multiagency national guideline on the appropriate use of botulinum toxin in the management of spasticity in adults provides further details on many aspects of BoNT.⁵⁹

4.2.3 ORAL ANTI-SPASTICITY MEDICATION

Oral agents used to treat spasticity in patients with brain injury include medications which act centrally (baclofen, tizanidine, and benzodiazepines) and a medication which acts on muscle, dantrolene.

One RCT (n=17) showed tizanidine was more effective than placebo in treating both upper limb and lower limb spasticity in patients with ABI.⁶⁹

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A before and after comparison reported that baclofen was effective in reducing lower limb spasticity but not upper limb spasticity in patients with brain injury (n=35).⁷⁰

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The BNF notes that baclofen should be used with caution in the following groups: patients with psychiatric illness, Parkinson's disease, cerebrovascular disease, respiratory impairment, epilepsy, history of peptic ulcer (avoid oral route in active peptic ulceration), diabetes, hypertonic bladder sphincter and the elderly. Tizanidine should be used with caution in the elderly and in those where there is concomitant administration of drugs that prolong QT interval. The BNF also suggests liver function is monitored monthly for first four months and, beyond this, in those who develop unexplained nausea, anorexia or fatigue.²⁰

Adverse effects noted in both drugs include drowsiness, dizziness, dry mouth, gastrointestinal disturbances and hypotension.²⁰ The efficacy and dosing schedules for these drugs vary unpredictably from patient to patient.

D Oral baclofen or tizanidine may be considered for treatment of spasticity.

4.2.4 ELECTRICAL STIMULATION AND FUNCTIONAL ELECTRICAL STIMULATION

Functional electrical stimulation is a technique to correct for muscular imbalance at a joint by stimulating, and thereby strengthening the weaker of the opposing muscle groups. No evidence regarding the use of functional electrical stimulation interventions in patients with brain injuries was identified. There is weak evidence that electrical stimulation may be effective for decreasing lower extremity spasticity for up to 24 hours.⁵⁰

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4.2.5 SURGERY

Surgical intervention is generally a last resort in spasticity management. Techniques developed from orthopaedic surgical work on patients with cerebral palsy are sometimes applied in TBI. Only one relevant case series was identified comparing two tendon transfer procedures for ankle spasticity which showed decrease in the use of ambulatory aids and improvement in ambulatory status following both procedures.⁷¹

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4.2.6 OTHER INTERVENTIONS

One case series of patients with ABI and muscle hypertonia (n=28) showed an inconclusive effect of intrathecal baclofen on range of motion of lower extremities.⁷² No evidence was identified for specific occupational therapy interventions for the reduction in spasticity. Further research into therapy modalities is required.

4.3 PHYSICAL THERAPEUTIC INTERVENTIONS

A significant proportion of patients who sustain a TBI are left with physical function problems. It is therefore important to establish whether any therapeutic interventions are effective in regaining physical function in these patients.

4.3.1 UPPER LIMB FUNCTION

There are limited studies which address the effect of upper limb recovery following TBI. One RCT assigned patients with ABI to either experimental (five one-hour sessions of individualised task-specific motor therapy in addition to 30 minutes of usual motor control therapy to shoulder and elbow five times per week) or control (10 minutes of individualised task specific motor therapy three times a week plus 30 minutes of usual motor control therapy). Hand and overall arm function of all participants improved over the six-week period, however there was not a clear benefit from providing additional hand therapy.⁷³

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A systematic review found insufficient evidence to support or refute the effectiveness of any one specific rehabilitation intervention to improve upper limb function.⁷⁴ No evidence directly related to brain injury was identified concerning the effect of constraint induced therapy on measurable components of physical function.

4.3.2 GENERAL THERAPEUTIC INTERVENTIONS

A Cochrane review investigated music therapy delivered using a number of different therapeutic interventions.⁷⁵ It suggested that rhythmic auditory stimulation may be beneficial in improving elements of gait, although the relevant trials were carried out on a stroke population. Further RCTs need to be undertaken before recommendations for clinical practice can be made.

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An RCT on motor imagery effectiveness came to no conclusion about the effectiveness of this intervention due to low levels of compliance of both patients and therapists.⁷⁶

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There is no clear evidence that any specific therapeutic interventions in patients with TBI, other than those involving task-specific and repetitive task training (*see section 4.1.3*) or for managing spasticity (*see section 4.2*) improve measurable components of physical function.

4.4 CONTINENCE PROBLEMS

Urinary and faecal incontinence are frequently reported following neurological illness or injury and specifically following a brain injury.⁷⁷ Up to 62% of patients will have urinary incontinence issues at admission, reducing to 18% at six months post injury.⁷⁸ The frequency of faecal incontinence can be correlated to increase in severity of a brain injury.⁷⁹ Urinary disturbances are also associated with a poor overall function following TBI, including impaired cognitive function.^{80,81}

A Cochrane review of management of incontinence and constipation in adults with neurological diseases reported that there was insufficient evidence to make any recommendation on the management of neurogenic bowel function.⁸² The review noted that, in the absence of a robust evidence base, bowel management protocols will continue to be developed empirically using an individualised and patient-centred approach.

One very small non-comparative study (n=3) reported that voiding dysfunction can be a significant problem following brain injury, but that it carried a good prognosis and resolves spontaneously. Treatment with anticholinergics may be required in the acute phase.⁸³

A prospective study of 20 patients with moderate or severe TBI reported that motor difficulties are more frequent in patients with urodynamic abnormalities. The study noted that while only two patients reported lower tract symptoms when screened using a questionnaire, urodynamic evaluation revealed abnormalities in 55% of the patients. Subtle dysfunction may not be clinically evident but can be picked up on urodynamic evaluation and may have short and long term implications.⁸⁰

Further advice on the care and treatment of people with a neurological condition and urinary incontinence can be found in NICE clinical guideline 148: urinary incontinence in neurological disease.⁸⁴

It is not possible based on the evidence reviewed to make a specific recommendation for treatment of incontinence in patients with brain injuries. However, the suggestion in studies of the influence of cognitive impairment and incontinence would suggest that an individualised approach including behavioural management strategies could influence a positive outcome.



Full assessment of bladder and bowel function should be undertaken over a period of days following admission. The physical, cognitive and emotional function of the patient should be considered and the multidisciplinary team should be involved to plan an individualised approach.

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5 Cognitive rehabilitation

5.1 INTRODUCTION

Prevalence of cognitive dysfunction following ABI varies due to the heterogeneous nature of the studies which report it. However, it is widely recognised that disorders of cognitive functioning resulting from brain injury are very common and have significant long term consequences.⁸⁵ Cognitive dysfunction includes impairments in memory, attention and concentration, executive functioning (eg planning, problem solving and self regulation), language and perception (using visual information to understand the world). Cognitive impairment, together with disorders of mood, emotion and behaviour, is considered to be one of the most important factors affecting a person's ability to participate in rehabilitation, function effectively in everyday life and return to participation in meaningful activities including work, social and leisure activities.⁸⁶⁻⁸⁸

5.1.1 APPROACHES TO COGNITIVE REHABILITATION

A number of different strategies for the rehabilitation of cognitive impairments exist. These can be divided into two main approaches – compensatory and restitution approaches. Compensatory approaches refer to interventions that aim to improve functioning in everyday life by provision of some form of aid or strategy that compensates for a deficit but does not aim to restore normal operation of the cognitive process. These include 'external' aids such as diaries or electronic reminding devices or 'internal' strategies such as using visual memory to compensate for a deficient verbal memory. Restitution approaches aim to restore normal functioning, often through repetitive practice of cognitive tasks (including computerised cognitive training packages).

Although this section addresses evidence relating to interventions for specific cognitive impairments (eg memory, attention, executive functioning and perception), it should be noted that most interventions are not carried out in isolation but rather in the context of a broader rehabilitation programme that also addresses mood, emotion and behaviour (*see section 6*) and is focused on enabling individuals with ABI to return to participation in meaningful activities.

There is a considerable body of evidence relating to the effectiveness of cognitive rehabilitation interventions after brain injury including meta-analyses, systematic reviews and RCTs. Although the methodological quality of at least some of the meta-analyses and systematic reviews is good, the quality of many of the studies included within the reviews is reported to be poor, with only a very limited number of high quality studies on which to base recommendations. Most of the systematic reviews have examined evidence for interventions in relation to a number of specific cognitive domains (eg memory, attention, perception and executive functioning), and although the overall volume of evidence is large, within each domain the volume of evidence is small and the quality very variable.

In relation to adults with brain injury, one meta-analysis and two well conducted systematic reviews that examine studies on interventions for a broad range of cognitive domains conclude that there is evidence for the effectiveness of cognitive rehabilitation interventions in at least some domains of cognition.^{89,90,91} In most domains, the evidence suggests that the most effective interventions are those that focus on provision of cognitive strategies or external aids that compensate for a cognitive impairment in order to improve everyday functioning. Those interventions that aim to reduce levels of impairment are less effective.

5.2 SELF AWARENESS AND INSIGHT

Lack of self awareness or insight is characterised by an inability to recognise difficulties following an acquired brain injury.⁹⁰ There is ongoing debate about what the concept refers to and the degree to which it impacts on rehabilitation and everyday functioning. Numerous explanations have supported the idea that poor self awareness is not a unitary construct but is complex involving interacting neurocognitive, psychological and social factors.

It has been argued that there are various forms of awareness including intellectual, emergent and anticipatory.⁹¹ Unfortunately, this complexity and lack of consensus means that the term is often misunderstood and many interventions have arguably developed out of a perceived clinical need with inadequate theoretical grounding.⁹² In clinical contexts a variety of treatment approaches have been suggested, including behavioural interventions, direct feedback, game formats, group work, structured experiments, and psychotherapy.

Despite the importance afforded this area in clinical practice, there is a very limited body of evidence examining the effectiveness of treatment interventions, with few systematic reviews or RCTs available. A systematic review revealed mixed findings concerning the association between awareness of deficits and rehabilitation outcome following brain injury (four supporting studies, six with partial support and two that did not support the association). It concluded, however, that awareness deficits represent a probable barrier to the client's own goals or personally valued outcomes.⁹³ An RCT reported that an awareness training protocol embedded within the practice of instrumental activities of daily living significantly but selectively improved self awareness as well as functional performance.⁹⁴ The need for a larger study with more treatment sessions was emphasised by the authors.

There is insufficient evidence available to support recommendations relating to the rehabilitation of poor insight or self awareness.

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5.3 MEMORY

There is evidence to support the use of compensatory approaches including memory strategy training and electronic aids (such as NeuroPage, personal digital assistants).⁹⁵⁻⁹⁷ There is no substantial evidence that repetitive practice improves memory impairment. There is some evidence that cognitive approaches, including errorless learning, may be effective in relation to learning specific information.^{95, 98}

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D Patients with memory impairment after TBI should be trained in the use of compensatory memory strategies with a clear focus on improving everyday functioning rather than underlying memory impairment.

- For patients with mild-moderate memory impairment both external aids and internal strategies (eg use of visual imagery) may be used.
- For those with severe memory impairment external compensations with a clear focus on functional activities is recommended.

B Learning techniques that reduce the likelihood of errors being made during the learning of specific information should be considered for people with moderate-severe memory impairment.

5.4 ATTENTION

In relation to attention, there is evidence that impairment focused training (eg computerised attention training) may produce small beneficial effects in the post-acute phase after TBI,⁹⁷ although evidence for generalisation of these effects is weak.^{89,95,99} However, larger effects are found when interventions focus on training-specific functional skills that make demands on attention through repetitive practice, or teaching strategies that compensate for attention impairments in everyday tasks.

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C Patients with attention impairment in the post-acute phase after TBI should be given strategy training relating to the management of attention problems in personally relevant functional situations.

5.5 EXECUTIVE FUNCTIONING

Two systematic reviews^{85,100} and two additional RCTs^{101,102} address the efficacy of interventions for executive deficits in relation to executive functioning. All four studies show that treatment approaches based on training patients in meta-cognitive strategies (eg training in problem solving, goal management and strategic reasoning) are effective at improving performance in practical or functional settings. Such interventions do not necessarily restore completely normal executive functioning, but nevertheless do improve functioning in everyday contexts or on tests that reflect well the demands associated with everyday problem solving, multitasking and goal management.

