BMJ Open

Randomised pragmatic waitlist trial with process evaluation investigating the effectiveness of peer support after brain injury: protocol

Nicola Kayes ,[1] Christine Cummins,[1] Mark Weatherall,[2] Greta Smith,[1] Braden Te Ao,[3] Hinemoa Elder,[4] Joanna Kirstin Fadyl ,[1] Christine Howard-Brown,[5] Allison Foster,[6] Paula Kersten[7]

To cite: Kayes N, Cummins C, Weatherall M, *et al*. Randomised pragmatic waitlist trial with process evaluation investigating the effectiveness of peer support after brain injury: protocol. *BMJ Open* 2023;**13**:e069167. doi:10.1136/bmjopen-2022-069167

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-069167).

Received 13 October 2022
Accepted 26 January 2023

For numbered affiliations see end of article.

Correspondence to
Nicola Kayes; nkayes@aut.ac.nz

ABSTRACT

Introduction Traumatic brain injury (TBI) is an important global health problem. Formal service provision fails to address the ongoing needs of people with TBI and their family in the context of a social and relational process of learning to live with and adapt to life after TBI. Our feasibility study reported peer support after TBI is acceptable to both mentors and mentees with reported benefits indicating a high potential for effectiveness and likelihood of improving outcomes for both mentees and their mentors.

Objectives To (a) test the effectiveness of a peer support intervention for improving participation, health and well-being outcomes after TBI and (b) determine key process variables relating to intervention, context and implementation to underpin an evidence-based framework for ongoing service provision.

Methods and analysis A randomised pragmatic waitlist trial with process evaluation. Mentee participants (n=46) will be included if they have moderate or severe TBI and are no more than 18 months post-injury. Mentor participants (n=18) will be people with TBI up to 6 years after injury, who were discharged from inpatient rehabilitation at least 1 year prior. The primary outcome will be mentee participation, measured using the Impact on Participation and Autonomy questionnaire after 22 weeks. Primary analysis of the continuous variables will be analysis of covariance with baseline measurement as a covariate and randomised treatment as the main explanatory predictor variable at 22 weeks. Process evaluation will include analysis of intervention-related data and qualitative data collected from mentors and service coordinators. Data synthesis will inform the development of a service framework for future implementation.

Ethics and dissemination Ethics approval has been obtained from the New Zealand Health and Disability Ethics Committee (19/NTB/82) and Auckland University of Technology Ethics Committee (19/345). Dissemination of findings will be via traditional academic routes including publication in internationally recognised peer-reviewed journals.

Trial registration number ACTRN12619001002178.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Routine provision of a peer support intervention could address unmet needs for people living with the enduring consequences of traumatic brain injury.
⇒ This research builds on findings from our feasibility work to produce outcomes, process and economic data to underpin future provision of peer support after brain injury.
⇒ This trial has been designed with healthcare service translation in mind from the outset including a parallel process evaluation to identify factors relating to intervention, context and implementation which may be critical to future uptake.
⇒ Peer support is a complex intervention where both mentees and mentors may be living with enduring cognitive, emotional and social consequences. This will need careful consideration for the well-being and safety of all participants and to ensure robust trial outcomes.

INTRODUCTION

Traumatic brain injury (TBI) is an important global health problem. Each year, 10 million people are hospitalised or die of TBI.[1] Survivors of TBI commonly experience significant, wide-ranging and persistent problems with physical, cognitive and psychosocial functioning.[2–5] Existing services save lives and support safe discharge to the community. However, people with TBI and their families largely manage the significant and longer term consequences alone. This is despite evidence that people with TBI benefit from clinical support and interventions in the chronic phase of recovery.[6] The personal aftermath of TBI is characterised by disruption to sense of self and personhood, and threatens the productivity and reciprocity of roles and relationships.[7] A longitudinal qualitative study exploring experiences of recovery over 2 years reported that recovery and adaptation involves

actively developing socially and culturally meaningful concepts of recovery and living with TBI. These concepts developed slowly over months or years after the TBI.[8 9] A notable finding of that study was that people with TBI, their family and communities had little concept of what the consequences of TBI were likely to be, and particularly what it could mean in the context of their lives. Indeed, even when it was part of acute TBI rehabilitation services, participants often found information about *living with* TBI difficult to process in a helpful way at that time.

