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Functional and employment outcomes following road traffic crashes in Queensland, Australia: Protocol for a prospective cohort study.

Elise M. Gane [a], Esther J. Smits [a], Charlotte L. Brakenridge [a], Vinay Gangathimmaiah [b], Jagnoor Jagnoor [c], Ian D. Cameron [c], Venerina Johnston [a,*]

[a] RECOVER Injury Research Centre, Level 7, Oral Health Centre, The University of Queensland, Herston, Brisbane, QLD, 4006, Australia
[b] Emergency Department, The Townsville Hospital, P.O Box 670, Townsville, QLD, 4810, Australia
[c] John Walsh Centre for Rehabilitation Research, Sydney Medical School, Edward Ford Building (A27), Fisher Road, University of Sydney, Sydney, NSW, 2006, Australia

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ABSTRACT

Introduction: Most road traffic crash injuries are minor to moderate in severity, but can still lead to persistent disability. One aspect of this disability is being unable to return to paid employment. Being unable to work has follow-on effects for personal financial stability, health and quality of life, as well as increasing costs for employers and society more broadly. In order to better understand the trajectory of returning to work in individuals injured in road traffic crashes, a prospective inception cohort study will be conducted across multiple sites in Queensland, Australia that will assess work and health outcomes in the first year after injury. This study protocol describes the process undertaken by the research team to design the methodology of this study.

Methods: Participants aged between 18 and 64 years, injured in a crash involving a motorised vehicle, will be recruited from public hospitals in Queensland. Participants will be excluded if their injuries are severe, including severe traumatic brain injury or spinal cord injury. Baseline data collection will occur within 28 days of the injury, with major follow up assessments occurring at 6 and 12 months post-baseline. Outcome measures include return to work status, health-related quality of life, musculoskeletal pain, disability, psychosocial well-being, and physical activity.

Ethics and dissemination: This study has been approved by Townsville Hospital and Health Service Human Research Ethics Committee, and The University of Queensland Human Research Ethics Committee.

Registration: Australian New Zealand Clinical Trials Registry reference number ACTRN12618001684213.

* Corresponding author.
E-mail addresses: e.gane@uq.edu.au (E.M. Gane), e.smits@uq.edu.au (E.J. Smits), c.brakenridge@uq.edu.au (C.L. Brakenridge), drvinaybg@gmail.com (V. Gangathimmaiah), jagnoor.jagnoor@sydney.edu.au (J. Jagnoor), ian.cameron@sydney.edu.au (I.D. Cameron), v.johnston@uq.edu.au (V. Johnston).

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1. Introduction

In Australia, more than 45,000 people are seriously injured in a road traffic crash (RTC) every year (Henley and Harrison, 2016), with an estimated cost to society as a whole of AU$18 billion annually (Bureau of Infrastructure Transport and Regional Economics, 2009; Connelly and Supangan, 2006). Almost one third of this cost are workplace and household losses, of which the former is a result of work absence, lost productivity and the requirement to train replacement staff (Bureau of Infrastructure Transport and Regional Economics, 2009). People who have been injured in a RTC can experience persistent disability, which may lead to individuals attempting and failing to return to work (RTW), or not attempting a return to paid employment at all (non-return to work, non-RTW) (Heron-Delaney et al., 2017). Each state and territory within Australia has its own Compulsory Third Party (CTP) motor vehicle crash injury insurance scheme. Within Queensland, the third most populous state in Australia (5 million residents), a lump sum benefit scheme is in operation (Collie et al., 2019). This differs from the current situation in the two more populous states, Victoria and New South Wales, and means the results of studies conducted in these states do not clearly translate into Queensland.

Even in those who do return to paid employment, individuals may not stay in paid employment and/or not be working at full duties or functioning optimally (Agnew et al., 2015). Previous research in this area has focused on RTW as a singular outcome at one point in time, but it is also important to understand someone's trajectory when returning to work (Gray et al., 2018), and other work-related outcomes such as whether someone is working at full or modified duties, and absenteeism and presenteeism. Presenteeism refers to persons being at work while working at a reduced performance level, because of their injury (Burton and Conti, 1999). Some workers may also need to take substantial time off work to manage the impact of the injury on their life, leading to potentially high absenteeism rates (Kenardy et al. 2014a, 2014b; Jagnoor et al., 2015).

Previous research in this field has identified factors that are predictive of non-RTW, such as: pre-injury chronic illness, hospital admission, baseline level of disability, and baseline mental health (SF-12 Mental Component Score) (Gopinath et al., 2015); 'not at fault' status (Gabbe et al., 2015); and low expectations of returning to work (Heron-Delaney et al., 2017). Predictors of returning to usual daily activities were also reported in these studies: having a tertiary qualification, lower pain rating scores, and better baseline quality of life (Gopinath et al., 2015); and being 'at fault' compared with 'not at fault' and 'denies fault' (Gabbe et al., 2015). However, these studies have either been conducted in a CTP environment that is different from Queensland (Gabbe et al., 2015); restricted to recruiting participants who were 'not at fault' (Gabbe et al., 2015) or have been limited to sourcing potential predictive factors several months after RTC (Heron-Delaney et al., 2017).

It is also widely recognised that being physically active contributes to improved overall health and wellbeing, including good mental and physical health (Reiner et al., 2013; Warburton and Bredin, 2017). People who have been injured in RTCs may have difficulty being physically active and engage in higher levels of sedentary time during their recovery. This behaviour may be associated with physical, cognitive or emotional difficulties, or pain as a result of their injury. Consequences of sedentary behaviour and inactivity can include an increased risk of cardiovascular disease and diabetes (Ford and Caspersen, 2012) as well as detrimental associations with RTW (Storm et al., 2016). In a study of patients with orthopaedic injuries, low levels of physical activity (i.e., <40 min/week) 6 months after a rehabilitation program were associated with higher levels of sick leave and lower levels of perceived employability at 12 months (Storm et al., 2016). Knowledge of the trajectory of physical activity recovery is necessary to plan interventions that target this clinical population, both to improve RTW, as well as to avoid a sedentary lifestyle that can lead to chronic disease.