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B Patients with TBI and deficits in executive functioning should be trained in meta-cognitive strategies relating to the management of difficulties with planning, problem solving and goal management in personally relevant functional situations.

5.6 VISUOSPATIAL FUNCTIONING

The available evidence on visual perception related mainly to patients with stroke and almost all of the evidence relates to the treatment of unilateral visual neglect. Evidence relating to treatment of other forms of visuospatial deficits is limited. (*SIGN 118 discusses the management of visuospatial functioning in patients following a stroke*).⁵

5.7 EMOTIONAL PROCESSING

There is limited evidence on the treatment of emotional perception deficits in ABI. Two good quality RCTs indicate that participants significantly improved in judging basic emotional stimuli when it was presented in a naturalistic format (video vignettes) and in making social inferences on the basis of speaker demeanour, but small numbers of participants limit the conclusions that can be drawn.^{103,104} There is insufficient evidence to recommend use of strategies to improve emotional processing.

5.8 COMPREHENSIVE/HOLISTIC TREATMENT PROGRAMMES

Treatment of cognitive impairment is not usually undertaken in isolation. One approach to rehabilitation after brain injury is comprehensive/holistic neuropsychological rehabilitation. This refers to programmes that aim to simultaneously address cognitive, emotional and behavioural difficulties in the context of a focus on returning to participation in meaningful activities. One systematic review concluded that there was sufficient evidence to recommend the use of comprehensive-holistic neuropsychological rehabilitation during post-acute rehabilitation to minimise the impact of moderate or severe traumatic brain injury.⁹⁷ A limitation of studies of such programmes is that it is not possible to identify the specific components that lead to positive change and improvement. However, it does appear that such programmes, which have in part an explicit focus on addressing cognitive impairment, do improve functioning after brain injury.

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D In the post-acute setting interventions for cognitive deficits should be applied in the context of a comprehensive/holistic neuropsychological rehabilitation programme. This would involve an interdisciplinary team using a goal-focused programme which has the capacity to address cognitive, emotional and behavioural difficulties with the aim of improving functioning in meaningful everyday activities.

6 Rehabilitation of behavioural and emotional disorders

6.1 CHALLENGING OR AGGRESSIVE BEHAVIOUR

Challenging behaviours are frequent neurobehavioural sequelae of a brain injury. Behavioural disturbance may include inappropriate vocalisation, intolerance of medical management or equipment, directed or diffuse aggressive, disinhibited or sexualised behaviour. Agitated patients may resist direct care, be disruptive or pose a physical risk to themselves, family and staff. Reported prevalence ranges from 10-96% of patients with estimates varying according to the exact definition used and the setting studied. All studies recognise that it is a major burden on care givers.

Agitated behaviour in brain injured patients may not be the result of their brain injury in itself but reflect other factors including:

- premorbid personality
- drug/alcohol intoxication and withdrawal
- mood disorder, phobic anxiety and emotional adjustment
- pain
- urinary retention
- constipation.

✓ After acquired brain injury medically remediable causes of agitation should be excluded before therapies are started. Therapies should take account not just of the nature of the brain injury but the characteristics of the individual affected and the potential adverse effects of treatment.

6.1.1 NON-PHARMACOLOGICAL INTERVENTIONS

A wide range of non-pharmacological interventions has been used with adults presenting with challenging behaviours following ABI, including specifically tailored contingency management procedures based in operant learning theory; positive behaviour interventions focusing on proactive prevention of maladaptive behaviours through supportive work with the individual and environmental modifications; CBT; music therapy; and comprehensive neurobehavioural rehabilitation programmes. In many cases elements of different therapeutic models are combined in order to devise a multimodal treatment programme suited to the needs of the individual.

Contingency management and positive behaviour interventions

Two systematic reviews identified 98 studies which adopted contingency management procedures (CMP), positive behaviour interventions (PBI) or a combination of both.^{105,106} This evidence included only three RCTs while the remaining studies were individual case reports or case series. Two trials adopted a combined treatment approach with samples of patients with acquired brain injury of mixed causes but failed to find a substantial improvement for the treatment sample relative to the control groups. The uncontrolled case series showed inconsistent results in terms of treatment effect.

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Comprehensive neurobehavioural rehabilitation programmes

A systematic review reported one study of patients with ABI of mixed causes (n=76) who presented with persisting aggressive behaviour and were unable to live independently.¹⁰⁷ The cohort underwent a programme of social and neurobehavioural rehabilitation for a mean duration of 14 months. The intervention was supported by non-professional therapy care assistants, however the intensity of input and make up of the rehabilitation team was not specified. Positive outcomes were reported in terms of improved living arrangements, hours of care required and employment. These effects were maintained at follow up (mean=2.8 years).

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Cognitive behavioural therapy

A systematic review identified three observational studies which adopted CBT to treat challenging behaviours.¹⁰⁵ No substantive treatment effects were reported across these studies. There is insufficient evidence to recommend cognitive behavioural therapy as a treatment for challenging behaviour.

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Music therapy

A systematic review of music therapy following acquired brain injury highlighted one study (n=22) which demonstrated a positive effect of listening to live and taped music on levels of agitation.⁷⁵ The authors concluded that there was insufficient evidence to support the use of music therapy for improving agitation following ABI.

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- ✓ The family and key members of the affected individual's social network should be provided with education about appropriate management of behaviour and emotion.

6.1.2 PHARMACOLOGICAL INTERVENTIONS

One systematic review included six RCTs evaluating propranolol and pindolol, methylphenidate or amantadine.¹⁹ There was some evidence that the beta-blockers propranolol and pindolol can reduce aggressive behaviour. The studies used very large doses, although no significant adverse effects were reported and clinical experience suggests this is not usually a problem. It was notable that there were no included trials reporting the use of antipsychotics or anticonvulsants. The authors concluded that there was insufficient evidence on which to make firm recommendations regarding the use of these treatments, although beta-blockers had the best evidence for efficacy.

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- B** Propranolol or pindolol may be considered as a first line treatment option for moderate levels of agitation/aggression.

- ✓ Drug treatments should be individually tailored and commenced in very low doses. The patient's progress should be monitored with surveillance for possible adverse effects.

6.2 DEPRESSION AND ANXIETY

The emotional impact of brain injury can be profound. For many people, a process of emotional adjustment to changed circumstances is required. Rates of disorders of emotion are high after brain injury. Although estimates of the prevalence of depression and anxiety have varied widely, findings have indicated that rates of mood disorder are typically considerably higher than in non-brain-injured populations and may occur at any stage after a head injury.¹⁰⁸ For some people, low mood or anxiety are transient and part of the adjustment process. For others, symptoms may persist to the extent that they can be classified as a formal mood disorder.

Levels of disability a year after a head injury are significantly related to psychological disorders rather than physical impairment (*see section 3.2*).⁸⁶ There is therefore a compelling need to treat depression and anxiety after brain injury. However, overall there is a limited body of evidence relating to the treatment of depression and anxiety following TBI.

An important issue to consider in relation to TBI is injury severity. Although there is a broad range of severity represented in the evidence considered, the majority of studies include participants with mild-moderate injury. This limits the generalisability of the evidence and any recommendations, such that conclusions may be less applicable to people with more severe injury.

Another difficulty commonly reported is emotional lability. This is the tendency for a person's emotion to be quick to change and to be more extreme than usual and is associated with poor self regulation of emotion. No evidence was identified that specifically addressed the treatment of emotional lability in patients with ABI.

The literature that is relevant to the treatment of mood disorder after brain injury is varied in the extent to which mood disorder is the primary focus of an intervention or a primary outcome measure. For example, mood management interventions are common components of comprehensive or holistic neuropsychological rehabilitation programmes. This presents a difficulty in relation to reviewing the evidence as the precise

relationship between specific components of a comprehensive programme and outcomes are difficult to determine. In some studies mood may not be the primary focus of an intervention programme, but may improve as part of a rehabilitation programme that is addressing the factors that are contributing to the development or maintenance of a mood disorder. For example, someone who is depressed as a result of inability to return to work may be supported through a vocational rehabilitation programme to gain some form of employment, with an associated improvement in mood. So while the therapeutic intervention was not a traditional treatment for mood disorder (pharmacological or psychotherapy), improvement in mood is a secondary outcome.

6.2.1 DEPRESSION

A survey of 666 people after TBI reported that 27% of the participants reported five or more symptoms of depression.¹⁰⁹ Another large single cohort study found higher rates in a sample of 559 participants followed for up to a year post injury. They found that 53.1% of their sample met criteria for depression at some point in the year after injury, almost eight times the rate in the general population who did not have a brain injury. At any one point in time around 20-30% of participants were depressed.¹⁰⁸

Pharmacological interventions

A systematic review of 13 studies (n=301) of pharmacological agents to treat depression in patients following TBI identified only small studies which varied widely in design, diagnostic and outcome assessment, severity of brain injury, and time post injury. The authors concluded that there was insufficient evidence on which to base strong recommendations.¹⁵ However, based on weak evidence and expert opinion, the use of sertraline in clinical practice was suggested. One RCT with 99 participants found evidence that prophylactic administration of sertraline reduced the incidence of depression in the first year after a head injury, but overall rates of depression were lower than usual, and no conclusions can be drawn regarding who benefits most from the intervention.¹¹⁰

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The evidence relating to the pharmacological treatment of depression after brain injury is inconclusive and no specific recommendation can be made. A systematic review showed that antidepressant treatment is more effective than placebo in treating depression in the context of a wide range of neurological conditions including stroke, Parkinson's disease, epilepsy, multiple sclerosis and brain injury, although this review which included 20 RCTs only involved one study with patients who had suffered brain injury. Of eight adverse effects reported to be associated with antidepressant use only dry mouth was statistically more common in intervention groups than controls (odds ratio 2.41, 95% CI 1.32 to 4.40).¹¹¹

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Psychological interventions

A systematic review of interventions in patients following TBI included eight studies, most of which were uncontrolled, and which involved widely different treatment models. Although all studies included both pre- and post-treatment measures of depressive symptoms (an inclusion criterion for this review), none of them were designed specifically to evaluate treatments for depression. The authors concluded that no recommendations regarding psychological interventions could be made. They noted that depression was improved in the context of multimodal interventions and that cognitive behavioural interventions appeared to have the best preliminary evidence, but in the absence of clear evidence relating to the specific individual elements which might impact on depressive symptoms among these complex treatments, many of which were deliberately multifaceted and not directly targeted at depression originally, no specific recommendations could be made.¹⁵

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Three RCTs of telephone counselling interventions reported different findings. One study of people after admission to an ED found no significant benefit of the telephone intervention (five phone calls over a 12-week period) in terms of psychological symptoms at six months.¹¹² By contrast, another trial reported significant benefit in people with more severe injury who received seven calls over nine months when followed up at one year.¹¹³ A third, multicentre, study found no effect of a scheduled telephone intervention over either one or two years although this study did not separate data on depression and anxiety.¹¹

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One non-randomised controlled trial of 20 participants found a strong effect on measures of distress including depression, anxiety and stress from a CBT intervention delivered either via a group (n=5) or by telephone (n=5) when compared with an education control also delivered either via a group (n=5) or telephone (n=5).¹¹⁵ The interventions were delivered over nine weeks, followed by a one month follow up. The CBT intervention is described as being an individually tailored intervention taking into account participants' cognitive impairment. However, the lack of randomisation and very small sample size in each subgroup limits the conclusions that can be drawn from this study.

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The evidence relating to the psychotherapeutic treatment of depression after head injury is inconclusive and therefore no specific recommendation can be made. General guidance is available in SIGN 114 on the non-pharmaceutical management of depression in adults.¹¹⁶

6.2.2 ANXIETY

A Cochrane review noted that anxiety symptoms occurred following TBI with a frequency ranging from 18% to 60%.¹¹⁷ Studies examining specific anxiety disorders have found that in people with brain injury, 24% to 27% were diagnosed with generalised anxiety disorder and 4% to 6% with panic disorder.^{118,119} An observational study found that 27.1% of patients who sustained a severe TBI had developed post-traumatic stress disorder at six months after the injury.¹²⁰

Pharmacological interventions

No evidence was identified on the use of pharmacological interventions to reduce anxiety in patients with brain injuries.

