



The effectiveness of a case management approach to care for adults who suffer trauma through injury: protocol for a systematic review.

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Introduction

Background

As a major cause of disability, it is estimated that injuries account for 6% of all Years Lived with Disability (YLD) (WHO, 2014). The main causes of injury are violence, traffic accidents, attempted suicide, drowning, poison and war which can leave survivors with temporary or permanent disability (WHO, 2014). Trauma through injury can be the result of blunt force causing concussion, deep cuts or broken bones or it can be the result of penetrating trauma such as an open wound (NIGMS, 2018). Hospital Episode Statistics (HES) indicate a 117% increase in trauma patients in the UK for the period 2008-17 (Moran et al., 2018).

Evidence has also indicated a rise in the survival of trauma patients due to improvements in critical care such as the establishment of Major Trauma Centres (Galgano *et al.*, 2017; Moran et al., 2018). The increase in Major Trauma Centres have been associated with reductions in mortality in the US, Australia and the UK (Moran et al., 2018).

The impact of trauma through injury

For the trauma patient there may be significant physical, social and lifestyle consequences.

Traumatic brain injury (TBI) can impact multiple domains of health causing a range of significant behaviour and lifestyle changes. This can affect relationships, employment, independence, social skills and hence overall quality of life (Fleminger and Ponsford, 2005; Headway, 2020). Depression, anxiety and an increased risk of substance abuse following TBI are associated with poorer rehabilitation outcomes (Fleminger and Ponsford, 2005; Weil et al., 2016). In some cases, Chronic Traumatic Encephalopathy can lead to suicidal behaviour (Galvano et al., 2017). Fleminger and Ponsford (2005) described the potential impacts of TBI in terms of neuro-physical and neuro-psychiatric sequelae. The neuro-physical impacts are many but include sensory loss, sexual dysfunction, loss of coordination (khan et al., 2003), ataxia, incontinence (Fleminger and Ponsford, 2005) and speech difficulties (Headway, 2020). Neuro-psychiatric problems impact memory, attention, behavioural control and regulation of mood (khan et al., 2003; Fleminger and Ponsford, 2005). Hidden problems where hormonal imbalances lead to personality changes manifest as mood swings or anger (Headway, 2020). The resulting social disability can affect practicalities such as competency to drive, give informed consent and manage finances necessitating retraining and development of individualised compensatory strategies (khan et al., 2003). One example of a practical challenge is returning to employment. A change of role, a reduction of hours or adaptations to the workplace may be required. In the UK under the Equality Act 2010, employers are required to make reasonable adjustments for employees returning to the workplace with a disability but this entails consultation with the employer which may also involve divulging personal information (Headway, 2020). Some job centres offer a Disability Employment Advisor (DEA) service that provides specific advice about returning to work,

however this service has been a reduced and is no longer universally available (Headway, 2020). The effects on the employment status of carers can also be significant leading to a decrease in working hours, a lack of support from employers or in some cases early retirement (Headway, 2012). Carers may also experience additional burden to physical and emotional health, social life and finances which in turn may impact the ability to provide care (Headway, 2012).

Injury to the spinal cord can cause complete or incomplete paraplegia or tetraplegia which affects movement and sensation below the site of injury (Spinal Injuries Association, 2020). As with TBI, this can have multiple life altering consequences. Secondary medical complications include respiratory, gastrointestinal, and urological disorders (Munce et al., 2013) which increase the risk of re-hospitalization and negatively impact quality of life (Dorsett and Geraghty, 2008). Pressure ulcers are a major complication which involve life-long medical treatment (Dorset and Geraghty, 2008). Approximately 80% of patients develop ulcers which can entail months of bed rest or in some cases surgery, making daily skin checks a vital part of self-care (SIA, 2020). As with TBI, patients face a range of logistical, housing, financial and mental well-being challenges in adapting to life with a disability (Bloemen-Vrencken et al., 2005). Community reintegration is especially demanding for a patient with SCI (Boucher et al., 2019) and the transition from hospital to home may be gradual and initiated with home visits (SIA, 2020). Although housing may require appropriate adaptation, a study of UK adults found 49% of respondents had experienced a delay in acquiring the necessary housing adaptations (Kennedy et al., 2010). Transportation may also prove challenging which can lead to feelings of isolation (Boucher et al., 2019). Other issues include lack of access to a quality wheelchair, persistent chronic pain, reductions in sporting activities and employment (Kennedy et al., 2010). Poor quality of life