Peer support is a strategy for managing long-term health and well-being in chronic disabling conditions. A synthesis of existing theoretical, conceptual and empirical evidence for peer support in a healthcare context, articulates key characteristics of a peer mentor. This is defined as 'a created source of support, internal to a community, who shares salient target population similarities (eg, age, ethnicity, health concern, or stressor) and possesses specific knowledge that is concrete, pragmatic, present-oriented, and derived from personal experience rather than formal training' (p. 326).[10] Published research provides evidence of a positive effect of peer support interventions on health and social outcomes for both the mentee and mentor in a variety of health conditions including cancer,[11] diabetes[12] and mental health.[13] In spinal cord injury, peer support is associated with improvements in psychosocial functioning, community integration and independence and greater satisfaction with life.[14 15] There is little published evidence about peer support after TBI. Three US-based studies report positive effects on knowledge, quality of life, general outlook and depression.[16–18] However, design limitations, such as lack of a control group, small sample sizes with lack of statistical power to detect important differences; and possible bias in effect sizes (from high rates of drop-out), means that results of these studies are difficult to generalise and adapt to other healthcare settings. A scoping review of rehabilitation interventions after brain injury highlighted that gaps remain in robust research evaluating peer support interventions in TBI, despite this being a priority area for service users.[19]

To address these gaps, we carried out a feasibility study[20] to inform the design of a definitive trial. Our feasibility study identified that peer support was acceptable to mentors and mentees, with numerous perceived benefits, indicating a high potential for effectiveness and likelihood of improving outcomes. These findings are consistent with those more recently reported by Lau *et al*,[21] whose qualitative descriptive study was also performed to support a randomised controlled trial on peer support after brain injury.

The aim of this paper is to describe a protocol for a randomised controlled trial, based on our feasibility study, of peer support after TBI.

OBJECTIVES

The primary objective of the randomised controlled trial is to test the effectiveness of a peer support intervention for improving participation, health and well-being after TBI.

Secondary objectives include to:

1. Determine key process variables relating to intervention (eg, mentor–mentee relationship, mentoring activities), context (eg, location, living situation) and implementation (eg, service coordination, mentor training and support) to underpin an evidence-based framework for ongoing service provision.
2. Explore mentor experiences and perceived impact of their involvement in the delivery of a peer support intervention on their well-being.
3. Undertake an economic evaluation to determine the relative cost-effectiveness of a peer support intervention compared with usual care.

METHODOLOGY

Design and setting

This is a randomised pragmatic waitlist trial with process evaluation. The pragmatic trial design mimics future service provision. A waitlist control design enables (1) control participants subsequent access to the service; (2) testing of a rolling mentor recruitment approach and (3) exploration of a range of secondary questions such as the impact of mentoring at different times after the TBI. Consistent with principles of implementation science research,[22] this project is designed to consider translation from the outset, to inform the development of a service framework for peer support after brain injury. The design was optimised by drawing on key findings from our feasibility study.[20] See table 1.

Recruitment for the trial will be from three locations in the North Island of Aotearoa New Zealand including Auckland, Kaitaia and Gisborne. These settings include urban, rural and remote communities. Kaitaia and Gisborne were selected as smaller regional locations with high proportions of Māori, the Indigenous peoples of Aotearoa New Zealand, and because these areas have limited direct access to specialist brain injury services. In each setting, a local service coordinator has been employed to oversee recruitment, mentor training and to provide support to mentors. An overview of study design is included in figure 1.