Psychological interventions

One Cochrane review identified three trials meeting initial review inclusion criteria, of which two (with a total of 44 participants) were of good quality.¹¹⁷ It concluded that there was some evidence to support CBT for the treatment of acute stress disorder following TBI and for the use of CBT combined with neurorehabilitation to alleviate anxiety symptoms following mild-moderate TBI.

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One RCT evaluated an 'information plus writing' intervention (three 20 minute sessions writing about thoughts and feelings in relation to the accident) for acute stress disorder after TBI, but found that it was no more effective than information alone.¹²¹

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A non-randomised controlled study found a strong effect on measures of distress including depression, anxiety and stress from a CBT intervention.¹¹⁵ However, the lack of randomisation and very small sample size in each subgroup limits the conclusions that can be drawn from this study.

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B Cognitive behavioural therapy should be considered for the treatment of acute stress disorder following mild TBI.

B Cognitive behavioural therapy should be considered for the treatment of anxiety symptoms following mild to moderate TBI, as part of a broader neurorehabilitation programme.

7 Communication and swallowing

7.1 MANAGING COMMUNICATION PROBLEMS

7.1.1 INTRODUCTION

There is limited evidence describing the efficacy of specific communication interventions post TBI, and the methodological quality of the studies is generally poor with little replication of relevant studies. Most studies have not exclusively included patients with TBI. Many have targeted the more general population of ABI, with frequent reference to stroke. The presence of cognitive impairments in conjunction with communication impairments in people with TBI means that interventions described as being successful in the stroke population may not successfully transfer (or be assumed to transfer) to the TBI or non-stroke ABI population.

Research into the effectiveness of interventions in this area is made difficult because of the heterogeneous nature of the patient group. They present with diverse combinations of communication disorders, generally with additional cognitive, behavioural and physical deficits. Treatment approaches therefore need to be individually tailored to each patient's pattern of disorder, and this reduces the possibilities for carrying out RCTs. In addition, treatments in ABI are often given as an integrated package, with blurring of professional roles across the rehabilitation team. Studies of efficacy are further complicated by the difficulty in identifying the relative contributions of different members of the team.

7.1.2 DEFINITIONS

Traumatic brain injury may result in a variety of communication impairments of varying degrees of severity. These include:

dysarthria - a group of motor speech impairments affecting clarity of speech, voice quality and volume and overall speech intelligibility

dysphasia/aphasia - these two terms are now generally used interchangeably to refer to an acquired multimodal language disorder which can affect someone's ability to comprehend auditory and written language and to talk or write. It may or may not coexist with cognitive deficits including visuo-perceptual problems

cognitive-communication disorder, social communication disorder, pragmatic impairments, right hemisphere language disorder - these terms (which are not interchangeable but denote different disorders) refer to various impairments of communication affecting language use and discourse, producing a variety of symptoms, such as reduced use of facial expression, poor eye contact, reduced turn-taking, verbosity/taciturnity, poor listening skills, reduced relevance, and so on. These impairments may or may not coexist with aphasic symptoms, and affect the ability to converse successfully.

motor aprosodia - a neurological condition characterized by the inability of a person to properly convey emotional prosody by means of the pitch, stress and rhythm functions of normal speech production.

7.1.3 PROBLEMS WITH LANGUAGE OR FUNCTIONAL COMMUNICATION

Several systematic reviews and one meta-analysis suggest language deficits and/or functional communication deficits can be remedied.

One review presents findings which largely apply to patients with stroke (40 studies in total, of which eight included patients with TBI). The authors summarise that there is substantial evidence to support cognitive-linguistic therapies for language deficits following left hemisphere stroke.⁸⁵ Specifically, group treatment has been shown to be effective in remediating language deficits, a greater intensity of treatment produces improved communication skills, interventions for specific language impairments such as acquired dyslexia are effective (but the nature of the interventions was not described), and computer therapy provides a useful adjunct to face-to-face (FTF) treatment by a therapist. The authors recognise a compelling need for more studies to evaluate treatments of pragmatic communication problems in TBI.

A non-systematic, but comprehensive, review covered studies of stroke as well as TBI. It showed that although few good quality RCTs have been carried out in the area of aphasia rehabilitation, there is considerable evidence from lower grade studies indicating the probable effectiveness of aphasia rehabilitation (of various kinds).⁹⁵ In particular, it is commented that massed therapy (a large amount of therapy over a short period of time) is superior to smaller amounts of therapy over a longer period of time. However, it comments that there is a need for further studies to provide more evidence.

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A third review covered stroke and other forms of non-traumatic brain injury, as well as studies where the cause of injury was not described (21 studies; 52% of the subjects had TBI and 35% had non-traumatic brain injury). It excluded studies of interventions for speech and writing. It reported only three studies which it considered to have positive outcomes with a conclusive level of certainty, but the nature of the brain injuries of the participants in the studies was not clear so it is not possible to say if the outcomes are relevant to TBI.¹²² The studies are said to demonstrate positive outcomes of the following interventions: graphic and conversational partner support to improve successful conversational exchanges in aphasia; the use of computer based therapy to improve the complexity of utterances in aphasia; the use of a verbal prompting hierarchy to improve naming. These studies collectively included only 12 study participants.

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One meta-analysis attempted to separate out the treatment effect sizes in studies of TBI versus studies of stroke, and concluded that at best there was only weak evidence in favour of effective language rehabilitation after TBI, partly because only four studies of language treatment after TBI were identified, and one of those had a negative effect size (the control group did better than the treatment group).⁸⁹ The authors found a small-medium language treatment effect in stroke. They note that the evidence is weakened by the dominance in the literature of studies using single group pre-post designs, as opposed to stronger study designs.

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Almost all of the evidence above relates to stroke rather than TBI. Only one study noted weak evidence in favour of language rehabilitation after TBI. One further non-comparative study suggested that aphasic patients with TBI can make the same functional and cognitive gains as non-aphasic patients, but over a longer time span.¹²³ This study did not detail any of the therapeutic techniques used. A survey suggested that adults with TBI who are introduced to augmentative and alternative communication generally find it acceptable and use it for extended periods of time, but this was a non-experimental study.¹²⁴

7.1.4 INTONATION AND PROSODY PROBLEMS

Intonation refers to variations of pitch in speech. Prosody refers to the use of rhythm, stress and intonation in spoken output. A systematic review, an RCT and a non-comparative study provide evidence that intonation/prosody problems can be remediated.^{51,125,126} Treatments researched were a song-singing programme, an imitative programme and a cognitive-linguistic treatment. The systematic review reported evidence that a pitch biofeedback and expression modelling intervention is beneficial to a patient with motor aprosodia, improving affective prosody. In the RCT, only one of the 14 subjects had a TBI, all the other subjects had stroke which limits the generalisability of the study.

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7.1.5 SOCIAL COMMUNICATION PROBLEMS

A systematic review, an RCT and a non-comparative study suggest social communication deficits can be improved through group treatment. The systematic review identified evidence that conversation group therapy has a beneficial effect on pragmatic and quality of life concerns in patients with ABI.⁵¹ The RCT excluded the most typical patients with TBI and there was a risk of bias with some of the outcome measures.¹²⁷ The non-comparative study was limited by the lack of a control group, a small number of participants and a 43% dropout at six months.¹²⁸

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7.1.6 TRAINING COMMUNICATION PARTNERS

A systematic review and an RCT suggest that training communication partners to improve communication with people after ABI is beneficial.^{51,129} Two of the studies related to stroke. In the study focusing exclusively on TBI, there was only a small number of participants. The systematic review suggested that interventions that focus on training the communication partners of individuals with severe ABI were effective. It also showed communication strategies used by those who work with individuals who have sustained an ABI are effective in improving communication exchanges.⁵¹

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7.1.7 DYSARTHRIA

Six studies focus on the treatment of dysarthria in adult patients, one Cochrane review,¹³⁰ three other systematic reviews^{51,131,132} and two non-comparative studies.^{133,134} The Cochrane review identified no appropriate studies. Two of the reviews did not allow conclusions to be drawn regarding patients with TBI because they took as their topic the diagnosis of stable dysarthria, as opposed to any single aetiology.^{131,132}

This body of evidence provides some evidence of the benefits of Lee Silverman Voice Treatment (LSVT) (an intensive programme of voice exercises which aims to improve loudness, quality and variation, and promotes self-monitoring) but otherwise no conclusive evidence for the management of dysarthria in patients following brain injury. One of the systematic reviews identified studies which suggested that combination treatment incorporating LSVT-type exercises, direct respiration treatment, and physiotherapy exercises has a mild and inconsistent effect on outcome. Three further studies indicated that LSVT has some potential in treating dysarthria in individuals with ABI.⁵¹ Further research using a control group is needed. This review also identified evidence that external pacing techniques (eg metronome, pacing board) are effective in increasing intelligibility through rate reduction outcomes in patients with ABI.

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One non-comparative study investigated the use of LSVT for improving dysarthria in seven patients with TBI and three with stroke. It assessed patients at baseline, after treatment and at six months follow up but did not compare LSVT with another treatment. Positive results were described, but there were limitations in study design including a lack of treatment comparison.¹³³ The authors assumed stability of the patients' dysarthria simply because the participants were six months or more post onset, but did not test this with initial assessment. Several of the outcome measures required judgements made by the participants, their carers and their therapists, introducing an element of bias. There were only seven participants with TBI.

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A further case series explored the suitability for and benefits of commencing individualised dysarthria treatment for people with TBI whilst in later post-traumatic amnesia (PTA).¹³⁴ The authors report on two cases and state that PTA did not preclude the provision of therapy but certain neurobehavioural characteristics affected the quality of the therapy. They report improvement in the dysarthria over the period of intervention (which extended from later PTA until emergence from PTA), but note that as parameters other than those included in therapy also improved, the improvement could be due to spontaneous recovery rather than the therapy itself.

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Although this treatment approach looks promising, there are few studies and small numbers of participants. In addition, LSVT requires a specially trained therapist and very intensive input which may not be realistic for some clinicians.

7.1.8 OTHER INTERVENTIONS

A systematic review identified evidence which suggested that some patients with severe head injuries may improve their ability to communicate yes/no responses after undergoing consistent training and environmental enrichments.⁵¹ This review also identified evidence which suggested that pragmatic interventions including role playing improves a variety of social communication skills as well as self concept and self confidence in social communications, and evidence which suggested that peer-group training of pragmatic language skills may benefit individuals with communication deficits following brain injury. For patients in minimally responsive states, there was evidence that structured intervention does have a positive effect on an individual's ability to communicate.

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Expert opinion and uncontrolled case series suggest value in interventions designed to improve communication disorders post TBI.^{85,135-139} | 3
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The low quality of evidence should not be interpreted to mean that intervention in this area has no clinical value. However, it is not possible on the basis of this body of evidence to make recommendations about specific interventions for communication deficits post TBI. There remains a pressing need to design and implement methodologically sound and well powered research studies in this field.

D Patients with communication deficits post TBI should be referred to speech and language therapy for assessment and management of their communication impairments.

7.2 ASSESSING AND MANAGING DYSPHAGIA

Dysphagia refers to a difficulty with swallowing, and estimates of its incidence post ABI vary from 25% to 78%.⁵¹ SIGN guideline 119 contains recommendations for the assessment and management of patients with dysphagia following stroke.⁶

7.2.1 ASSESSMENT

Dysphagia is generally assessed by speech and language therapists using a combination of bedside and instrumental approaches. The two most widely used instrumental assessments are videofluoroscopy and Fiberoptic Endoscopic Evaluation of Swallowing (FEES). Instrumental assessment allows diagnosis of pharyngeal stage swallowing problems including aspiration. It therefore allows more informed decision making about feeding and therapy, whilst helping to avoid the risk of silent aspiration, compared with bedside assessment alone. Potentially, individuals may progress more quickly following instrumental assessment because of the ability to identify the intactness or otherwise of the pharyngeal swallow. However, there are resource implications in relation to the availability of videofluoroscopy and FEES and the ability to carry out the assessments in patients with acute brain injury and those in low arousal states. Additionally, patients are exposed to radiation in videofluoroscopy and FEES is an invasive procedure.