2. Proposed study

To address these gaps in the literature, a prospective inception cohort study is proposed to follow people injured in an RTC from within 28 days of injury to 12 months following injury. The primary outcome will be RTW status with information collected at several time-points concerning work status as well as details of work duties, sick leave, and other economic outcomes. The overarching aim of the study is to plot the trajectory of recovery of vocational and functional outcomes following RTC. Specific sub-aims include:

- To explore associations between key sociodemographic, injury, quality of life, physical activity, symptomatic, and psychosocial wellbeing factors collected within 28 days of injury with vocational and functional outcomes 6 and 12 months post-RTC.
- To determine the factors that predict vocational and functional outcomes at 6 and 12 months post-RTC, for people who had been working prior to RTC.
- To determine the factors that predict functional outcomes at 6 and 12 months post-RTC, for people who had not been working prior to RTC.
- To explore the pattern of physical activity changes, measured with an objective tool, in a subgroup of participants at baseline, 6 and 12 months post-RTC.

3. Methods and analysis

3.1. Process of formulating study methodology

We undertook several steps in formulating the design of this study. The authors had prior knowledge of two key studies in the Australian context: *The University of Queensland study of physical and psychological outcomes for claimants with minor and moderate injuries following a road traffic crash* (UQ SuPPORT), from Queensland (Kenardy et al. 2014a, 2015, 2017); and *Factors influencing social and health outcomes after motor vehicle crash injury* (FISH) from New South Wales (Gopinath et al. 2015, 2017; Jagnoor et al. 2014, 2015).

Both studies were prospective cohort studies featuring patients who had sustained mild to moderate injuries in RTCs. The UQ SuPPORT study was conducted by former researchers from our own institution, allowing us to make contact with the research team to discuss in depth the strengths, weaknesses, successes and challenges within the study. The FISH study was conducted by researchers known to our lead investigator (VJ), and contact was also easily established. Two of the investigators from the FISH study (IC, JJ) were subsequently invited to join the research team on the present study. Consequently, many decisions made in planning the present study around recruitment, participant eligibility, data collection time points and outcome measures were based on those used in the FISH and UQ SuPPORT studies so that participant outcomes from these studies would be comparable to the outcomes collected in the current study. The FISH study collected patient-reported data as well as data from the Medicare and Pharmaceutical Benefit scheme. We decided not to replicate this part of the study in the present study as the data available would not have answered our key research questions.

One of the limitations of the UQ SuPPORT study (Kenardy et al., 2014b) was that they recruited claimants from the Queensland CTP insurer at a timeframe of between 2 and 10 months post-RTC. These timeframes were dictated by when claimants lodged a claim, i.e., there was commonly a delay of two or more months between RTC and claim lodgement. This did not allow an understanding of the RTW experiences in the early post-injury phase. The evidence demonstrates that the more time a person is away from work, the longer it will take them to return to work (Australasian Faculty of Occupational and Environmental Medicine, 2011; Waddell and Burton, 2006). Therefore, understanding potential challenges for work in the early post-injury phase was established as an aim. In addition, findings could not be generalised to non-claimants, as the CTP scheme within Queensland limits claims to only those who were 'not at fault' during RTCs and all participants recruited into the UQ SuPPORT study were recruited through the CTP regulator. In fact, since the recruitment phase of the UQ SuPPORT study, changes to the legislation governing the CTP scheme in Queensland have also been implemented, meaning that a new look at claimant outcome in Queensland is warranted. In New South Wales, the FISH study (Gopinath et al., 2017) was conducted prior to the change in legislation around fault status: at the time of the FISH study, the CTP scheme in New South Wales was also fault-based. As such we thought it was important that a study be designed to recruit and collect data closer to the RTC and to include all claimants regardless of fault status.

Key learning points from both of these studies included:

- Targeted population: Findings from both studies support the present study's focus on minor to moderate injuries, as these injuries can have long-term impacts on an individual's health, social and vocational outcomes as a result of RTC;
- Recruitment: This would ideally occur via hospital emergency department presentations and not via the insurance regulator, as not all "not at fault" injured persons file insurance claims;
- Baseline testing: Baseline data collection would ideally occur within 28 days of the RTC; this was a limitation of the UQ SuPPORT study as baseline testing occurred between 2 and 10 months following RTC, resulting in missing information related to RTW before 2 months post-crash;
- Follow up testing: RTW rates were reported at 12 and 24 months post-RTC. This is an opportunity to explore the first 6 months post-RTC in more detail, as this may be the crucial time to start an intervention;

Multiple stakeholders are present in the RTW space, adding to the complexity of the system. An important stakeholder that was also consulted in the planning of this study was the Motor Accident Insurance Commission (MAIC), the state regulatory authority for CTP insurance in the state of Queensland, and a source of funding for our research centre. MAIC has a minimum data set of information that it collects from each claimant who lodges a claim with them. This minimum data set was consulted when determining the socio-demographic data to collect for the present study. Collecting data consistent with MAIC's records will allow the research team to determine if the sample of participants in the study is similar or different to the total cohort of claimants in our state.