may be further exacerbated by inadequate coping skills and self-neglect making intervention strategies that facilitate self-care, necessary resources and patient education essential (Dorsett and Geraghty, 2008). A systematic review by Barclay et al. (2014) found social and community participation was facilitated by adequate personal care and equipment, social support and appropriate occupational therapy, while barriers were issues with healthcare services and rehabilitation providers. And as with TBI patients, there is a risk of psychological impacts such as depression and suicide (Kennedy et al., 2010). Improving trauma care by removing barriers to services and social care may assist patients cope with the impact on their lives (WHO, 2014). A tailored case management plan may ensure appropriate service provision and support to maximise independence for injury survivors who face permanent disability and its associated challenges.

Case management

When contemporary case management emerged in the U.S. during the 1970s (Eastes, 2000) the focus was on coordination, management and cost control exclusively in the medical services as delivered by a nurse or social worker (Lukersmith, 2017). There were limitations to this approach which excluded patient involvement such as goal-setting and capacity building (Lukersmith, 2017). Case management has since evolved into a personalised patient centred service delivered in a variety of settings targeting a range of health conditions by case managers from both clinical and non-clinical backgrounds. Examples of where case management has been implemented for trauma care include amputation (Pasquina, 2004), Traumatic Brain Injury (Lannin et al., 2014) and Spinal Cord Injury (Bloemen-Vrencken et al., 2005). Case managers work with the trauma patient to identify current and future needs while working collaboratively with other professionals to coordinate support (British Association of Brain Injury and Complex Case Management,

2019). Case managers guide the rehabilitation process and offer support to the client and their family (Clark-Wilson and Holloway, 2015). However, patients are not just the recipients of the intervention but are engaged in the planning process to develop self-management skills (Ross et al., 2011). The patient's family, social circumstances, beliefs, attitudes and aspirations all guide formation of a personalised care plan (Clark-Wilson and Holloway, 2015). Case management transcends boundaries to include the non-clinical such as social and lifestyle impacts. Case managers may assist with organising appropriate housing adaptations (BABICM, 2019). Case managers may also serve as a link between employer and employee in a return to work context (Eliff, 1998). Other aims of case management have included reductions in unplanned use of services (Department of Health, 2005; Huntley et al., 2013), increased self-management (Goodman et al., 2010), improved quality of life (Lannin et al., 2014) and enhanced patient experience (Althaus et al., 2011; Ross et al., 2011).

Case managers come from diverse occupations for example, nursing, occupational therapy and social work. Training varies, from those with no medical training to clinicians (Franche et al., 2005). According to Finkelman (2011), many experts endorse nurses as the ideal candidate for the case management role. The nurse case manager may prevent unnecessary hospital admissions, improve patient experience and anticipate needs (Williams et al., 2011). As advanced practitioners they provide clinical care and health education to promote better self-management (Williams et al., 2011). Nurses may also be qualified to prescribe medicine which has the potential to reduce GP contact time. Case managers working in the independent sector come from both healthcare and non-healthcare professions but may develop specialist skills according their area of case management (Clark-Wilson and Holloway, 2015). Regardless of professional background, case managers must have the

appropriate skills and expertise to carry out the role effectively (Ross et al., 2011). Required skills identified by Ross et al. (2011) include interpersonal, problem-solving, the ability to advocate for the patient in a wider context and access to suitable training. A positive relationship between case manager and patient can be the basis for psycho-social support, assist with behaviour change and increase patient satisfaction (Ross et al., 2011).