There is little evidence comparing outcomes following instrumental assessment versus bedside assessment in patients post TBI. One small non-comparative study suggests that FEES is an objective and sensitive tool that can be used to evaluate dysphagia in patients with acute TBI,¹⁴⁰ and another small retrospective case control study suggests that patients with prolonged disordered consciousness following ABI can feasibly be assessed instrumentally in terms of swallowing function, allowing swallowing as a treatment modality whilst in a state of disordered consciousness.¹⁴¹ | 3

D Instrumental assessment of dysphagia in patients post TBI should be considered where:

- **bedside assessment indicates possible pharyngeal stage problems** (which would potentially include the aspiration of food and fluid into the lungs)
- **the risks of proceeding on the basis of the bedside assessment outweigh the possible benefits** (the patient at very high risk of choking or aspiration if fed orally), and
- **the bedside assessment alone does not enable a sufficiently robust clinical evaluation to permit the drawing up of an adequate plan for swallowing therapy.**

7.2.2 MANAGEMENT

Managing dysphagia is important for the maintenance of nutrition and hydration as well as the prevention of complications, such as chest infection. Typical management of dysphagia post TBI incorporates compensatory techniques, restorative exercises and modification of the texture of the diet as appropriate. Compensatory techniques are designed to enable oral feeding despite the presence of swallowing impairments; for example, adopting a different posture or an alternative swallowing technique to increase the safety of the swallow. Restorative exercises are aimed at directly improving the swallow physiology; for example, exercises to improve the strength of the tongue to improve oral transit of food. Texture modification is undertaken where safe swallowing can only be achieved with specific food textures; for example, a minced-mashed consistency diet may help where oral preparation of food is impaired.

No evidence was identified relating to any form of restorative exercises in dysphagic patients post-TBI other than two studies concerning neuromuscular electrical stimulation (NMES) (a technique involving electrical stimulation of relevant peripheral nerves with the aim of improving swallowing function). One very small non-comparative study including only one participant with TBI concludes that NMES can be an effective treatment for chronic pharyngeal dysphagia.¹⁴² One systematic review concludes that some aspects of NMES might be beneficial for dysphagia treatment, but further research is required.¹⁴³ Only one study included in the review included patients with TBI, and the authors noted that the studies reviewed were generally poor quality with a high risk of bias. Neuromuscular electrical stimulation is used widely in the US but is a little-used technique in the UK and the Royal College of Speech and Language Therapists does not endorse its use.

There is insufficient evidence to support a recommendation on restorative exercises to improve outcome in dysphagia post TBI.

7.3 ORAL HYGIENE

Rigorous oral hygiene forms part of the routine care of patients with dysphagia, although physical deficits and problems with patient compliance can make it difficult to carry out satisfactorily. No evidence was identified that oral hygiene programmes reduce the incidence and severity of aspiration-associated chest infection and pneumonia in patients with TBI. One methodologically poor RCT considered oral hygiene post TBI but not in relation to dysphagia and aspiration pneumonia.¹⁴⁴

It is not possible to make a recommendation on the basis of the evidence. However, common sense dictates that thorough oral hygiene in TBI patients would be beneficial for oral comfort and dental health.

8 Vocational rehabilitation

Vocational rehabilitation (VR), or supported employment, focuses on the return to work, education or duty of an individual following injury. Return to work following ABI has been identified as the most challenging task that a patient will face in the course of their recovery and remains the most significant marker of return to their pre-morbid level of function.¹⁴⁵ It has been estimated in a US study published in 2001 that the annual loss of productivity and wages together with cost associated with care and management of TBI are estimated to be \$28 billion to the US economy.¹⁴⁶ Vocational rehabilitation is not the core business of the NHS. However, it is clearly important for TBI rehabilitation and supporting patients towards achieving their goals.

The evidence related to the efficacy of VR remains scattered and inconclusive. One review found it difficult to ascertain employment outcomes considering the range of outcomes and measures that exist and showed a range of return to work rates from 20% to 90%.¹⁴⁷ Most of the evidence reviewed was carried out in US, Canada, Australia and New Zealand which should be taken into account when generalising to a Scottish population because of differences in funding streams and legislation. Evidence in this section was identified by searching for interventions which were defined by researchers as vocational rehabilitation. This may underestimate the total available evidence as other interventions which may be defined using cognitive, physical or behavioural terms may also impact on the individual's ability to return to work.

8.1 BENEFITS OF RETURNING TO WORK

Return to work is an important stage in rehabilitation after traumatic brain injury for a number of reasons. Firstly, being employed has been associated with better quality of life in TBI survivors and secondly the financial costs associated with unemployment after TBI are substantial given that TBI disproportionately affects young people of working age.¹⁴⁸

8.2 VOCATIONAL REHABILITATION INTERVENTIONS

The evidence on the effectiveness of specific VR interventions is inconclusive.

A quantitative synthesis of 26 studies (n=3,688) which used a wide range of interventions indicated that patients who received VR returned to work quicker than patients who had no VR (mean percentage successful adjusted return to work 71% v 47%).¹⁴⁷

A systematic review included three studies that looked at VR. The results suggested that there is limited evidence that VR results in improved outcomes for patients with TBI, however, the study designs were of widely varying populations and settings.¹⁴⁵ The authors also included one study of supported employment and suggested that it improves the level of employment outcomes where there are aspects of competition involved in securing the post, particularly for ABI survivors who are older, have more education, have no prior work experience or who have suffered more severe injuries. There were significant problems with the methodology of the study.

A systematic review published in 1999 identified no direct evidence from RCTs about the efficacy of supported employment. Participants in the supported employment programme showed significantly better results but the comparison group were so heterogeneous with multiple factors affecting employment that no conclusions could be drawn from the results.¹⁴⁹

There is insufficient evidence on the effectiveness of VR to make a recommendation on either approaches or intensity of intervention and further research is required.

- ✓ Early in the rehabilitation pathway patients should be asked about vocational activities and liaison initiated with employers. Once work requirements are established patients should have appropriate assessments made of their ability to meet the needs of their current or potential employment.
- ✓ NHS Boards should consider providing a specific local expert therapist to provide advice to rehabilitation teams including signposting to relevant statutory services such as Disability Employment Advisors at Job Centres, organisations specifically providing opportunities for people with disabilities, eg Momentum, or voluntary services which can provide help and support, eg Headway, Disability Alliance (*see section 11.1*).

9 Management of the patient in the minimally conscious or vegetative state

Advances in acute medical and neurosurgical treatments are resulting in increasing numbers of individuals surviving severe TBI. The annual incidence for individuals surviving severe brain injury in the US has been estimated at around 170 per million population¹⁵⁰ with annual incidence in the UK around half this figure.¹⁵¹ For patients who survive acute coma, the annual incidence of individuals remaining in the vegetative state (VS) in the UK has been estimated at 14 per million population at one month post injury, eight per million at three months and five per million at six months for acute causes.^{152,153} Prevalence estimates have only been computed for the US and vary between 40 and 168 per million population.^{152,153} Due to developments in diagnostic terminology and assessment procedures, no figures regarding incidence or prevalence for the minimally conscious state (MCS) are available.¹⁵¹

This patient group presents with complex ongoing nursing and medical needs and represents a considerable challenge in terms of assessment and multidisciplinary rehabilitation. The importance of closely monitoring patients in order to reliably differentiate states of disordered consciousness was underlined by two studies which found that up to 40% of patients considered to be in a chronic or persistent vegetative state were actually demonstrating behavioural responses consistent with the MCS thereby indicating a higher level of awareness and rehabilitation potential.^{154,155}

9.1 DEFINITIONS

Considerable progress has been made in reaching consensus regarding the specific diagnostic criteria used to differentiate patients at various points after injury.¹⁵⁶ This work has focused on identifying patterns of behavioural responses which indicate increased conscious level and emergence from coma, through the VS into the MCS and beyond. For patients who remain in the VS, issues of chronicity and permanence have been described in relation to prognosis.

9.1.1 VEGETATIVE STATE

Diagnosis of VS can only be made a minimum of one month after injury and requires the presence of all the following:

- no evidence of awareness of self or environment and an inability to interact with others
- no evidence of sustained, reproducible, purposeful, or voluntary behavioural responses to visual, auditory, tactile or noxious stimuli
- no evidence of language comprehension or expression
- intermittent wakefulness manifested by the presence of sleep-wake cycles
- sufficiently preserved hypothalamic and brain stem autonomic functions to permit survival with nursing and medical care
- bowel and bladder incontinence
- variably preserved cranial nerve reflexes and spinal nerve reflexes.¹⁵⁷

It has been proposed that the issue of permanence of the VS may be raised when a patient has remained in the VS for more than 12 months after a traumatic brain injury and more than three months after a brain injury of non-traumatic cause (eg cerebral anoxia). After this point, recovery of consciousness can be considered highly improbable but not impossible¹⁵⁶ and critical issues regarding life sustaining treatment and interventions may therefore become pertinent in individual cases.

9.1.2 MINIMALLY CONSCIOUS STATE

A patient can be considered to be functioning in the MCS if there is clear evidence of being able to perform one or more of the following behaviours:¹⁵⁶

- follow simple commands
- demonstrate gestural or verbal yes/no responses (regardless of accuracy)
- verbalise intelligibly
- demonstrate purposeful behaviour, including movements or affective behaviours which are contingent upon environmental stimuli (eg appropriate smiling/crying, visual tracking object, vocalised/gestural response appropriate to questions or instruction).

A patient can be considered to have emerged from the MCS when they are able to reliably and consistently demonstrate one or both of the following:

- functional interactive communication (eg verbal/gestural yes/no responses to questions, or written questions)
- functional use of two different objects.

A wide range of medical, surgical, pharmacological, environmental and sensory stimulation intervention techniques has been used with patients in states of disordered consciousness. Many published studies have reported outcomes with single cases or a small case series. There are very few group designs reported in the literature and a lack of control data for comparative purposes.

9.2 ASSESSING CHANGES IN CONSCIOUS LEVEL

One systematic review evaluated the evidence for assessment scales to measure disorders of consciousness and concluded that the Coma Recovery Scale – Revised (CRS-R) can be used with minor reservations due to unproven criterion validity.¹⁵⁸ The Sensory Modality and Rehabilitation Technique, Western Neuro Sensory Stimulation Profile, Sensory Stimulation Assessment Measure, Wessex Head Injury Matrix and Disorders of Consciousness Scale may be used with moderate reservations due to limited evidence of reliability or criterion validity.

2++

A systematic review of individual cases investigated the use of functional imaging techniques (eg positron emission tomography, functional magnetic resonance imaging) with patients in the vegetative state and concluded that evidence of 'higher level' cortical activation in response to complex, personally salient auditory stimuli can provide important information regarding residual brain function and prognosis. However, the available literature was noted to be sparse, with unblinded and uncontrolled studies using a wide range of different assessment and intervention procedures.

3

B The Coma Recovery Scale - Revised should be used to assess patients in states of disordered consciousness.

✓ Given the challenges associated with assessing patients with disorders of consciousness, it is important that clinicians should have training in administering disorders of consciousness assessment tools and also an appreciation of the range of assessment tools available for use with this population.

9.3 PHARMACOLOGICAL THERAPY

One systematic review of mostly single case series evaluated pharmacological interventions for patients in the VS or MCS.¹⁵⁹ The authors found some supporting evidence for the use of dopaminergic agents (levodopa and amantadine) to improve conscious level with a very small number of patients (n=6). There was also some evidence to support the use of the hypnotic agent zolpidem (n=21), however conflicting treatment effects were seen across patients with only a small proportion showing a clear benefit (n=7). The authors report the results of a small series of patients (n=5) treated with intrathecal baclofen for spasticity who also demonstrated associated improvements in conscious level. Considerable limitations were noted within the literature, including a lack of cohort or blinded and controlled study designs, a lack of consistency

3

regarding measures of conscious level, and considerable heterogeneity regarding patient characteristics. It is not possible to draw robust conclusions from this evidence base.