Setting the length of follow up within this study was an important consideration, and the decision was made to end follow up of participants at 12 months post-RTC. Our main focus of the trial was to collect detailed information on the trajectory of RTW. MAIC data (not publically available) indicates that most claimants (85%) do RTW within 3 months of their RTC (personal communication). Thus, this initial period was of most interest to us to objectively quantify this rate. Furthermore, the FISH study reported on 2 years outcomes and found little change in return to work status between 12 months (145 of 170, 85.3%) and 2 years (121 of 147, 82.3%). Both studies also experienced high levels of drop out at 2 years (31% and 35% respectively), making this follow up less feasible.

Having established an outline of the study methodology, the research team began approaching leaders within the emergency departments of public hospitals within Queensland. Contact details for these leaders were identified and an introductory email was sent. Interest was received from four hospitals, and Townsville Hospital was identified as the most suitable site at which to commence the study due to their ability to engage more quickly than other sites. A relationship was built with several staff within the Townsville Hospital Emergency Department, including those responsible for management of reports on patient admissions. Together with author EG, these staff trialed several sources and methods of screening patients presenting to the Townsville Hospital Emergency Department. Three mechanisms for screening patients were identified: ICD-10 codes (World Health Organization, 2004); SNOMED codes (London, UK: SNOMED International) (Australian Digital Health Agency, 2019); and key words within key fields in the electronic medical record (FirstNet; North Kansas City, MO: Cerner Corporation). ICD-10 codes were unable to screen patients, as they were only applied to patient presentations/admissions several weeks after discharge from hospital. This would not have allowed for recruitment within 28 days of injury. A comparison of key fields within FirstNet and relevant SNOMED codes in a trial group of patients found that SNOMED codes were not used consistently in the entries made for patients presenting to the Emergency Department following RTC. Therefore, searching for key words within key fields in the FirstNet records of patients presenting to the Townsville Hospital Emergency Department was identified as the most reliable way of identifying all potentially eligible patients. Other sites that have been added to

the study have been able to employ the same method of identifying potential participants. We decided to commence the study at one site (Townsville) to ensure the study was running properly before implementing the study at other sites. The ability to show the study was running smoothly at one site assisted with getting the other sites on board.

3.2. Describing the study design and setting

In line with the UQ SuPPORT study and the FISH study, this study is a prospective inception cohort study that is being coordinated from the RECOVER Injury Research Centre at The University of Queensland (UQ), Australia. Participant recruitment is occurring from multiple sites across Queensland Health, the public provider of healthcare in Queensland, Australia: Townsville Hospital, Princess Alexandra Hospital, Mater Adults Public Hospital, and Caboolture Hospital.

3.3. Participant eligibility and recruitment

Individuals who have been involved in an RTC within the past 28 days will serve as the participant group for this study. To be eligible to participate in the study, individuals must: (1) have sustained an injury as the result of an RTC for which the individual has sought advice from a medical practitioner or other healthcare provider (the diagnosis of the injury as well as recruitment must be completed within 28 days of the RTC); (2) be injured due to a crash involving a motorised vehicle on land (public/private road/driveway/parking space or private/public land) in Queensland, Australia; (3) be an injured person who is a driver, rider, passenger, pillion passenger, cyclist, pedestrian (e.g. a person travelling on foot, or operating a toy vehicle, pedal car, barrow, billy-cart, non-motorised wheelchair or riding on a skateboard), involved in an RTC; (4) be aged 18–64 years; (5) have proficient English language skills to understand and complete all questionnaire-based assessments, and to provide informed consent; (6) be a resident of Queensland, Australia. Participants will be excluded from the study if they: (1) incurred an injury as a result of a crash involving types of land transport other than motorised vehicles such as trains and light rail, or bicycle crashes without the involvement of a motorised vehicle; (2) had an injury requiring hospitalisation for more than 10 days; (3) sustained an injury that occurred as a result of intentional self-harm; (4) have dementia or significant cognitive impairment affecting their ability to provide informed consent; (5) sustained a severe injury, including severe traumatic brain injury, spinal cord injury, severe burns or multiple amputations. Severe traumatic brain injury is defined as a loss of consciousness for >24 h (Lange et al., 2016). Damage to the spinal cord will be identified on imaging conducting within the Emergency Departments. The criteria for severe burns is based upon the criteria used by the American Burn Association: >20% of total body surface area (TBSA) in adults aged ≤50 years, or 10% TBSA in adults aged >50 years, or a full

Table 1
Schedule of data collection points and the relevant outcomes collected at each time point. A tick indicates an outcome is collected at that particular time point.

Data collection timepoints (months):	Baseline	1 m	2 m	3 m	4 m	5 m	6 m	9 m	12 m
General information									
Socio-demographic	✓								
Health status (at time of injury)	✓								
Injury epidemiology	✓								
Vocational pre-injury	✓								
Return to Work									
Vocational, insurance and treatment questions	✓	✓	✓	✓	✓	✓	✓	✓	✓
Return to Work Self-Efficacy Scale	✓						✓		✓
WRFQ-5	✓						✓		✓
Health related QOL									
SF-12	✓						✓		✓
EQ-5D-5L	✓						✓		✓
GPE scale	✓						✓		✓
Pain/Symptoms									
ÖMPSQ (short form)	✓						✓		✓
Disability and Functioning									
WHODAS 2.0	✓						✓		✓
Psychosocial Wellbeing									
HADS	✓						✓		✓
IES-R	✓						✓		✓
IEQ	✓						✓		✓
SPRS – 3 items	✓						✓		✓
BRS	✓						✓		✓
Perceived threat to life question	✓								
Sleep and activity									
Sleep, physical activity and sedentary behaviour	✓						✓		✓
Physical activity objective measure in subsample of participants	✓						✓		✓

Abbreviations: WRFQ-5 = Work Role Functioning Questionnaire 5 items; SF-12 = Short Form 12; EQ-5D-5L = EuroQol 5 Dimensions 5 Levels; GPE = Global Perceived Effect; ÖMPSQ = Örebro Musculoskeletal Pain Screening Questionnaire; WHODAS = World Health Organisation Disability Assessment Schedule; HADS = Hospital Anxiety and Depression Scale; IES-R = Impact of Event Scale-Revised; IEQ = Injustice Experience Questionnaire; SPRS = Sydney Psychosocial Reintegration Scale; BRS = Brief Resilience Scale.

thickness burn with TBSA >5% (American Burn Association, 1990). A patient will be considered to have multiple amputations if more than one limb was amputated.