Case management in the UK

In an acute setting in the UK, Trauma Coordinators play a key role in the case management of patients by ensuring good communication, support and liaising with other providers such as housing services (NICE, 2016). Within this setting case management has been found to identify and coordinate social services for vulnerable patients, clarify responsibilities within patient pathways, assist with delayed discharge and organise navigation from acute care to appropriate pathways such as rehabilitation services (Yarnell and Plumb, 2018). In a community setting case management may be funded by clinical commissioning groups (CCGs), social services or through litigation claims. However, public sector funded continuing care can entail an initial waiting period before assessment and is then dependent upon availability, eligibility criteria and funding (SIA, 2018; Clark-Wilson et al., 2016). In this context, patients with hidden cognitive or behavioural problems may not meet criteria for public sector funding (Clark-Wilson et al., 2016) with some forced to receive care in a nursing home rather than their own home (SIA, 2018). Independent case managers offer community care for injured clients with complex needs and may be assigned to coordinate rehabilitation through litigation claims or occasionally through statutory care (Clark-Wilson and Holloway, 2015). Many independent case managers belong to case management organisations such as British Association of Brain Injury and Complex Case Management and the Case Management Society UK. BABICM and CMSUK offer professional and

developmental support to registered case managers and require adherence to a joint Code of Ethics (Clark-Wilson and Holloway, 2015).

Existing evidence for the effectiveness of case management

Existing evidence from systematic reviews for the effectiveness of case management is mixed and covers a range of health conditions, however there are limited reviews evaluating case management for trauma through injury. One existing review focusing on TBI drew no conclusion in either direction (Lannin et al., 2014). Included studies (n=6) scored poorly on quality appraisal, and synthesis was not conducted due to the heterogeneity of participants, case management intervention, timing and outcome measures (Lannin et al., 2014). A further review evaluated a range of care programmes for adults with spinal cord injury but included only one case management intervention (Bloemen-Vrencken et al., 2005).

Restriction of the search strategy to only two databases, CINAHL and MEDLINE may have limited scope for identifying potential studies. The reviewer reported low quality of included studies and also drew no conclusion in either direction. As the two reviews were conducted in 2005 and 2014 and were restricted to TBI and SCI, there may be justification for a new broad review of recent research covering a range of injuries.

In addition, the complexity of case management has often been cited as a barrier to high quality research. Progress towards a commonly accepted definition or frame-work has been challenging for the case management community. This is due to heterogeneity in for example, model, service provider and setting which leads to both shared and contrasting case management components across care programmes. There is variation in interaction (homes, clinics, telephone), programmes are free standing or embedded in a clinical setting and case managers work independently or as part of a team (Hickam et al., 2013). Common core themes of case management have been described as meeting client needs by

coordinating and linking services for continuity of care and improved outcomes (Lee et al., 1998; Lannin et al., 2014) while others have included individualised delivery, collaboration and empowerment of the client (Schuttermaier et al., 2011). Potentially the most methodical approach to understanding case management has been proposed by researchers in Australia who developed a case management taxonomy designed to be applicable to all health conditions and for use in research on case management effectiveness and outcomes (Lukersmith, 2017). The Case Management Taxonomy (CMT) was developed inductively from a scoping mapping review of international case management literature, informed by validated scientific classifications and reviewed by an expert panel (Lukersmith, 2017). The CMT maps the case manager's actions, setting and the type and frequency of interaction to determine the case management model. Thomas et al., (2019) in the Cochrane Handbook for Systematic Reviews recommends taxonomies as tools to assist in development of eligibility criteria and the classification of study interventions in systematic reviews. Where there is adequate description of a coordinated care programme, the CMT may assist with determining whether the specific model being described fits under the umbrella of case management, regardless of what the model is called. This may enable systematic reviewers to include studies that were otherwise excluded from previous reviews on the basis of model name or title alone. Case manager is commonly used interchangeably with a range of titles such as care manager (Köpke and McCleery, 2015), care coordinator, case worker (Lukersmith et al., 2016) community matron (Challis et al., 2010) and patient navigator (Finkelman, 2011). Examples in practice include the community matron described as 'case managers with clinical nursing skills' (Challis et al., 2010, p. 16) and trauma coordinators (NICE, 2016). Given the rise in patients requiring multifaceted trauma care, the lack of systematic reviews with up-to-date searches evaluating trauma case management

across a range of conditions and limitations of previous research, further investigation into its effectiveness is warranted.