Patient and public involvement

The impetus for exploring the potential for peer support after TBI originally came from our long history of qualitative research exploring experiences and perspective of people with TBI and their families regarding their unmet rehabilitation and support needs.[7–9 23] Furthermore, as above the experiences and perspectives of people with TBI involved in our earlier feasibility work[20] has been formative to the design of this trial. We will invite and support people with TBI taking part and employed as mentors in this trial to contribute to dissemination activities.

Table 1 Overview of findings from feasibility study and implications for the current trial

Feasibility issue	Feasibility study design	Outcomes from the feasibility study	Implications for trial design
Mentor–mentee pairing	Matching on key characteristics with priority given to matching by ethnicity, gender and age	It was difficult to attend to matching on all key characteristics partly because it depended on who was in our mentor pool, their availability and location. Regardless, mentees reported an inherent sense of connectivity with their mentor through their shared experience as TBI survivors. This transcended the need to match on all key characteristics. Beyond this, pairing by shared interest, gender and mentor availability appeared the most important criteria.	Pair according to mentee personal preference and mentor availability/ location.
Mentor training and support	Two-day interactive workshop and face-to-face group debriefings at regular intervals with access to urgent debriefing when required	Mentors reported this to be sufficient and reported no safety concerns. We took care not to professionalise the mentoring role and provided only limited education about the consequences of TBI to mentors, instead giving primacy to personal experiences of TBI. They preferred group debriefing over 1:1 as it provided peer support and they learnt from other's experiences. They did however benefit from access to 1:1 support during mentoring periods. Mentors reported having their own emotional response to the mentoring experience due to the revisiting their own trauma in sharing their experience.	Replicate feasibility study approach, but also make counselling available for mentors should they wish to have additional support to manage their own emotional response.
Intervention timing	Recruited in inpatient setting with peer mentoring intervention commencing immediately postdischarge	The period immediately postdischarge is a chaotic period where people with TBI and their families are engaging with a range of community-based services, as well as trying to manage the complexity of reintegrating into the community. The complexity of this period meant many potential participants were overwhelmed by other competing demands, frequently leading to difficulty scheduling mentoring sessions.	Recruit mentees up to 18 months postinjury to allow potential participants flexibility to engage at a time that works best for them.
Intervention length	Six sessions over 3 months	The mentoring relationship requires time to establish a trusting relationship. Furthermore, the mentoring intervention is being delivered in the context of a broader recovery process as the mentees work on getting back to life post-TBI. As such, more sessions over a longer period would allow flexibility to tailor the mentoring sessions to meet the unique needs of the individual.	Offer eight sessions over 5 months.
Family involvement	Mentees could invite family participation if they wished	Only one mentee invited active involvement of family members. In that instance, the mentees' wife attended early sessions and the final session, and both the mentee and his wife valued her involvement. Beyond this, feedback was variable regarding the potential for family involvement. One of the reported benefits of the mentoring relationship was the ability to be open and transparent in a way mentees had struggled to be with family. Family involvement could constrain this.	Family involvement welcomed but determined by personal preference of the mentee; invite family to a single 1:1 session with the mentor.
Recruitment	Recruited mentees just prior to discharge from inpatient setting	Capturing people immediately predischarge was complex the window between being identified for discharge and actual discharge was small, resulting in missed opportunities.	Expanding inclusion criteria to up to 18 months postinjury will increase the recruitment window, as well as enable involvement of additional recruiting localities.
Trial design	A small number of participants completed outcomes data only to inform sample size calculations	Recruitment of people with TBI for outcomes data only was difficult as the perceived burden of taking part surpassed any perceived benefit.	Adopt waitlist control design to allow control participants access to the intervention.

TBI, traumatic brain injury.

Hypotheses

The primary hypothesis is that people with TBI receiving a peer support intervention will have better participation, measured by the IPA questionnaire, after 22 weeks (on completion of the 5-month intervention period) compared with those in the waitlist control. The associated Null Hypothesis is that there is no difference in participation.