Offers to participate in this study will be extended to patients regardless of their employment status at the time of the RTC, and regardless of their compensable status. Under the Queensland CTP scheme, individuals who are "not at fault" are eligible to submit a claim for compensation, and those who are "at fault" are ineligible to submit a claim. This decision was made to keep the study in line with the FISH study, who recruited both compensable and non-compensable injured persons, and to overcome a weakness of the UQ SuPPORT study (limited to compensable claimants only).

Eligible patients will be identified from electronic medical records within hospital emergency departments (EDs). Medical, nursing, or research staff assisting with the study will review on a weekly basis the presentations to ED during the preceding week, and identify potentially eligible patients who meet the selection criteria. An introductory letter and the participant information and consent form will be posted to participants. UQ research team members will subsequently follow up patients via telephone to confirm eligibility and to obtain verbal consent from patients to participate in the study. Written informed consent will be collected from participants via the online survey (see Study Procedure), or participants will return a signed copy of the consent form via post in the reply paid envelope provided.

In designing this element of the study, several ethical considerations had to be addressed related to privacy of patient data. Within Queensland Health, health professionals involved in the clinical care of an individual can access their identifiable and health-related data. There are some staff within departments that have access to this data also, for the purposes of generating in-house service delivery reports. Both of these types of staff are able to assist the research team in screening patient presentations to the participating emergency departments. In order for the contact information of potential participants to be sent outside of Queensland Health to the research team based at UQ, approval was sought via a Public Health Act application to the Health Innovation, Investment and Research Office (Queensland Health). This approval formed part of the research governance approval process at each site.

3.4. Study procedure

Participants will be asked to complete a series of patient reported outcome measures (questionnaires) at baseline (within 28 days of injury) and at several points across the first year following their injury. After the baseline assessment, post-injury outcomes will be measured at 6 and 12 months post-baseline assessment (see Table 1). In addition, a small number of questions pertaining to employment, insurance and treatment will be administered on a monthly basis for the first 5 months and again at 9 months post-baseline assessment. Questionnaire data will be managed within an online service called REDCap (Research electronic data capture). REDCap was recommended for this purpose by the FISH study investigators as well as our institution (UQ).

The choice of outcome measures implemented in this study was informed by a number of sources. First, previous work within our organisation had identified key and relevant measures, such as perceived threat to life (Kenardy et al., 2015). Second, outcome measures employed within previous (Jagnoor et al., 2014) and current studies in New South Wales, Australia, were chosen to enable comparison between the different jurisdictions. Third, several outcome measures were included to enable comparison with results from data collected from workers compensation authorities in Australia (e.g. Safe Work Australia).

3.5. Measures

3.5.1. Work-related measures

The status of participants as working or not working at the follow up assessment time points within this study is considered the primary outcome. A series of questions concerning employment status and other work-related outcomes have been compiled based on the expertise of the research team in the fields of occupational health and vocational rehabilitation. Participants will be asked if they have attempted (successfully or unsuccessfully) to RTW, what paid employment they engage in relative to their pre-injury employment (e.g., same job/same company, different job/same company), and how many days were taken to RTW. This will result in RTW being considered as both a dichotomous measure and a count measure. To further explore the process of RTW, specific questions will be asked concerning: (1) receipt of medical certificates; (2) degree to which one's job is physically or mentally demanding; (3) level of support from family/employers/health professionals/insurance case managers; (4) lodgment of a claim for compensation, and associated levels of stress (Grant et al., 2014); (5) engagement of legal representation; (6) types of job modifications made; and (7) types of medication and other treatments (e.g., physiotherapy, ergonomic assessment, psychology), received for their RTC-related injury.

Three other work-related outcomes were identified based on reading of the existing literature as understudied in the post-RTC population, but important in the occupational injury management sphere: worker productivity, worker self-efficacy, and worker role functioning. Three suitable tools were identified to record this data:

- Questions from the Work Productivity and Activity Impairment Questionnaire v2.0 (Reilly et al., 1993) and the World Health Organization Health and Work Performance Questionnaire (Kessler et al. 2003, 2004) will be used to assess absenteeism and presenteeism (productivity). These two measures were used as there is no single measure for objectively quantifying productivity across different occupations;
- The Return to Work Self-Efficacy Scale (Brouwer et al., 2011) will be used to measure self-efficacy regarding RTW on a 10-item scale. This scale has three factors: ability to cope with pain, obtaining help from supervisor, obtaining help from co-workers. Higher scores indicate higher levels of self-efficacy. The UQ SuPPORT study used one item from another tool (the ÖMPSQ, see section 3.5.2.2), whereas we felt it important to use a validated tool in its entirety to measure this construct;

- Work Role Functioning Questionnaire 5-item version (Abma et al., 2019) will measure the ability of a worker to meet job demands considering their current state of health (Abma et al., 2018). This tool has five questions that sum to a total score between 0 (worst work role functioning) to 100 (best work role functioning). Many individuals who have RTW may not be functioning optimally – this tool will provide us with information as to how well a worker is meeting their expected job demands.