3

A systematic review identified evidence for the use of amantadine in improving cognition, arousal and other behavioural/functional responses following traumatic brain injury.¹⁶⁰ The review included three retrospective studies (n=209), two randomised, double blinded, placebo controlled crossover studies (n=45), two case reports (n=2) and one retrospective case series (n=12). Inconsistent results were found between the two randomised controlled trials which may reflect differences between the two study designs, including patient samples, outcome measures and treatment duration. The authors conclude that there may be evidence to support the use of amantadine (200-400 mg/day) to improve cognition and arousal post-traumatic brain injury, however further prospective controlled studies are required.

3

A further randomised, placebo controlled trial of amantadine with a large sample of patients enrolled between 4-16 weeks after severe traumatic brain injury (n=184) and presenting in the VS and MCS found that whilst both groups improved during the four-week treatment period (measured by changes on the CRS-R) the active treatment group demonstrated a significantly faster rate of recovery.¹⁶¹ During a two week post treatment wash out period these gains were maintained in both groups, however the rate of improvement slowed in the active treatment group, such that at the six week point there was no significant difference between the two groups in CRS-R scores. There was no evidence of increased risk of adverse side effects in the active treatment group. The authors concluded that a dosage of 200-400 mg of amantadine can be used safely in patients following severe traumatic brain injury and may facilitate faster recovery of behaviours consistent with improved conscious level.

1++

A general overview of awakening agents in patients with a range of disorders of consciousness, including akinetic mutism concluded that in the early phase of recovery (ie <1 month post injury) there is evidence to support the use of bromocriptine with patients in the vegetative state and akinetic mutism and methylphenidate and hyperbaric oxygen for patients in coma or the minimally conscious state.¹⁶² In the chronic phase (ie >1 month post injury) there is evidence to support the use of bromocriptine and levodopa for patients in the vegetative state, amitriptyline, hyperbaric oxygen and amantadine for patients in the MCS and hyperbaric oxygen for patients in prolonged coma. Considerable methodological issues were noted by the authors, including a lack of adequate baseline measures of conscious level, heterogeneity regarding assessment of outcome and conflicting results between studies.

4

B Amantadine may be considered as a means of facilitating recovery of consciousness in patients following severe brain injury.

9.4 NON-PHARMACOLOGICAL THERAPY

One RCT with methodological limitations provided evidence regarding the efficacy of a family visiting programme in improving conscious level.¹⁶³ Fifty patients in coma were randomly allocated to either a treatment condition (n=25) or to standard nursing care condition (n=25). The treatment condition incorporated six daily visits from a close family member lasting 15 minutes during which the visitor was trained to verbally interact with the patient and provide tactile stimulation to the hands and face. The authors reported a significant difference between the two groups' conscious level (mean GCS scores) after the final treatment session on day six but no significant difference at baseline.

1-

An overview of intervention options reviewed the evidence for multisensory stimulation, music therapy, and contingent stimulation and assistive technology.¹⁶⁴ The three multisensory stimulation studies (n=15) incorporated two single cases and one case series of 13 patients using a multiple baseline methodology. Some positive effects were noted following stimulation however the results as a whole are equivocal and methodological issues were noted (eg lack of clear diagnosis of conscious level, lack of adequate control data, use of multimodal treatment techniques with variation between studies and lack of clarity with regards to specific techniques used). The three music therapy studies (n=36) included two single case reports and one case series which provided some evidence of improved response level and behavioural changes following treatment. However, in the absence of control data, conclusions regarding treatment efficacy must be made with considerable caution.

4

A Cochrane review of evidence for multisensory stimulation of patients in coma or vegetative state identified one RCT (n=14) and two controlled clinical trials (n=54). Due to methodological and statistical limitations in all three studies, the authors concluded that the results were invalid and therefore no clinical outcomes or practice recommendations could be made.¹⁶⁵

An RCT reported positive effects on conscious level for a sample of patients in the vegetative state or minimally conscious state less than three months post injury treated with branched chain amino acids via intravenous infusion (n=22) compared with isonitrogenous placebo (n=19) over a 15 day period.¹⁶⁶ All patients were assessed using the Disability Rating Scale (log transformation score) the day after active treatment/placebo intervention and at the point of discharge from hospital (mean=137 days since injury). The trial did not report randomisation methods and caregivers were not blinded to treatment allocation. Further studies are warranted in order to establish treatment efficacy beyond the results of this single sample.

1

9.5 SURGICAL INTERVENTIONS

Two studies reviewed evidence for transcranial and deep brain stimulation surgical interventions for patients in the vegetative state and minimally conscious state.^{159,164} The one transcranial stimulation (n=1) and two deep brain stimulation (n=6) studies provided some evidence for the effectiveness of these treatments on arousal, interaction with the environment and functional ability. However, the numbers of patients under review were very small and only one study introduced a control component by incorporating a crossover single case design. One review reported the results of one large, prospective observational study using spinal cord stimulation in a sample of patients in the vegetative state (n=214) with mixed aetiology and found a response incidence rate of 54%.¹⁶⁴

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4

Although a number of surgical interventions have shown some promise in enhancing arousal/consciousness level, given the lack of consistency of results and the methodological limitations of most studies, no specific recommendation can be made.

10 Service delivery

10.1 INPATIENT CARE

There is little direct evidence to support the rehabilitation of brain injured patients within a specialist unit compared with a non-specialist/general unit. Ethical considerations surrounding the differential provision of care to different groups limit the availability of high quality randomised data.

A specialist service has been defined as a group of (therapeutic) interventions delivered by one or more people or organisation(s), which may incorporate one or more programmes, methods, techniques or approaches. Such services are:

- not generic primary, intermediate or secondary health or social services (although much of the care received by people with these conditions are provided by such generic services), and
- generally provided by more than one professional grouping.¹⁶⁷

One Cochrane systematic review considered multidisciplinary rehabilitation for ABI in adults aged 16-65 years.¹⁸ The review included all causes of ABI including stroke and compared specialist inpatient rehabilitation with rehabilitation carried out by local services. Two studies specifically considered specialist inpatient rehabilitation in patients with either TBI or stroke. Both of these studies were small and of low methodological quality and provided limited evidence that specialist inpatient rehabilitation improved functional outcome over local non-specialist services. The review cited the UK National Clinical Guidelines for Stroke which suggests the key features of a successful rehabilitation service comprise a specialist multidisciplinary team with relevant expertise which is generally found in a specific geographical base or location.

2⁺⁺

A systematic review of multidisciplinary rehabilitation services identified twelve reviews covering five populations - stroke, brain injury, rheumatoid arthritis, hip fracture and older adults.¹⁶ In addition to the above Cochrane review, this reported a further review which included 2,183 people with mixed diagnoses (mostly stroke) which showed that specialised rehabilitation resulted in increased likelihood of discharge home from hospital, greater functional outcomes and higher rates of survival.

1⁺

The Evidence Based Review of Rehabilitation of Moderate to Severe Acquired Brain Injuries, (ERABI),⁵¹ a modular systematic review including randomised and non-randomised studies concluded that ABI patients benefit from a dedicated inpatient rehabilitation service. These services vary from institution to institution but generally include some type of intensive therapy programme for physical, social, behavioural and cognitive difficulties. The review also showed that early rehabilitation is associated with a shorter length of stay, higher cognitive levels on discharge, better FIM scores and increased chance of discharge to home. Patients receiving increased intensity of therapy had better outcomes in most aspects of FIM and FAM and experienced shorter lengths of stay.

2⁺

One single-blinded RCT (n=68) in patients with moderate to severe TBI compared different intensities of treatment (two versus four hours per day for up to six months).¹⁶⁸ This demonstrated that after the second week most patients could tolerate more than two hours of therapy per day. While no significant difference was found between the two groups beyond three months, a higher number of patients in the high intensity group achieved a maximum FIM score at three months and Glasgow Outcome Scale score (GOS) at two months although these early gains did not impact on overall length of stay. This study suggests that intensive rehabilitation may speed up overall recovery.

1⁺

Intensity of rehabilitation is a relative term defined differently by different studies. Some studies of intensity compare interventions carried out for longer duration than controls, while others define it in terms of the volume or frequency of delivery of rehabilitation. While there is evidence suggesting an association between both increased intensity and earlier intervention with positive outcomes, it is not possible to quantify a threshold for recommendation.

B

For optimal outcomes, higher intensity rehabilitation featuring early intervention should be delivered by specialist multidisciplinary teams.

10.2 COMMUNITY REHABILITATION

10.2.1 INTRODUCTION

Post-acute inpatient rehabilitation is not available comprehensively throughout Scotland and in many areas community rehabilitation services of variable composition are providing both short and long term rehabilitation support to patients with traumatic brain injuries.¹⁶⁹

While there is limited research comparing the outcomes of community rehabilitation with other or no rehabilitation, there is evidence of beneficial outcomes for patients with TBI who have access to the following features of community rehabilitation services:

- interdisciplinary rehabilitation¹⁷⁰⁻¹⁷³
- planned transfer of patient care from hospital to community services^{169,170}
- ongoing family and carers support¹⁷⁰
- neuropsychology rehabilitation programmes¹⁷¹
- community rehabilitation many years post injury^{172,173}

There is no consistency in current studies regarding the definition and make up of optimal community rehabilitation services nor of specific rehabilitation programmes, however common themes emerge which are outlined in the following sections.

10.2.2 INTERDISCIPLINARY COMMUNITY REHABILITATION

Patients who have access to services providing interdisciplinary rehabilitation in their community demonstrate benefits that outlive the treatment period in comparison to those who have 'usual care'.

A case control study compared a group receiving multidisciplinary outpatient rehabilitation with a group receiving no rehabilitation.¹⁷⁴ Patients who participated in the multidisciplinary rehabilitation programme achieved greater improvement on the community integration questionnaire outcome measure than controls. However, there was no significant improvement in community socialisation outcome or work or school status. The small sample size and lack of randomisation limits its application to other areas.

✓ Community rehabilitation services for patients with brain injuries should include a wide range of disciplines working within a co-ordinated interdisciplinary model/framework and direct access to generic services through patient pathways.

✓ Each patient should have a named worker.

A guideline from the British Society of Rehabilitation Medicine and Royal College of Physicians recommends that, as a minimum, a community specialist service to support people with brain injuries should include:¹⁷⁵

- specialist brain injury nurses
- physiotherapists
- occupational therapists
- speech and language therapists
- clinical psychologists
- specialist social workers
- dietitians
- technical instructors
- generic assistants
- consultants in rehabilitation medicine
- with access to other relevant services such as neurology, neurosurgery, neuropsychology, neuropsychiatry and mental health services as required.

10.2.3 TRANSFER FROM INPATIENT TO COMMUNITY REHABILITATION

The transition of patient care from hospital to home is covered in section 10.4. The recommendation for planned discharge is also relevant when transferring patients from hospital to community rehabilitation services. It is important that the transition is planned with community services which have an awareness of the problems faced by individuals with ABI.^{169,170}

10.2.4 FAMILY AND CARER SUPPORT

The National Traumatic Brain Injury Study followed up patients referred to community rehabilitation services across ten sites in England and included interviews with 507 adults (of whom 68% had severe injuries, 25.5% had moderate injuries and 6.5% had mild injury severity).¹⁷⁰ Authors of this study noted through narrative analysis that if family and carers are supported, it has been shown to have a positive outcome for the person with a brain injury. They noted the difficulties in demonstrating this effect in objective terms: "The presence of an informed and competent carer and the location of the head-injured person within an effective support network revealed their importance only gradually as implicit contrasts were made between those clients who seemed to do well and those who did badly. It was not, and may never be, possible to set up programmes to demonstrate these effects by means of statistical analysis." The study reported that ongoing support for families and carers helped to maintain social networks and personal resilience.