Our secondary hypotheses include that

1. People with TBI receiving a peer support intervention will have better subjective well-being, life satisfaction, hope, self-efficacy, health status and employment outcomes after 22 weeks compared with those in the waitlist control.
2. Mentors engaged to deliver a peer support intervention will report improvements in subjective well-being, anxiety, depression and employment outcomes on exit from their role as mentor compared with baseline.

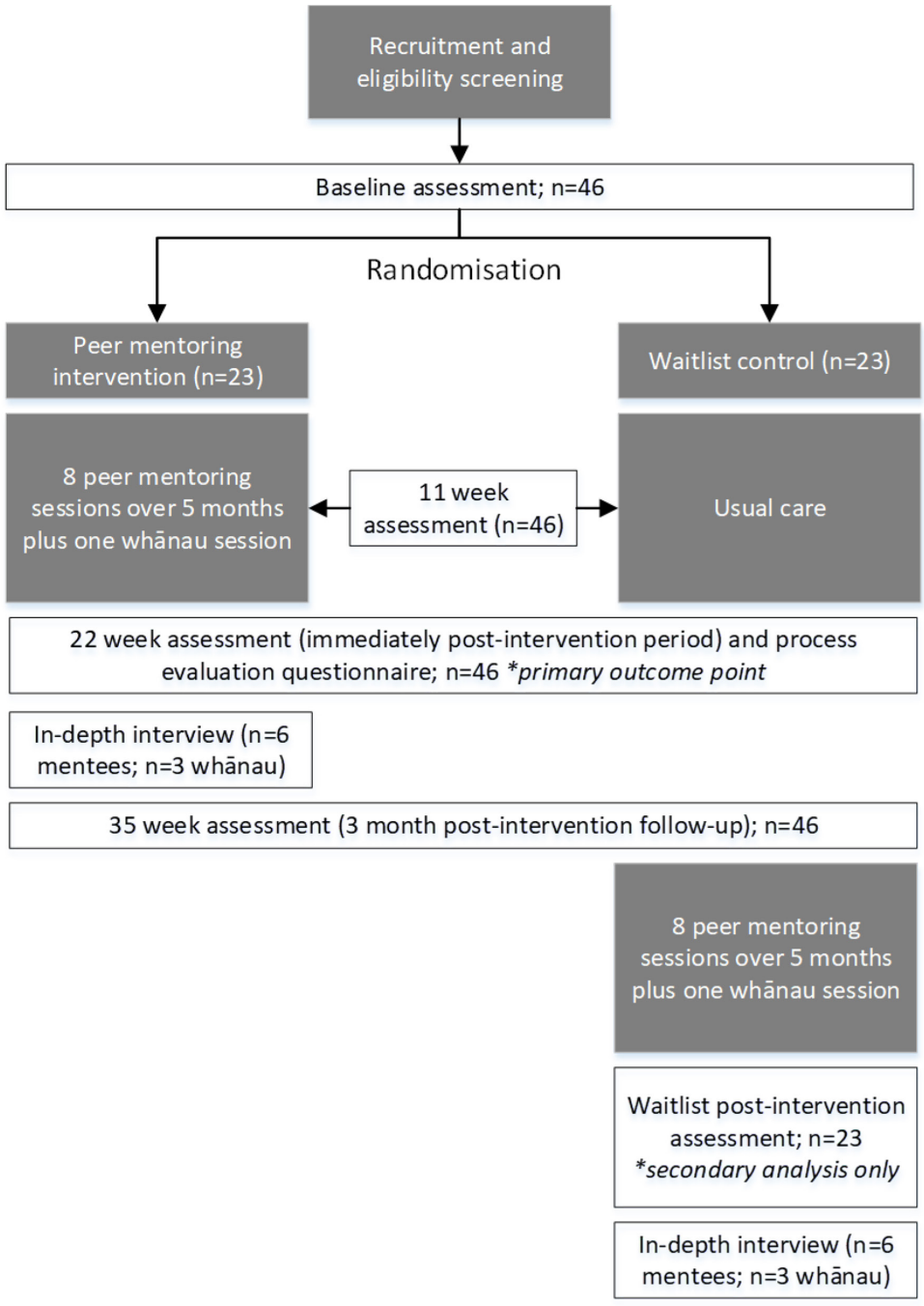

Figure 1 Study design overview.