3.5.2. Functional measures

3.5.2.1. Quality of life. Health-related quality of life (HRQOL) is a concept often measured in studies of recovery, and individuals are often considered 'recovered' if their HRQOL has either returned to baseline or become comparable to population norms. We wanted to measure HRQOL in the present study with recovery in mind. The three outcome measures chosen to capture HRQOL in the present study are consistent with the FISH study, and in keeping with our wish to ensure the findings from the present study will be comparable to those in the FISH study.

The Short Form-12 (SF-12) v2.0 (Ware et al., 1996a) is a 12-item questionnaire which measures health-related quality of life across eight domains. The tool produces two component summary scores: the Physical (PCS-12) and Mental (MCS-12) Component Summary scores, which range between 0 (poor health) to 100 (better health). The SF-12 is a widely used measure of quality of life across a variety of medical conditions and has been shown to demonstrate change over time (Layte et al., 1997a). There is a licensing fee associated with administering the SF-12.

The EuroQol 5 dimensions 5 levels (EQ-5D-5L) (Herdman et al., 2011b) is a measure of health-related quality of life that consists of a descriptive system plus the Visual Analogue Scale (VAS). The descriptive system includes five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The participant is asked to indicate their health state by indicating their level of difficulty in each of the five dimensions. Analysis will be conducted in line with available recommendations (van Reenen and Janssen, 2015). The EQ VAS records the participant's self-rated health on a vertical visual analogue scale where the endpoints are labelled 'best imaginable health state' (100) and 'worst imaginable health state' (0).

Participants will be asked to rate their current health status in comparison to their health status immediately before their RTC on the Global Perceived Effect (GPE) scale (Kamper et al., 2010). This is an 11-point numerical scale ranging from -5 (Vastly worse) to 5 (Vastly better), where 0 is completely recovered (i.e., back to pre-injury health).

3.5.2.2. Pain. Musculoskeletal pain has the potential to be the determining factor in an individual's perception of themselves as recovered or not recovered. It was important for us to consider the disability related to having pain, as well as the intensity of pain itself, in this study. To comprehensively evaluate pain and other known barriers for work, the 10-item Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPSQ) – Short-form (Linton et al., 2011) was included. . The ÖMPSQ is a multi-dimensional screening questionnaire used to predict long term disability and failure to return to work due to personal and environmental factors. There are five domains: pain; self-perceived function; distress; RTW expectancy; and, fear avoidance beliefs. The summary score ranges between 1 and 100, with higher scores indicating greater disability. One item has been added from the longer version of the tool (Linton and Boersma, 2003) to record expectations of return to normal working duties in 6 months as well as 3 months. This item was added to enable comparison with previously collected data on predictors for RTW following RTCs (Heron-Delaney et al., 2017).

3.5.2.3. Disability. There is more to disability than the limitations of pain on physical function. Therefore another measure in addition to the ÖMPSQ was required. Again, in keeping with the FISH study, disability will be measured in the present study with the World Health Organization Disability Assessment Schedule version 2.0 (WHODAS 2.0) (Saltychev et al., 2017b). This tool is a self-report questionnaire with 12 items that assesses activity limitations and participation restrictions (i.e., disability) in the prior month. It assesses disability across six domains: understanding and communicating; getting around; self-care; getting along with people; life activities (i.e., household, work, and/or school activities); and, participation in society. Summary scores range from 0 (no disability) to 100 (full disability).

3.5.2.4. Psychosocial wellbeing. Psychosocial wellbeing of participants within this study will be explored from a number of different angles, such as the presence of a mental health condition like depression, to the degree of one's own resilience. In choosing suitable outcome measures to characterise the psychosocial health of our participants, we deferred to the judgement of our predecessors and colleagues from the UQ SuPPORT study, who have extensive training and experience in these topics.

The Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983a) is a 14-item scale used to assess depression and anxiety symptoms in the past week. Anxiety and depression are measured by seven questions each, which produce sub-scale scores that are summed to produce a total score. 'Cases' of depression or anxiety will be defined as a sub-scale score of 11–21. The HADS has demonstrated good psychometric properties (Bjelland et al., 2002) and has been used in various study populations (e.g., hospital patients (Johnston et al., 2000), general population (Mykletun et al., 2001)). The HADS does have a licensing cost associated with its use in research.

The Impact of Event Scale-Revised (IES-R) (Weiss, 2004) scale is a 22-item self-report measure that assesses subjective distress caused by traumatic events. Participants rate their degree of distress during the past seven days. Items are rated on a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely). Subscale scores can be produced for avoidance, intrusion and hyperarousal.

The Injustice Experience Questionnaire (IEQ) (Sullivan et al., 2008a) is a 12-item scale that asks respondents to indicate the frequency with which they experience different thoughts concerning the sense of unfairness in relation to their injury on a 5-point Likert

scale ranging from 0 (not at all) to 4 (all the time). The IEQ yields two correlated factors of severity/irreparability of loss, and blame/unfairness.

The research team felt that the SF-12 and the WHODAS did not adequately explore participation in the community, particularly for individuals who may have sustained a mild brain injury. The Sydney Psychosocial Reintegration Scale (SPRS) (Tate et al., 2012a) was

Table 2
Outcome measures for collection.