Objectives

To undertake a systematic review to determine the effectiveness of a case management approach to care for adults who have suffered trauma through injury compared to no care or an alternative of model care. The review will take a broad approach by including a range of international studies, case management models and injuries. Inclusion criteria guided by the CMT (Lukersmith, 2017) and combined with a comprehensive search strategy may yield additional evidence. The review further aims to use this range of evidence to determine if effect is modified by model of case management, discipline of case manager service provider, participant characteristics, risk of bias rating and length of intervention.

Methods

This protocol followed international standards for systematic review protocols by referring to the PRISMA-P elaboration and explanation paper (Shamseer et al., 2015). The systematic review will adhere to the PRISMA 27-item checklist and flowchart for transparent reporting of systematic reviews of healthcare interventions (Liberati et al., 2009).

Eligibility criteria

Studies will be selected according to the following criteria.

Study design The review will include randomized controlled trials (RCTs) which is recommended as a robust research design for investigating the effects of interventions (Chandler et al., 2019). Non-randomised trials risk introducing bias (Schünemann et al., 2019).

Participants Adults (>18 years) who have suffered trauma as a result of any type of injury and require a programme of coordinated care or rehabilitation. This systematic review will take a broad approach by including a range of physical injuries to increase the scope for analysis. All injuries of the head, neck, thorax, abdomen, spine, upper and lower extremities. Injury as a result of a slip, trip or fall, injuries suffered in the work-place, sporting injuries, general accident, self-harm, attempted suicide, injuries stemming from substance abuse, violence, disaster or war.

Intervention Case managers working independently or as part of a multi-disciplinary team will be included. Case management funded by the private sector, the public sector or third sector will be included as funding and access to resources may vary between these groups. Details of the case management intervention will be mapped using the CM Taxonomy to determine the model and actions. If a programme of care is described using a title other than case management but can be mapped using the CMT then this will be included as a case management intervention.

Exclusion:

1. Any studies that do not provide a description of case management or the case manager's actions (interventions). Any studies that do not provide a description of the comparison intervention.
2. Other non-injury health conditions unless they were the result of the injury or were pre-existing.

Comparators The control or comparison group will be an alternative non-case management programme of care, standard care or an alternative model of case management. A description of the programme content must be provided.

Outcomes Case management transcends the boundaries between the clinical, social and lifestyle aspects of life, as such the primary outcome will be patient quality of life (QoL) score as an indicator of the overall impact of the intervention. Quality of life is defined as a broad concept encompassing physical health (ex. fitness, symptoms, signs of disease and wellness), physical functioning (ability to perform daily activities and physical roles), social functioning and social health (relationships, social support and activities), psychological well-being (depression, anxiety), emotional well-being (life satisfaction, morale, control, coping and adjustment) and perceptions (Bowling, 2009). Only data that was collected using validated tools will be extracted.

Where measured independently of QoL, behavioural, physical, psychological or social functioning score will be included as secondary outcomes. Patient satisfaction scores will be used to assess and compare the quality of interventions. A reduction in the use of acute care services is cited as an aim of case management interventions (DoH, 2005; Althaus et al., 2011; Huntley et al., 2013; Stokes et al., 2015). As such, number of emergency department visits and readmissions to hospital will be included for both trial arms as a subjective outcome measure.

Setting Case management delivered in any setting including in a hospital or a community setting such as a home, work-place, clinic or by telephone without restriction on country or location.

Timing The length of the intervention and time to follow-up from baseline measurement must be stipulated.

Language and publication status There will be no search restriction in language or geographical location as case management is implemented globally. Unpublished

information will be eligible for inclusion to reduce publication bias. Efforts will be made to obtain translations of abstracts using Google translate or contacting authors.

Year of publication There will be no restriction in year of publishing as this review may include studies that can be mapped to the CM Taxonomy but were excluded in previous systematic reviews.