- ✓ Family and carers should be provided with access to ongoing support when the patient with brain injury is living within the community.
- ✓ Children and adolescents affected by a family member with brain injury may require referral to specialist support services through education, health or social work.

10.2.5 NEUROPSYCHOLOGICAL REHABILITATION PROGRAMMES

Section 5 of this guideline, covering cognitive rehabilitation, is as relevant in the context of community rehabilitation services as in the inpatient setting. In community rehabilitation it is important for patients with TBI to have access to comprehensive and holistic neuropsychology rehabilitation programmes.

An RCT of 68 patients with moderate to severe brain injuries showed that a group receiving a comprehensive, holistic programme of neuropsychological rehabilitation in a community setting demonstrated greater improvement in the community integration questionnaire and the perceived quality of life scale than a group receiving standard rehabilitation in the same setting.¹⁷¹ The Intensive Cognitive Rehabilitation Program consisted of 15 hours of individual and group therapies conducted three days per week. Patients used a variety of functional and social problem-solving tasks to tackle their individual problems, while pragmatic and interpersonal communication was addressed through role playing, interpersonal and videotaped feedback, and analysis of social interactions. Functional compensatory strategies were used (for example, note-taking) and the application and monitoring of strategies reviewed within each participant's home and community, including regular homework exercises. At completion of treatment, significantly more patients in the neuropsychological rehabilitation programme group were engaged in community based employment than in the standard rehabilitation group (47% v. 21%; p=0.02).

10.2.6 LONG TERM ACCESS TO REHABILITATION

An RCT of multidisciplinary rehabilitation in the community for patients with moderate to severe TBI (n=110) showed improvements in functional outcomes compared with an information provision intervention. Outreach participants who received individualised programmes of rehabilitation from a multidisciplinary team which used a goal planning framework where participants were seen for two to six hours per week demonstrated significantly larger gains on the Barthel Index (35% v. 20%, p<0.05), the Brain Injury Community Rehabilitation Outcome-39 (BICRO-39) (80% v. 70%, p=0.05) but not in FIM and FAM scales (85.4% v. 88.9%, not significant). Median changes on individual subscales were small, reflecting the diversity of the clinical population; however, 40% of outreach but only 20% of information participants made a clinically significant improvement of at least 2 points on at least one BICRO-39 scale. The cohort included patients up to 20 years post injury, and the authors noted a weak positive correlation between time since injury and extent

of improvement. There were no significant improvements in socialising, predictive employment or anxiety and depression.¹⁷³ | 1+

In one small retrospective cohort study (n=55) which used the European Brain Injury Questionnaire, patients with a traumatic brain injury who received post acute community based rehabilitation subjectively reported improved psychosocial outcomes. The effect was demonstrated even for a subgroup (n=26) beyond two years post injury. Carers in this subgroup did not report the same improvements as patients.¹⁷² | 3

The British Society of Rehabilitation Medicine and Royal College of Physicians, commenting on rehabilitation in the community, recommend that it “should move progressively from formal therapy to a guided and supported resumption of chosen activities over months or years.”¹⁷⁵

10.3 TELEMEDICINE

Scotland is a demographically varied nation with areas of high density urbanisation as well as many large areas which are remote and rural. Telerehabilitation (TRH) is a potentially useful delivery method for outreach rehabilitation.

10.3.1 DEFINITIONS

Telehealth is the provision of health care to patients at a distance using a range of technologies, such as (but not limited to) mobile phones, internet services, digital televisions, video-conferencing and self monitoring equipment.

Telecare is the use of technology (for example, falls monitors, motion sensors, alarms) to support individuals with a range of health and/or social care needs to live more independently and remain at home safely. These services are mainly provided by local authorities.

Telerehabilitation is the provision of rehabilitation services at a distance using telecommunications technology as the delivery medium.¹⁷⁶

10.3.2 LIMITATIONS IN THE EVIDENCE BASE

Many patients with a brain injury have particular difficulties with new learning and concentration. It may be unsafe to assume that telerehabilitation strategies shown to be effective in other conditions could be extrapolated to be effective in patients with a brain injury. One crossover study found that younger participants with TBI did less well than older participants following stroke at learning to use a telemedicine intervention despite having a presumed generational advantage of being more familiar with digital technologies.¹⁷⁷ For this section of the guideline, evidence from studies where the majority of the population did not have TBI was excluded.

There are also concerns about the generalisability of some studies which originate from healthcare systems which are significantly different from NHSScotland.¹⁷⁸

10.3.3 INTERVENTIONS USING TELEREHABILITATION

One high quality systematic review considered TRH for different medical conditions.¹⁷⁹ RCTs involving patients with TBI showed TRH to be effective in reducing depressive symptoms, improving behavioural outcomes and increasing the probability of returning to employment. Non-randomised studies cited in this review suggested that TRH was as effective as standard methods. One quasi-experimental study showed that telephone groups were as effective as FTF groups in providing support and education with rural caregivers of people with brain injury. An observational study found that there was no difference in performance to retell stories between participants in the TRH or FTF groups. | 1++

The authors of one RCT cited in this systematic review, which showed that telephone counselling was more effective than usual care in patients with moderate to severe TBI measured up to one year post injury, aimed to replicate this result in a larger multicentre RCT using a more diverse patient group. This second RCT, however, did not show benefit of TRH in the main comparisons, or in pre-specified patient subgroups, nor was there any dose-response effect.¹¹⁴ The reasons for this inconsistent result are not clear, although may be related to subtle differences in how the treatment protocols were implemented by counsellors providing the interventions. The authors concede the possibility that the treatment may simply have been ineffective in the specific population in this trial.

1⁺⁺

A small controlled trial (n=20) compared CBT delivered either remotely or face-to-face with an education intervention control in patients with chronic TBI and reported that CBT was more effective. The authors conclude that CBT administered either by telephone or in a FTF group setting can significantly improve emotional wellbeing in chronic ABI (*see section 6.2.1*).¹¹⁵

2⁺

One small, randomised crossover study with a high drop-out rate reported that two types of cognitive intervention using diaries/calendars were of comparable effectiveness. In one group the intervention was delivered mainly using the internet.¹⁸⁰

1⁻

A small case series of the use of videophone support for carers of patients with severe brain injury following discharge from hospital included only nine patients. Although the videophone support was reported to be acceptable to participants, no conclusions regarding effectiveness or outcomes could be drawn from this report.¹⁸¹

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Further information about follow up after acute admission for head injury, including the use of telephone follow up, can be found in section 9 of SIGN 110 on early management of patients with a head injury.³



Where further rehabilitation is indicated for patients with brain injury who are discharged from inpatient care, it may be offered by telephone or face-to-face methods to alleviate long term burdens due to depression, behavioural and cognitive consequences.

10.4 DISCHARGE PLANNING

Early assessment of discharge needs and involvement of patients and carers are important in discharge planning. Discharge should be divided into three parts: pre-discharge, discharge and post-discharge. The level of intervention required by an individual will depend on their ability to participate.⁵



Discharge policies should be implemented for inpatient rehabilitation to home transitions for patients with brain injuries.

The strength of the evidence base is limited by ethical difficulties, for example randomly allocating treatment to some patients with brain injuries while discharging others as part of the design of an RCT. Furthermore, while many of the randomised studies carried out in this area involve patients with stroke,^{16, 182} the results of these are confirmed in observational studies in patients with brain injury.

10.4.1 DISCHARGE PLANNING

Planned discharge for patients with brain injuries has been associated with:

- improvement in knowledge of their disability¹⁸²
- improvement in Mayo Portland Adaptability Inventory results¹⁸³
- improvement in functional status¹⁸⁴
- slight decrease in mortality rates¹⁸⁴
- improvement in Activities of Daily Living scores¹⁶
- improvement in psychological re-integration and global functioning.¹⁸³

1⁺2⁺

3

Studies identified the need for individualised programmes and a focus on early intervention and participation.^{183,185-187}

Evidence has also suggested the potential for increased carer and patient stress levels and lack of integration back into family, community and activities of daily living if there were no planned discharge in place.⁵¹

It may be helpful to consider planned discharge as a specific and distinct phase following on from acute care, post-acute care and linked to improved community reintegration. Such phases should be linked in a planned manner, appropriate to each NHS area.¹⁸⁶

D Planned discharge from inpatient rehabilitation to home for patients who have experienced an ABI provides beneficial outcomes and should be an integrated part of treatment programmes.

SIGN 118 on Management of patients with stroke: rehabilitation, prevention and management of complications, and discharge planning includes the following evidence statement and good practice point on discharge planning.⁵

Discharge planning should be documented in a discharge document. Discharge documents may be paper or electronic (eg in Electronic Clinical Communications Implementation format). See SIGN 128, the SIGN discharge document for further advice on discharge documentation.¹⁸⁸

The following information should be accurately and legibly displayed in the discharge documents:

- Diagnoses
- Investigations and results
- Medication and duration of treatment if applicable
- Levels of achievement, ability and recovery (including patient goals and outcome measures)
- Team care plan
- Further investigations needed at primary care level with dates
- Further investigations needed at hospital and dates
- Further hospital attendance with dates (including follow-up therapy and review arrangements)
- Transport arrangements
- The hospital name, hospital telephone number, ward name or number, ward telephone number
- Consultant's name and named nurse
- The date of admission and discharge.

Consideration should be given to such information being retained by the patient as a patient-held record, to allow all members of the primary care team, allied health professionals (AHPs) and care agencies to see clearly what the care plan for the patient should be. The wishes of the patient in respect of the confidentiality of this record should be paramount. There is evidence that patient-held records may enhance the patient's understanding and involvement in their care.¹⁸⁹ There is also evidence to show that discharge planning increases patient satisfaction.¹⁹⁰

- ✓ At the time of discharge, the discharge document should be sent to all the relevant agencies and teams.

10.4.2 PRE-DISCHARGE

The following evidence statements and recommendations are drawn from SIGN 118.⁵

Pre-discharge home visits performed by various members of the multidisciplinary team (usually an occupational therapist) aim to give staff (hospital and community), patients and carers the opportunity to identify actual and likely problems, as well as to address any other needs that the patient/carer may have.

The UK College of Occupational Therapists defines a home visit as a visit to the home of a hospital inpatient which involves an occupational therapist in accompanying the patient to assess his/her ability to function independently within the home environment or to assess the potential for the patient to be as independent as possible with the support of carers.¹⁹¹

✓ The pre-discharge process should involve the patient and carer(s), primary care team, social services and allied health professionals as appropriate. It should take account of the domestic circumstances of the patient or, if the patient lives in residential or sheltered care, the facilities available there.

✓ Essential alterations to the patient's home should be completed and necessary aids installed prior to discharge.

Pre-discharge home visits are considered a vital part of the discharge planning process.¹⁹²

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D Pre-discharge home visits should be undertaken for patients who require them.

10.4.3 POST DISCHARGE

More research is required regarding optimal post-discharge care for patients with brain injuries following inpatient rehabilitation. The NHSScotland National Managed Clinical Network for Acquired Brain Injury (www.sabin.scot.nhs.uk) has mapped services in each NHS Board area.

11 Provision of information

This section reflects the issues likely to be of most concern to patients and their carers. These points are provided for use by health professionals when discussing brain injuries with patients and carers and in guiding the production of locally produced information materials.

11.1 SOURCES OF FURTHER INFORMATION

11.1.1 NATIONAL ORGANISATIONS PROVIDING SUPPORT FOR PATIENTS

Brain and Spine Foundation

3.36 Canterbury Court, Kennington Park, 1-3 Brixton Road, London SW9 6DE

Tel: 020 7793 5900 • Fax: 020 7793 5939

www.brainandspine.org.uk • Email: info@brainandspine.org.uk

Brain and Spine Helpline: 0808 808 1000

Email: helpline@brainandspine.org.uk

The Brain and Spine Foundation develops research, education and information programmes aimed at improving the prevention, treatment and care of people affected by disorders of the brain and spine.