Data collection tools:	Construct	Items and sub-scales	Anchors	Other
Absenteeism and presenteeism				
WPAI (Reilly et al., 1993)	Health-related impairment of work productivity	2 questions taken from the original tool (questions 5 and 6), modified to be specific to RTC	0 (my injury had no effect on my work or daily activities) to 10 (my injury completely prevented me from working or doing my daily activities)	
WHO HWPQ (Kessler et al. 2003, 2004)	Absenteeism and presenteeism	7 items	Hours lost per month	
Return to Work				
Return to Work Self-Efficacy Scale (Brouwer et al., 2011)	Self-efficacy for RTW	10 items	Higher scores indicate higher levels of self-efficacy	
WRFQ-5 (Abma et al., 2019)	Work ability	5 items	Total score between 0 (worst) to 100 (best)	
Health related QOL				
SF-12 (Ware et al., 1996b)	Quality of life	12 items; 8 domains; 2 component sub-scores (Physical, Mental)	0 (poor health) to 100 (better health)	Demonstrates change over time (Layte et al., 1997b)
EQ-5D-5L (Herdman et al., 2011a; van Reenen and Janssen, 2015)	Health-related quality of life	5 items (5 dimensions) plus VAS	VAS: 0 (worst imaginable health state) to 100 (best imaginable health state)	
GPE scale (Kamper et al., 2010)	Current health state	1 item	-5 (vastly worse) to 5 (vastly better)	
Pain/Symptoms				
ÖMPSQ (short form) (Linton et al., 2011)	Disability	10 items; 5 domains	1 to 100, higher scores = greater disability	1 item has been added from the longer tool – expectation of return to normal work at 6 months (Linton and Boersma, 2003)
Disability and Functioning				
WHODAS 2.0 (Saltychev et al., 2017a)	Disability	12 items; 6 domains	0 (no disability) to 100 (full disability)	
Psychosocial Wellbeing				
HADS (Zigmond and Snaith, 1983b)	Depression and anxiety symptoms	14 items; 2 sub-scales (anxiety, depression)	'cases' of depression or anxiety = scores of 11–21	
IES-R (Weiss, 2004)	Subjective distress caused by traumatic events	22 items; 3 sub-scales	Each item has a Likert scale for responses from 0 (not at all) to 4 (extremely)	
IEQ (Sullivan et al., 2008b)	Sense of unfairness related to an injury	12 items; 2 correlated factors	Each item has a Likert scale for responses from 0 (not at all) to 4 (all the time)	
SPRS – 3 items (Tate et al., 2012b)	Leisure, communication, social skills	3 items	Each item has a Likert scale for responses from 4 (not at all) to 0 (extreme)	
BRS (Smith et al., 2008b)	Ability to recover from stress	6 items	Total score between 6 (low resilience) and 30 (high resilience)	
Perceived threat to life question (Holbrook et al., 2001a)	Perceived threat of dying during accident	1 item	Likert scale from 1 (not at all) to 5 (very strongly)	Other available answers include "don't know/can't remember"
Sleep and activity				
Modified AAS (Brown et al., 2008)	Amount of physical activity	13 items	Number of days, minutes of activity	
IPAQ – 1 question (Hagstromer et al., 2006)	Sedentary behaviour	1 item	Minutes of sitting	

Abbreviations: WPAI = Work Productivity and Activity Impairment; WHO HPQ = World Health Organization Health and work Performance Questionnaire; WRFQ-5 = Work Role Functioning Questionnaire 5 items; SF-12 = Short Form 12; EQ-5D-5L = EuroQol 5 Dimensions 5 Levels; GPE = Global Perceived Effect; ÖMPSQ = Örebro Musculoskeletal Pain Screening Questionnaire; WHODAS = World Health Organisation Disability Assessment Schedule; HADS = Hospital Anxiety and Depression Scale; IES-R = Impact of Event Scale-Revised; IEQ = Injustice Experience Questionnaire; SPRS = Sydney Psychosocial Reintegration Scale; BRS = Brief Resilience Scale.

identified from the brain injury evidence base as a suitable measure of community participation. In order to avoid duplication between some items on the SPRS and the SF-12 and WHODAS, three specific items related to the topics of leisure, communication, and social skills will be included from the SPRS in data collection. Responses to these items are on Likert scales between 'not at all' (4) and 'extreme' (0).

The Brief Resilience Scale (BRS) (Smith et al., 2008a) assesses the ability to bounce back or recover from stress. The BRS consists of six items: three negative items and three positive items. Respondents are asked to answer each question by indicating their agreement with each statement by using a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The sum of the 6 item scores is divided by the total number of items answered to produce a total score between 6 (low resilience) and 30 (high resilience).

Perceived threat to life (Holbrook et al., 2001b) will be assessed by asking "How much did you believe you were going to die during the accident?". Responses will be measured on a 5-point Likert scale ranging from 1 (not at all) to 5 (very strongly). There will also be an option to answer "Don't know/can't remember". Perceived threat to life has been found to predict post-traumatic stress disorder onset and early symptoms of acute stress reaction (Holbrook et al., 2001b).

3.5.3. Physical activity, sedentary behaviour and sleep

Increasingly, research is turning to evaluate a participant's whole 24 h day of activity in terms of their physical activity, sedentary behaviour and sleep. Physical activity will be measured using the Active Australia Survey (AAS) (Australian Institute of Health and Welfare, 2003). This measure has acceptable validity and reliability for assessing physical activity (Brown et al. 2004, 2008). The AAS has been modified to assess physical activity frequency as days per week instead of sessions per week and to include one item on household chores and one item on activities to increase muscle strength. One item from the International Physical Activity Questionnaire (Hagstromer et al., 2006) will be used to measure sedentary behaviour. This measure was chosen because it is brief, and has adequate validity and reliability for measuring prevalence of sedentary behaviour in populations (Rosenberg et al., 2008). Sleep will be assessed through participants' self-reporting their sleep quality and reporting of average number of hours spent asleep per night.