Information sources

The following electronic databases will be searched for published and unpublished studies:

- Cochrane Register of Controlled Trials (CENTRAL)
- CINAHL
- MEDLINE
- British Nursing Database
- OTseeker
- PDQ-Evidence
- NICE Evidence Search

To ensure literature saturation the reference section of included primary studies will be checked for relevant studies. The following case management society websites will be searched for additional grey literature:

- Case Management Society UK
- Case Management Society of Australia and New Zealand
- Case Management Society of America
- The British Association of Brain Injury and Complex Case Management.

Search strategy

Guidance was sought from an academic liaison at the University of York Information

Services to generate an initial search strategy which will be adapted to the syntax of each

database. An initial broad free-text search will be performed for case management,

synonyms of case management; different terms or types of injury (Table 1). Truncation and

wildcards will be used to find plurals or different spellings. Where subjects that are

irrelevant appear repeatedly in searches, 'NOT' will be applied to exclude the subject.

Where available on database filters, the age-group category of ‘all adults’ will be selected to exclude children. Where there is a filter option for ‘randomized controlled trials’ this will be chosen. If a wide range of irrelevant titles are found, the search strategy will be narrowed down using MeSH or subject trees to identify traumatic injury and case management categories. All search histories will be saved and made available upon request. RCTs will be searched for with no restriction on language or date.

Table 1: Initial search terms for electronic database searching.

Population	Intervention	Study design	
Broad terms: Trauma, injury, multiple trauma. Narrow terms: brain injur*, head injur*, TBI, traumatic brain injury poly-trauma, fracture*, spinal cord, paraplegia, orthopaedic, amput*, musculoskeletal. work-place, self-harm, suicide, violence, disaster, war veteran or servicemen or military, motor-vehicle injury.	Case manag*, co?ordinated care, community matron, patient cent?ed care, patient navigat*, continuity of care, care manage*, care plan*, discharge plan*, rehabilitation, nurse navigator, guided care, trauma nurse coordinator, trauma coordinator, client cent?ed, rehabilitation, care transition, integrated care.	Randomi?ed controlled trial, RCT.	OR 
AND 			

Sample of an initial search strategy for CINAHL database following assistance from an academic liaison:

Limiters: all adult, randomized controlled trial

S1) "case manage*" OR "patient navigat*" OR "nurse navigat*" .ti

S2) injur* OR accident* OR trauma* .ab

S3) "spinal cord injur*" OR sci or paraplegic OR quadriplegic .ab

S4) "brain Injur*" OR TBI OR "head injur*" OR "traumatic brain injur*" .ab

S5) S2 AND S3 AND S4

S6) S1 AND S5

Study records

Studies for screening will be uploaded to Rayyan QCRI a free online reference management software programme that facilitates collaboration (Ouzzani et al., 2016; Lefebvre et al., 2019). Citation abstracts and full-text PDFs will be uploaded for screening. Reasons for excluding full studies will be recorded.

Selection process

For transparency, the search process will be recorded on a PRISMA flow diagram which will be made available in the review (Liberati et al., 2009).

Stage 1 screening: The reviewer will screen titles, subject headings and abstracts for key words guided by population, intervention and study design (Table 2). In stage 1 screening, any coordinated care or rehabilitation programme will be selected. For those selected full-text articles will be obtained.

Stage 2 screening: Full text articles will be screened for inclusion. The CMT (Lukersmith, 2017) will be used to map the case management model and results will be recorded on data extraction forms. A record of the decision process will be saved and also a record of excluded studies. For studies reporting the same results more than once, only the most complete or most recent study will be used.

Table 2: Stage 1 screening process.

Population	Adults (>18 years), trauma, any injury
Intervention	Case management or model of case management referred to by an alternative title.
Study design	RCTs

Data collection process

Data extraction sheets will be created, piloted by the reviewer on a random sample RCT and stored on Google Drive. Extracted data will include participant and setting information, intervention and comparison model and description, study characteristics and methodology, outcomes, key findings and funding or sponsor details. Where there is missing data or uncertainty, authors will be contacted for clarity. A second reviewer will extract data independently from the full text articles with any disagreements resolved through discussion.