Participants

Mentees

Inclusion and exclusion criteria

Potential participants, as mentees, are those with TBI, who have moderate or severe TBI, defined as an initial Glasgow Coma Scale score <13 and/or post-traumatic amnesia duration of more than 1 hour. Other criteria are as follows: up to 18 months after TBI; ≥16 years old; able to communicate with or without assistance; able to give informed consent and living in one of the three study locations. Potential participants will not be recruited if: their medical situation is considered unstable and could severely limit participation in mentoring activities; or they are enrolled in other intervention trials.

Recruitment

Potential mentee participants will be identified by brain injury rehabilitation providers and relevant non-government organisations in the three study locations. Furthermore, targeted advertising in local newspapers, via social media and primary care clinics, will be used to identify people not already known to those services. Potential participants will be provided with a web link to access a video providing information about peer support

and what taking part in the research will involve. Potential participants will be encouraged to share the video with family or other support people to inform their decision. Those interested will then be referred to their local service coordinator who will arrange to meet with individuals, and their family if desired, to discuss their potential participation in person and seek their informed consent.

Mentors

Inclusion and exclusion criteria

Potential participants, as mentors, are those with TBI who are: >18 years of age, up to 6 years after TBI, at least 1 year after discharge from inpatient rehabilitation, satisfied with their current level of participation, health and well-being, able to communicate and engage in intervention delivery and living within one of the three study locations. Potential participants will not be recruited if they experience persistent drug or alcohol difficulties; they have a recent history of violence; criminal record checks indicate significant potential ongoing risk and/or they are experiencing severe mental illness that would impact their ability to fulfil mentor roles and responsibilities.

Recruitment

An initial pool of potential mentors meeting eligibility criteria will be identified from a database of clients who received intensive brain injury rehabilitation through the primary inpatient service provider in the Northern region of New Zealand. As well as provision of information about the study, they will receive an invitation to apply for a mentoring role. If that does not yield enough applications, potential mentors will also be identified through relevant community-based rehabilitation providers in service locations. Consistent with usual institutional employment processes, a shortlist of eligible applicants will be invited for interview. Final appointments will be subject to referee reports and criminal record checks being satisfactory, with consideration given to the inclusion and exclusion criteria specified above. Recruitment processes will target each of the three study locations with the aim to recruit up to six mentors per locality. As the study progresses, suitable mentees who have completed data collection commitments for the trial will be invited to take on a mentorship role. This rolling cohort approach, used successfully in spinal cord injury,[24] will ensure a readily available pool of peer mentors in each location. Mentors will be paid on a casual basis and reimbursed for time spent engaged in training activities, preparatory work, mentee visits, record keeping and debriefing sessions, both one-to-one and in group sessions, with their local service coordinator.

Intervention

Peer support programme

The peer support programme will include up to eight face-to-face sessions over 5 months, including an introductory session organised by the service coordinator. Mentors will be encouraged to meet with their mentee on a regular basis, fortnightly, with flexibility to work around mentor and mentee schedules and preferences. Mentoring sessions may take place in a rehabilitation facility, at the mentee's home or at another mutually agreed location. During sessions, mentors will spend time getting to know the mentee and their needs and preferences; and share their own experience of recovery from TBI. Mentors will explore mentees' hopes for meaningful participation and will provide opportunities and encouragement for mentor-supported participatory activities, for example, going to a local cafe, shopping, using public transport, leisure and cultural activities. An example of how these components might be organised across eight sessions is shown in table 2. However, while there are core components (eg, getting to know, identifying hopes for meaningful participation, planning mentor-supported activities); our feasibility study suggested that a more fluid, organic and dynamic process is valued rather than the more structured, linear approach implied in the example. As such, how, when and if the components are incorporated, will be tailored to the mentees' unique psychosocial context, and the mentoring relationship.