Physical activity and sedentary behaviour will also be measured objectively with a small activity monitoring device (activPAL micro, Glasgow, Scotland; an accelerometer that records tri-axial accelerations) in a sub-set of independently mobile participants (can include walking aid) identified in the initial screening. The activPAL device has high reliability and validity for measuring sitting, standing and stepping time (Kozey-Keadle et al., 2011; Lyden et al., 2012). Device-measured physical activity and sedentary behaviour is a more accurate measure of these behaviours compared to self-report (Edwardson et al., 2017; Shephard, 2003), but the devices are costly ($380+), thus we chose to only assess a subset of participants. Participants will wear the device for 7 days continuously on three separate occasions (baseline, and 6 and 12 months post-baseline). The device is small and rectangular in shape (23.5 × 43 × 5mm; weight 10 g), waterproofed with a hypoallergenic dressing, and will be attached to the front of the thigh with another hypoallergenic, breathable, adhesive dressing (e.g., Tegaderm). Participants will be asked to wear the device at all times across the 7-day period and to avoid changing their normal daily routine of activity. Accompanying the device will be a written daily diary, to record the date and time of placement of the monitor, removal of the monitor, waking and sleeping times, removal of device for more than 15 min, reasons for removal, and to track any adverse skin reactions. The activPAL device is a commonly used assessment tool (Edwardson et al., 2017) in people with and without medical conditions (e.g., stroke (Paul et al., 2016)). The data collected by the activPAL will include the following variables: (1) time spent in light, moderate, and vigorous intensity activity; (2) time spent sitting, standing, and stepping; and, (3) number of steps taken. The primary outcome will be total physical activity (light, moderate and vigorous) in minutes. The sample size determined to be adequate for analyses is 34, based on using an effect size of 0.5, an alpha of 0.05 and power of 0.80 at 12 months post-initial assessment. The expectation of a 35% loss to follow up is consistent with the main study, therefore the target sample size for participants in this sub-study is 53.

Table 1 summarises when specific outcome measures will be collected. Table 2 lists the construct, number of items, and anchors or interpretation descriptors of each of these previously published outcome measures. In addition to these outcome measures, the investigatory team collated some questions on specific areas of interest.

3.5.4. Socio-demographics, pre-injury status and the crash itself

Participants will be asked to self-report sociodemographic information (e.g., date of birth, age, gender) and injury details (e.g., type of injury and treatment received), as well as information about their health (e.g., comorbidities) and work (e.g., usual occupation) prior to their RTC. Regarding the crash itself, participants will be asked to describe the crash and their role in the crash consistent with the categorical descriptors used by MAIC. For example, participants might identify the RTC as involving a car vs car or car vs motorcyclist; and their role as driver, passenger or rider, to name a few. This information is being sought to adequately characterise the including cohort, and to determine if the nature of the RTC or the injured person's role within the RTC are associated with consenting or declining to be a part of the study.

3.6. Sample size calculation

One of the aims of the study is to determine the factors that predict vocational outcomes at 6 and 12 months post-RTC, for people who had been working prior to RTC. RTW status (yes/no) at 12 months will be the primary dependent variable within a binary logistic regression. In order to detect an odds ratio (OR) of 1.5 as significant (alpha = 0.05) for each factor we consider (with 80% power), a sample size of 297 participants is needed. Using an OR of 1.5 equates to a medium effect size for the probability of returning to work by 12 months. Accounting for a loss to follow up of 35% over 12 months based on similar existing studies (Jagnoor et al., 2014; Kenardy et al., 2014b) the target sample size for this inception cohort study will be 456. The other analyses proposed for this study are

exploratory, and are therefore not incorporated into the sample size calculation.

3.7. Data analysis

The data from questionnaires will be cleaned and analysed in SPSS version ≥25 (Armonk, NY: IBM Corp) and STATA version >15 (College Station, TX: StataCorp LLC). Reporting of all results will be consistent with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement (von Elm et al., 2007). Summary statistics will be used to describe the profile of (1) participants who joined the study versus non-participants at baseline, and (2) participants in the study at each time point including loss to follow up. Frequencies and percentages, means and standard deviations, or medians and interquartile ranges, will be used to summarise key predictors and outcomes, as appropriate. Differences in key demographic variables between (1) participants who join the study versus non-participants at baseline, and (2) participants who continue to provide data and those lost to follow up will be investigated with chi-square tests or Student's independent t-test, as appropriate. Univariate comparisons of grouped data (e.g., compensable/non-compensable) will be made using chi-square tests for categorical variables (with a Fisher's exact test conducted for counts of less than five), and either Student's independent t-tests or Mann-Whitney U-tests for continuous variables, as appropriate. These tests will be conducted with an alpha = 0.05.

Regression analyses will be used to determine the factors that predict vocational and functional outcomes and to explore changes in physical activity outcomes. Mixed models will be used to analyse continuous outcomes, accounting for repeated measures (6 and 12 month time points). This will maximise data usage, increase the power of data analyses, and reduce the bias associated with complete case analysis (i.e., only cases with complete data). Logistic regression will be used to analyse categorical dependent outcomes such as RTW status (yes/no) at 6 and 12 months. Modified Poisson regression analysis (with robust error variance) will be used to analyse count data (e.g. days to RTW) (Zou, 2004).

Covariates will be identified through the process of univariate testing with the relevant dependent outcome. If the p-value is < 0.2 in the univariate analysis, the covariate will be included in the multivariate regressions. Table 3 lists the pre-injury or baseline covariates that will undergo univariate testing for inclusion in the multivariate models.

Within the regression models, the threshold for significance will be alpha = 0.05. Each model will be assessed for the model assumptions, such as linearity, normality and heteroscedasticity. The presence of multicollinearity will be detected with the variance inflation factor (VIF): VIF >5 will indicate multicollinearity.