Headway – The Brain Injury Association

Scotland Office, Astley Ainslie Hospital, Canaan Lane, Edinburgh EH9 2HL

Tel: 0131 537 9116 • Helpline: 0808 800 2244

www.headway.org.uk • Email: office@edinburgh.org.uk

Headway is a charity set up to give help and support to people affected by a head injury. A network of local groups throughout the UK offers a range of services including rehabilitation programmes, carer support, community outreach and respite care.

Health and Social Care Alliance Scotland

Venlaw Building, 349 Bath Street, Glasgow G2 4AA

Tel: 0141 404 0231 • Fax: 0141 246 0348

www.alliance-scotland.org.uk • Email: info@alliance-scotland.org.uk

Health and Social Care Alliance Scotland represents the two million people who live with long term conditions in Scotland. It has members drawn from over 250 organisations and works as a conduit between these groups, the people they represent and key stakeholders across government and statutory services.

Momentum Head Office

Pavilion 7, Watermark Park, 325 Govan Road, Glasgow, G51 2SE

Tel: 0141 419 5299 • Fax: 0141 419 0821

www.momentumscotland.org • Email: headoffice@momentum.org

Momentum is a voluntary organisation offering a range of support and rehabilitation programmes to those who have had a head injury.

National Managed Clinical Network for Acquired Brain Injury

NMCN Team, 2nd Floor, Waverley Gate, 2 - 4 Waterloo Place, Edinburgh, EH1 3EG

Tel: 0131 465 5574

www.sabin.scot.nhs.uk • Email: susan.whyte@nhslothian.scot.nhs.uk

The National Managed Clinical Network for Acquired Brain Injury is a Scottish national network. Its aim is to improve access to and the quality of services for children and adults with acquired brain injury.

Scottish Head Injury Forum

SHIF, c/o Charles Bell Pavilion, Astley Ainslie Hospital, 133 Grange Loan, Edinburgh EH9 2HL
www.shif.org.uk • Email: scottishhif@aol.co.uk

A registered Scottish charity with an educational purpose that organises training events aimed at professionals with limited specialist knowledge of brain injury but who treat or work with brain injured people as part of a wider remit.

Scottish National Disability Information Service

UPDATE, Hays Community Business Centre, 4 Hay Avenue, Edinburgh, EH16 4AQ
Tel: 0131 669 1600
www.update.org.uk • Email: info@update.org.uk

Range of disability information from commonly asked questions through to equipment information, holiday information and local sources of help and advice.

11.1.2 NATIONAL ORGANISATIONS PROVIDING SUPPORT FOR CARERS AND FAMILIES

Carers Scotland

The Cottage, 21 Pearce Street, Glasgow, G51 3UT
Tel: 0141 445 3070
www.carersuk.org/scotland

Carers Scotland provides information and advice to carers on all aspects of caring.

Contact a family – Scotland

Craigmillar Social Enterprise and Arts Centre, 11/9 Harewood Road, Edinburgh, EH16 4NT
Tel: 0131 659 2930

Helpline: 0808 808 3555 • Textphone: 0808 808 3556 • Email: helpline@cafamily.org.uk
www.cafamily.org.uk • Email: scotland.office@cafamily.org.uk

Contact a Family is a charity which provides support, information and advice to families of children and young people with a disability or health condition.

Crossroads Caring Scotland

24 George Square, Glasgow, G2 1EG
Tel: 0141 226 3793
www.crossroads-scotland.co.uk

Crossroads provides practical support to carers.

Princess Royal Trust for Carers in Scotland

Charles Oakley House, 125 West Regent Street, Glasgow G2 2SD
Tel: 0141 221 5066 • Fax: 0141 221 4623
www.carers.org • Email: info@carers.org

The Princess Royal Trust for Carers in Scotland works to improve support, services and recognition for anyone living with the challenges of caring, unpaid, for a family member or friend who is ill, frail, disabled

or has mental health or addiction problems.

11.2 CHECKLIST FOR PROVISION OF INFORMATION TO PATIENTS

This section gives examples of the information patients/carers may find helpful at the key stages of the patient journey. The checklist was designed by members of the guideline development group based on their experience and their understanding of the evidence base. The checklist is neither exhaustive nor exclusive.

At ALL stages	
Healthcare professionals should:	<ul style="list-style-type: none"> ensure that advice and support from the multidisciplinary team for patients (and, where appropriate, carers) is available in a variety of formats, taking account of each patient's communication abilities.
In primary care	
At presentation to primary care:	<ul style="list-style-type: none"> explain to patients the importance of accurately recording the full history including when problems were first noted, by whom and how they manifest ascertain what information or advice the patient was given if they attended the emergency department and reiterate this information (see also SIGN 110, Annexes 8-12)³ if the patient is presenting following MTBI in the post-acute period, provide reassurance and information about the likelihood of good prognosis.
At referral for further assessment:	<ul style="list-style-type: none"> explain to the patient and carers why they are being referred for further assessment and where this assessment will be carried out. ensure that the patient understands what they can do to help themselves and provide written information, if available.
At assessment appointment(s)	
The specialist team receiving the referral should:	<ul style="list-style-type: none"> ensure the patient receives information about the process which will follow referral, including likely timescale and who will be involved keep patients advised of correspondence with other members of the rehabilitation team when arranging further assessments.
Following assessment appointment(s)	
Specialist team should:	<ul style="list-style-type: none"> ensure that the referring healthcare professional is kept informed of any outcome and interventions that they should support or be involved in consider the inclusion of patient and family in goal setting or case planning.
At discharge from rehabilitation	
Specialist team should:	<ul style="list-style-type: none"> provide information tailored to the patient's individual needs and communication abilities which includes contact details for any liaison or outreach professionals who can provide ongoing contact and support following discharge.

12 Implementing the guideline

This section provides advice on the resource implications associated with implementing the key clinical recommendations, and advice on audit as a tool to aid implementation.

12.1 IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each NHS Board and is an essential part of clinical governance. Mechanisms should be in place to review care provided against the guideline recommendations. The reasons for any differences should be assessed and addressed where appropriate. Local arrangements should then be made to implement the national guideline in individual hospitals, units and practices.

The National Managed Clinical Network for Acquired Brain Injury (SABIN) is a Scottish national network established by the National Services Division in 2007. Its aim is to improve access to and the quality of services for children and adults with ABI. The Network will support the launch of the SIGN guideline through a combination of education events and other means of raising awareness and reference to the guideline. Full details will be available from the SABIN website (www.sabin.scot.nhs.uk).

12.2 RESOURCE IMPLICATIONS OF KEY RECOMMENDATIONS

No recommendations are considered likely to reach the £5 million threshold which warrants full cost impact analysis.

12.3 AUDITING CURRENT PRACTICE

A first step in implementing a clinical practice guideline is to gain an understanding of current clinical practice. Audit tools designed around guideline recommendations can assist in this process. Audit tools should be comprehensive but not time consuming to use. Successful implementation and audit of guideline recommendations requires good communication between staff and multidisciplinary team working.

The NHSScotland National Managed Clinical Network for Acquired Brain Injury has developed clinical standards for adults aged 16–65 years with TBI.¹⁹³ These standards define essential criteria which are expected to be met where services for people with TBI are provided, and desirable criteria, which are being met in some parts of the service, and which demonstrate levels of quality which other providers of a similar service should strive to achieve. Desirable criteria should be regarded as developmental and should still be met, albeit in a longer timescale to the essential criteria. Where criteria from these standards reflect recommendations from this guideline, this is indicated with an asterisk below.

The guideline development group has identified the following as key points to audit to assist with the implementation of this guideline:

- the proportion of patients managed by a dedicated multidisciplinary inpatient (or community based) team*
- the proportion of patients with planned discharge from rehabilitation to home which is coordinated by a designated member of the multidisciplinary team*
- the proportion of patients in states of disordered consciousness assessed using the Coma Recovery Scale*
- the proportion of patients recorded as having communication deficits on initial screening by admitting staff that is then referred on to SLT
- a case-note review (eg last six months) of patients documented to have dysphagia, answering the following questions: were there persisting concerns about the management of a patient's dysphagia following bedside assessment? If so, was the patient referred for instrumental assessment (eg videofluoroscopy or FEES)? If not, why was the patient not referred for instrumental assessment?

- the proportion of patients with cognitive impairment after TBI that receives interventions for cognitive impairments as part of a comprehensive-holistic programme delivered by a multidisciplinary team
- the proportion of patients with memory impairment after TBI that receives training in the use of compensatory memory strategies
- the proportion of patients with attention impairment after TBI that receives training in the use of strategies to manage attention problems in personally relevant situations
- the proportion of patients with executive functioning impairments after TBI that receives training in the use of metacognitive strategies focused on managing difficulties with planning, problem solving and goal management in personally relevant situations.

12.4 ADDITIONAL ADVICE TO NHSSCOTLAND FROM HEALTHCARE IMPROVEMENT SCOTLAND AND THE SCOTTISH MEDICINES CONSORTIUM

In October 2011, the Scottish Medicines Consortium (SMC) advised that botulinum toxin type A (Xeomin®) is accepted for use within NHS Scotland for adults with post-stroke spasticity of the upper limb presenting with flexed wrist and clenched fist.

In March 2011, SMC advised that botulinum toxin type A (Botox®) is accepted for use within NHSScotland for adults with focal spasticity, including the treatment of wrist and hand disability due to upper limb spasticity associated with stroke.

In January 2013, SMC advised that clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) is accepted for use within NHSScotland for focal spasticity associated with stroke, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy.

13 The evidence base

13.1 SYSTEMATIC LITERATURE REVIEW

The evidence base for this guideline was synthesised in accordance with SIGN methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Evidence and Information Scientist. Databases searched include Medline, Embase, Cinahl, PsycINFO and the Cochrane Library. The year range covered was 1990-2011. Internet searches were carried out on various websites including the US National Guidelines Clearinghouse. The main searches were supplemented by material identified by individual members of the development group. Each of the selected papers was evaluated by two members of the group using standard SIGN methodological checklists before conclusions were considered as evidence.

13.1.1 LITERATURE SEARCH FOR PATIENT ISSUES

At the start of the guideline development process, a SIGN Evidence and Information Scientist conducted a literature search for qualitative and quantitative studies that addressed patient issues of relevance to rehabilitation of patients with a brain injury. Databases searched include Medline, Embase, Cinahl and PsycINFO, and the results were summarised and presented to the guideline development group.

13.2 RECOMMENDATIONS FOR RESEARCH

The guideline development group was not able to identify sufficient evidence to answer all of the key questions asked in this guideline (*see Annex 1*). The following areas for further research have been identified:

- pharmacological and psychological therapies for the management of different symptoms in patients following MTBI
- the use of virtual reality training in rehabilitation following ABI
- the effectiveness and cost-effectiveness of specific therapies for spasticity in patients following ABI, including:
 - ~ physical therapies including casting and stretching
 - ~ pharmacological therapies
 - ~ functional electrical stimulation
 - ~ surgery
 - ~ occupational therapy
- the effects of AFO on mobility and muscle activity in discrete TBI populations
- physical interventions (eg fitness training, treadmill training, use of walking aids) for recovery of mobility and function in discrete TBI populations
- pharmacological and psychological therapies for the management of depression in patients with ABI
- pharmacological and psychological therapies for the management of patients in the minimally conscious and vegetative state
- pharmacological therapies for the management of anxiety disorders in patients with ABI
- the effectiveness of rhythmic auditory stimulation in improving elements of gait in patients with ABI
- a framework for vocational rehabilitation research which:
 - ~ addresses insensitivity regarding return to work outcomes
 - ~ takes account of the heterogeneous nature of rehabilitation
 - ~ develops a standardised measure of VR needs
 - ~ explores the provision of an intervention which is both standardised and allows for individualisation
 - ~ explores the long term impact of VR and employment after TBI
- therapies to manage incontinence in patients following ABI
- therapies to improve problems with language or functional communication

- therapies to improve disordered social communication skills
- restorative exercises to improve dysphagia
- restitution cognitive rehabilitation through computerised technology
- development and evaluation of interventions that can improve insight and awareness given the potential impact of insight difficulties on the ability to engage in rehabilitation. It is vital that studies also examine the impact of increased awareness/insight on participation in rehabilitation and long term outcome.