Data items

Study characteristics: title, author(s), year, country, study aims and objectives, study design, setting, length of intervention, trial size (intervention/comparison arms) funding or conflicts of interest, publication status.

Participant characteristics: age (SD), gender, socio-economic status, living status (for example alone or with a carer) pre-existing conditions.

Injury: details of injury, all secondary complications that resulted from the injury including psychological, context of injury (for example war, motor vehicle crash, work), Injury Severity Score or equivalent and region of injury.

Case management characteristics: description of case management model and actions (interventions) as per the CMT, setting, independent or multi-disciplinary, service provider, discipline of case manager, any alternative name used for case management, any additional training.

Comparison intervention characteristics: name of intervention, model, actions, independent or multi-disciplinary, service provider, discipline of coordinator, any additional training.

Study design: Recruitment details, inclusion criteria, exclusion criteria, methods.

Outcome data: Outcome data will be collected for both trial arms including any details of attrition where applicable. Mean score, standard deviation and number of participants will be collected for QoL, behavioural, physical, psychological or social functioning scores.

Patient satisfaction scores and response rate at follow-up.

Mean number, standard deviation and number of participants will be collected for emergency department visits and readmissions to hospital.

Risk of bias

Risk of bias in the trial design, conduct and reporting of the included RCTs will be assessed using the Risk of Bias Tool (RoB2) (Higgins *et al.*, 2019). Results of this will be tabulated and made available in the appendix to the systematic review. The results will be used to inform the narrative summary of the review.

Data synthesis

Patient, study characteristics, model of case management, provider, risk of bias results and primary and secondary outcomes will be tabulated. Meta-analyses will be performed where appropriate for primary and secondary outcomes. Weighted mean differences and 95% confidence interval (CI) will be calculated. Where different continuous measures were used to assess the same outcome (such as different QoL questionnaires) SMD (95% CI) will be calculated.

Results will be presented as forest plots. Where SMD is calculated effect size will be judged as 0.8 large effect, 0.5 a moderate effect, 0.2 a small effect.

Statistical heterogeneity will be assessed using the χ^2 test ($p = 0.1$) and quantified using I^2 statistic. Heterogeneity will be judged according to the following (Deeks *et al.*, 2019):

0% to 40%: might not be important.

30% to 60%: may represent moderate heterogeneity.

50% to 90%: may represent substantial heterogeneity.

75% to 100%: considerable heterogeneity

If there is evidence of substantial heterogeneity ($I^2 \geq 50\%$ or $P < 0.1$) a random effects model will be used (Deeks et al., 2019).

Where possible, sub-group analysis may be performed to explore potential sources for heterogeneity (Deeks et al., 2019) by model of case management, provider of the case management service (private, public, 3rd sector), discipline of case manager, characteristics of participants (age, socio-economic status, living status), risk of bias rating or length of intervention (0-12 months or >12 months).

Sensitivity analysis may be performed by excluding studies judged to be high risk of bias.

A narrative synthesis will be performed if meta-analyses of outcomes is not possible due to heterogeneity or incomplete reporting. In this instance, for transparency and to reduce bias, the review will follow SWiM (Synthesis Without Meta-Analysis reporting items) guidelines (Campbell et al., 2020).

Meta-biases

Trial protocols will be obtained to investigate the potential for selective reporting where pre-specified outcomes in the protocol are different to those reported in the trial results.

This may be the case where a trial used multiple QoL measurement tools but only reported those with beneficial outcomes. The potential for publication bias will be explored with a graphical funnel plot

Confidence in cumulative estimate

The GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach will be used to rate the overall quality of evidence in the systematic review as recommended by Cochrane (Schünemann et al., 2019). This is determined by risk of bias,

inconsistency, indirectness, imprecision and publication bias to categorize certainty of evidence as 'high', 'moderate', 'low' or 'very low' by outcome (Schünemann et al., 2019).

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