4. Discussion

This multicentre, prospective cohort study will provide greater detail than has been previously recorded related to the trajectory of RTW that an injured person with a mild to moderate injury may follow after RTC. The present study builds upon the work conducted by previous investigators from the UQ SuPPORT study and the FISH study, specifically in moving beyond reporting RTW status as the sole work-related outcome. Absenteeism and presenteeism, use of sick leave, RTW self-efficacy, and required job modifications are some of the aspects in which the present study will be able to provide further detail beyond what is currently represented in the evidence base for this clinical population. This information is critical to the promotion of and access to vocational, mental health, and physical

Table 3
List of pre-injury or baseline covariates that will be considered as potential predictors of dependent outcomes at 6 months and 12 months.

Pre-injury or baseline covariate
Age
Sex
Highest education level achieved
Marital status
Pre-injury health status (e.g. number of health conditions reported from the potential list of 8)
Injury type (categorical e.g. soft tissue, fracture, joint dislocation; or by body part e.g. lower limb, upper limb, cervical spine, trunk)
Type of RTC (e.g. car vs car, car vs motorbike)
Role in the RTC (e.g. driver, passenger, rider)
Hospital admission required (y/n)
Pre-injury vocational status
Pre-injury occupational category
Pre-injury occupation – physically demanding
Pre-injury occupation – mentally demanding
RTW self-efficacy at baseline
Compensation (y/n)
Legal presentation (y/n)
Baseline HRQOL (SF-12, and/or EQ-5D, and/or EQ-5D VAS)
Baseline pain (OMPSQ)
Baseline disability (WHODAS 2.0)
Baseline depression and anxiety symptoms (HADS)
Baseline subjective distress (IES-R)
Baseline sense of injustice (IEQ)
Baseline resilience (BRS)
Baseline perceived threat to life

rehabilitation services to this clinical population.

This study will also collect a range of functional outcomes, reflecting the physical and mental health of individuals with minor to moderate injuries following RTC. The tools chosen for data collection are well known and widely used, allowing for comparisons to be made with other clinical populations. Some tools, like the ÖMPSQ, can function as screening tools to identify those at risk of long term disability. Using patient-reported outcome measures in this way is an important part of practising patient-centred care, as opposed to rating scales administered by clinicians.

4.1. Strengths and limitations

A key strength of the present study is the use of the UQ SuPPORT study and FISH study to inform the methodology. Results will be comparable across the studies and jurisdictions, and significantly expand the knowledge base for RTW after RTC. Identifying potential participants from multiple hospital EDs is also a strength, and will contribute to the study cohort being representative of the population within Queensland. Recovery after minor to moderate injury following RTC and the immediate consequences on employment has rarely been investigated. Recruiting from EDs enables data collection to commence early in the recovery process, increasing the accuracy of information recall and enabling an in-depth exploration of this critical period of time. Recruiting participants who are both eligible and ineligible to claim compensation under Queensland's CTP insurance scheme will enable findings to be applicable to both claimants and non-claimants.

Objective measures of physical activity (e.g., accelerometers) have been recommended as 'best practice' outcome measures for physical activity in adults in free-living environments, compared with self-reported questionnaires (Dowd et al., 2018). However, the cost associated with such units can be a prohibitive factor in their use in research with large samples, and as such using a combination of self-report measures in all participants and objective measures in a subsample will be employed within this study as an appropriate solution. Very little data of this nature has been reported in the existing literature after RTC, and this study will deepen our understanding of physical activity and sedentary behaviour following RTCs.

There are several possible limitations to this study. Individuals with very minor injuries following RTC may not present to hospital ED for assessment. With respect to injury severity, there is not a consistent classification system for injury severity across the participating hospital EDs. Therefore, a classification system such as the Abbreviated Injury Scale (Stevenson et al., 2001) could not be implemented as an eligibility criterion. For those with brain injury, loss of consciousness was chosen as the basis for the exclusion criteria. However, there is variation within the literature regarding the definition of severe brain injury, and others have used Glasgow Coma Score (GCS) on presentation to categorise brain injury severity. This may affect the comparability of our study with similar studies in this field. The decision to use loss of consciousness was made based on two considerations. Firstly, the data sharing agreement between the university and hospitals involved in this project does not include GCS data. From our experience, patients are able to identify to us that they did or did not have a period of loss of consciousness upon secondary telephone screening, whereas asking patients to recall GCS is less accurate. In addition, our medical and nursing colleagues advised us that patients who do present with loss of consciousness >24 h would also be excluded because their subsequent hospital lengths of stay are often beyond 10 days (an additional exclusion criteria). Individuals who do not have sufficient English language comprehension to give informed consent will be excluded, leading to an absence of representation of this sector of the community in the study. This choice was made for pragmatic reasons (i.e. cost of telephone interpreters and translators). Eligible participants may still be from a non-English speaking background. This study does take place in the legislative jurisdiction of Queensland, Australia, where those who are "at fault" are not eligible for compensation through the CTP scheme, and those who are eligible for compensation do not receive wage replacement payments during the life of their claim. This may limit the translation of findings to other jurisdictions. Finally, due to the chronology of collecting physical activity data during participants' recovery, we cannot aim to show causality. Rather, our collection of physical activity data has been designed to be exploratory.

5. Conclusion

This prospective inception cohort study will follow participants injured as the result of a road traffic crash from within 28 days of injury for a period of 12 months in Queensland, Australia. The results will provide further insight into the return to work patterns, levels of disability, and physical activity behaviours in this population group, with the potential to inform future vocational and functional rehabilitation programs.

Ethics

Ethical and safety considerations

This study has been approved by Townsville Hospital and Health Service Human Research Ethics Committee (reference HREC/18/QTHS/131) and The University of Queensland Human Research Ethics Committee (reference 2018001693).

This protocol has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR), reference number ACTRN12618001684213.

Authors' contributions

Authors EG, ES, CB and VJ were involved in manuscript preparation, editing and approval. Authors VG, JJ and IC were involved in manuscript editing and approval.

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Declaration of competing interest

The authors declare that they have no competing interests.

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