13.3 REVIEW AND UPDATING

This guideline was published in 2013 and will be considered for review in three years. Any updates to the guideline in the interim period will be noted on the SIGN website: www.sign.ac.uk

14 Development of the guideline

14.1 INTRODUCTION

SIGN is a collaborative network of clinicians, other healthcare professionals and patient organisations and is part of Healthcare Improvement Scotland. SIGN guidelines are developed by multidisciplinary groups of practising clinicians using a standard methodology based on a systematic review of the evidence. Further details about SIGN and the guideline development methodology are contained in SIGN 50: A Guideline Developer's Handbook, available at www.sign.ac.uk

14.2 THE GUIDELINE DEVELOPMENT GROUP

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The membership of the guideline development group was confirmed following consultation with the member organisations of SIGN. All members of the guideline development group made declarations of interest and further details of these are available on request from the SIGN Executive.

Guideline development and literature review expertise, support and facilitation were provided by the SIGN Executive. All members of the SIGN Executive make yearly declarations of interest and further details of these are available on request.

Mrs Lesley Forsyth	<i>Events Coordinator</i>
Mrs Karen Graham	<i>Patient Involvement Officer</i>
Mr Campbell Reynolds	<i>Distribution and Office Coordinator</i>
Mr Stuart Neville	<i>Publications Designer</i>
Ms Gaynor Rattray	<i>Guideline Coordinator</i>

14.3 ACKNOWLEDGEMENTS

SIGN is grateful to the following former members of the guideline development group and others who have contributed to the development of the guideline.

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Mr Kevin Williams	<i>Lay representative, Isle of Lewis</i>

14.4 CONSULTATION AND PEER REVIEW

14.4.1 NATIONAL OPEN MEETING

A national open meeting is the main consultative phase of SIGN guideline development, at which the guideline development group presents its draft recommendations for the first time. The national open meeting for this guideline was held on 5 December 2011 and was attended by 137 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN website for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

14.4.2 SPECIALIST REVIEW

This guideline was also reviewed in draft form by the following independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. The guideline group addresses every comment made by an external reviewer, and must justify any disagreement with the reviewers' comments. All expert referees made declarations of interest and further details of these are available on request from the SIGN Executive.

SIGN is very grateful to all of these experts for their contribution to the guideline.

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14.4.3 SIGN EDITORIAL GROUP

As a final quality control check, the guideline is reviewed by an editorial group comprising the relevant specialty representatives on SIGN Council to ensure that the specialist reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. The editorial group for this guideline was as follows. All members of the SIGN Editorial group make yearly declarations of interest and further details of these are available on request from the SIGN Executive.

Dr Keith Brown	<i>Chair of SIGN; Co-Editor</i>
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Dr Sara Twaddle	<i>Director of SIGN; Co-Editor</i>

Abbreviations

AAC	alternative and augmentative communication strategies
ABI	acquired brain injury
ADL	activities of daily living
AFO	ankle foot orthosis
AHP	allied health professional
BDI	Beck Depression Inventory
BICRO-39	Brain Injury Community Rehabilitation Outcome-39
BNF	British National Formulary
BoNT	botulinum neurotoxin therapy
CBT	cognitive behavioural therapy
CI	confidence interval
CMP	contingency management procedures
CNS	central nervous system
CRS-R	Coma Recovery Scale – Revised
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, fourth edition
ED	emergency department
ERABI	Evidence Based Review of Rehabilitation of Moderate to Severe Acquired Brain Injuries
FAM	Functional Assessment Measure
FEES	fibreoptic endoscopic evaluation of swallowing
FIM	Functional Independence Measure
FTF	face-to-face
GCS	Glasgow Coma Scale
GMC	General Medical Council
GOS	Glasgow Outcome Scale
GOS-E	Extended Glasgow Outcome Scale
HADS	Hospital Anxiety and Depression Scale
ICD-10	International Classification of Diseases and Related Health Problems, tenth revision
LSVT	Lee Silverman Voice Treatment
MA	marketing authorisation
MCS	minimally conscious state
MDT	multidisciplinary team
MTA	multiple technology appraisal
MTBI	mild traumatic brain injury
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence

NMES	neuromuscular electrical stimulation
OT	occupational therapy
PBI	positive behaviour interventions
PCS	post-concussional syndrome
PDA	personal digital assistant
PICO	population, intervention, comparison, outcome
PTA	post traumatic amnesia
PTSD	post traumatic stress disorder
RCT	randomised controlled trial
SIGN	Scottish Intercollegiate Guidelines Network
SMC	Scottish Medicines Consortium
SPPARC	Supporting Partners of People with Aphasia in Relationships and Conversation
TBI	traumatic brain injury
TRH	telerehabilitation
TT	treadmill training
VR	vocational rehabilitation
VS	vegetative state
WHO	World Health Organisation

Annex 1

Key questions used to develop the guideline

This guideline is based on a series of structured key questions that define the target population, the intervention, diagnostic test, or exposure under investigation, the comparison(s) used and the outcomes used to measure efficacy, effectiveness, or risk. These questions form the basis of the systematic literature search.

<i>Key question</i>		<i>See guideline section</i>
1.	In patients who have had a mild/minor brain injury and later present (in primary care) what assessment/questions can be asked/applied to facilitate triage to the appropriate service?	3.1-3.3
2.	<p>What evidence is there that the following interventions in patients with brain injuries improve measurable components of physical function (see below)?</p> <ul style="list-style-type: none"> • daily/repetitive specific physiotherapy (early/late) • daily/repetitive specific occupational therapy (early/late) • daily/repetitive practice of remedial activities (early/late) <ul style="list-style-type: none"> ~ computer based exercise rehabilitation/virtual reality rehabilitation ~ Nintendo Wii™ ~ physical games, eg basketball, racquet games etc • daily/repetitive practice of functional activities (early/late) • constraint induced therapy. 	4.3 4.1.5
3.	<p>What is the evidence for the effectiveness of the following interventions in the management of spasticity and muscle tone in patients with brain injuries:</p> <ul style="list-style-type: none"> • exercise • splinting • electrostimulation /functional electrical stimulation • anti-spasticity drugs (baclofen, tizanidine, dantrolene and diazepam) • botulinum toxin • surgery • physiotherapy (early/late) • occupational therapy (early/late) • optimum seating and positioning including specialist equipment? 	4.2
4.	<p>In patients with brain injuries and continence problems, which of the following interventions are effective in improving continence:</p> <ul style="list-style-type: none"> • timed voiding/bladder retraining • oestrogen • anticholinergics, eg oxybutynin • biofeedback • anticholinergics • duloxetine • catheterisation? 	4.4

5.	<p>What is the evidence for the effectiveness of the following interventions in improving gait, balance and mobility in patients with brain injuries (consider also duration of therapy):</p> <ul style="list-style-type: none"> • treadmill training • biofeedback (any type) • electrostimulation (ES or FEES) • orthoses (any type) • task-related training • neurophysiological training • physical fitness training • electromechanical assisted gait training • repetitive task training • walking aids (sticks, zimmers, walking frames) • strengthening • intensity? 	4.1
6a.	<p>In patients with brain injuries, what is the evidence that the following interventions lead to reductions in impairment:</p> <ul style="list-style-type: none"> • daily/repetitive practice of activities (early/late)? 	5.3-5.7
6b.	<p>In patients with brain injuries, what is the evidence that the following interventions lead to improvement in self management of disability:</p> <ul style="list-style-type: none"> • compensatory approaches which would include; electronic aids (ie neuropage, sense cam, watches, ictaphones, mobile phones, alarms, PDAs), diaries, environmental modification • cognitive approaches including errorless learning, enhanced learning, mnemonics, holistic approach, paper based therapies? 	5.3-5.7
6c.	<p>In patients with brain injuries is there any evidence to guide the assessment and management of insight/awareness of the patient?</p>	5.2
7.	<p>Which of the following interventions reduce challenging/aggressive behaviour (eg absconding, non-cooperation, aggression, apathy) in patients with brain injury:</p> <ul style="list-style-type: none"> • any psychological treatment • any pharmacological treatment? 	6.1
8.	<p>What evidence is there that the following interventions in patients with brain injuries improve emotional lability, depression and anxiety:</p> <ul style="list-style-type: none"> • antidepressants • anxiolytics • any psychological therapy? 	6.2

9.	<p>Do the following speech and language therapy interventions (speech motor/oral exercises, computer based treatments, introduction of alternative and augmentative communication strategies (AAC), introduction of impairment based strategies, introduction of alternative/total communication strategies, communication partner training, eg SPPARC (Supporting Partners of People with Aphasia in Relationships and Conversation)) reduce/improve:</p> <ul style="list-style-type: none"> • dysarthria • dysphasia/aphasia • articulatory dyspraxia/apraxia of speech • acquired dyslexia • acquired dysgraphia • social communication skills/pragmatic impairment/right hemisphere language disorder and improve communicative effectiveness/functional communication? 	7.1
10.	<p>Compared with bedside evaluation alone, does instrumental assessment of dysphagia (eg videofluoroscopy; fibreoptic endoscopic evaluation of swallowing (FEES)) allow:</p> <ul style="list-style-type: none"> • more frequent resumption of oral diet and faster resumption of oral diet • more frequent removal of alternative feeding tubes and quicker removal of alternative feeding tubes? 	7.2.1
11.	<p>What is the evidence that restorative exercises improve outcome in dysphagia compared with compensatory techniques alone?</p>	7.2.2
12.	<p>In patients with brain injury, what is the evidence that oral hygiene programmes reduce the incidence and severity of aspiration-associated chest infection and pneumonia?</p>	7.3
13.	<p>What is the evidence that vocational rehabilitation improves outcome for patients with brain injuries?</p>	8.1, 8.2
14.	<p>In patients with brain injuries is rehabilitation in a specialist unit (a unit which specialises in the care of patients with ABI, ie a dedicated neuro-rehabilitation unit) better than rehabilitation in a non-specialised/general unit in terms of:</p> <ul style="list-style-type: none"> • increased understanding and awareness of condition • reduced aggressive/challenging behaviours • more rapid return to work • more rapid return to education • more rapid return to carer role • more rapid return to leisure pursuits • reduced carer stress • improved physical functioning • improved functional ability (activities of daily living - ADL)? 	10.1

15.	<p>Is there any evidence of improvement in the following if patients with brain injuries follow a formally agreed discharge pathway (goal planning meetings, pre-discharge planning) when they are discharged from rehab to home:</p> <ul style="list-style-type: none"> • increased understanding and awareness of condition • reduced aggressive/challenging behaviours • more rapid return to work • more rapid return to education • more rapid return to carer role • more rapid return to leisure pursuits • reduced carer stress • improved physical functioning • improved functional ability (activities of daily living - ADL)? 	10.4
16.	<p>What is the evidence that, in patients with brain injuries who live in remote and rural areas or have limited access to centralised care, the following are improved with telemedicine (remote assessment and delivery of interventions) compared to usual care:</p> <ul style="list-style-type: none"> • mood/depression (ie HADS, BDI, etc) • goal attainment • increased ability to carry out personal or domestic activities of daily living – by self report, carer/relative report/occupational therapy (OT) assessment • return to independent living • return to caring role • return to education • return to work • return to leisure pursuits • carer burden • Extended Glasgow Outcome Scale (GOS-E)? 	10.3
17.	<p>In patients with brain injuries who are minimally conscious or in a persistent vegetative state, do sensory stimulation and/or pharmaceutical interventions (zopiclone, zolpidem, levodopa) improve responsiveness or awareness?</p>	9.1-9.4
18.	<p>In patients with brain injuries is rehabilitation in the community by an MDT better than usual care (GP etc) in terms of:</p> <ul style="list-style-type: none"> • increased understanding and awareness of condition • reduced aggressive/challenging behaviours • more rapid return to work • more rapid return to education • more rapid return to carer role • more rapid return to leisure pursuits • reduced carer stress • improved physical functioning • improved functional ability (ADL)? 	10.2

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