Family and whānau (extended family) involvement will be encouraged, though mentees preferences regarding their involvement will be given primacy. Research in spinal cord injury indicates that family can benefit from debriefing with someone with lived experience.[25]

Table 2 Example of core components dispersed across eight sessions

Session 1/2	*Getting to know the mentor:* What are their likes/dislikes, needs/preferences, things that are causing them concern? Building connectivity through shared experience.
Session 3	*Exploring hopes for meaningful participation:* How would they describe their typical day? How do they want that to be different? What social and leisure activities would they like to do more of? What are their hopes regarding work/school/volunteering/social roles? What matters most of all these things?
Session 4	*Exploring barriers/facilitators:* What would help/ hinder the mentee doing the things that matter to them? How might the mentor/ mentor-supported activities help to overcome these? Develop a plan for a mentor-supported activity.
Session 5	Mentor-supported activity
Session 6	*Reflection on mentor-supported activity:* What went well/did not go well? Develop a plan for the next mentor-supported activity. Remind mentee that the intervention is limited to eight sessions and that they have two more sessions left.
Session 7	Mentor-supported activity
Session 8	Reflection on mentor-supported activity and planning for the future

Therefore, regardless of their involvement in the peer support process and if agreeable to the mentee, family members will be offered the opportunity to meet with the mentor to explore questions they have about what their loved one might be experiencing. These meetings may be with or without the mentee present, depending on their preference. If this is something the mentee and family members wish to proceed with, then we will work with all parties to agree basic groundrules, including exchanging expectations around confidentiality, to ensure it is safe, respectul and acceptable for all involved.

Mentor training and support

Mentors will attend a 2-day interactive workshop. The content of this workshop will mirror that used in our feasibility study[20] and will include a mix of presentations, discussion, role play and skill-building activities. The aim of this workshop is not to professionalise the role of mentor because our feasibility study identified that the value of the mentoring relationship is in their lived and shared experience. Topics covered in the training will include introducing the role of the mentor, the mentoring intervention and relationship, managing difficult and/or crisis situations and safety protocols. Training strategies that were useful in our feasibility study included strategies for supporting mentors to consider their own TBI story and how to share this with a wider group. As well as helping to articulate their story and decide what aspects they are willing to share, this also helps them gain an insight into other's stories and how they might be similar or different to their own.

Once mentoring begins, informal phone debriefings will be conducted by the local service coordinator following each intervention session. These debriefings will include an update on the mentoring sessions, any issues and concerns they may have, and checking in on mentor well-being. Group debriefing sessions will be carried out with mentors during active mentoring periods on a quarterly basis. These will provide an opportunity for the mentors to share their experiences and strategies with each other, as well as discuss common issues and concerns.

Fidelity

The mentoring intervention is a personalised intervention. The strength of this approach is in the mentor bringing their shared experience to support and enable the mentee to re-engage with life after TBI. Our feasibility study findings indicated that the substantive nature of the intervention is likely to matter less than the mentoring relationship itself. In this context, fidelity is arguably a contested concept and to reflect this, there will be several proxy measures of fidelity. Mentors will keep intervention records of the number, frequency and nature of their contacts for example, phone contact/face-to-face sessions/mentor-supported activities. Service coordinators will record details of informal debriefing conversations as a supplement to mentor notes. Group debriefing sessions will be audiorecorded and transcribed.

Randomisation and blinding

We will use computerised randomisation by a statistician using random block sizes of two and four, to ensure allocation in equal proportions to peer support and waitlist control—the latter receiving mentoring after their 35-week assessment, the 3-month follow-up time point. We will stratify by ethnicity at the point of randomisation. The allocation sequence will remain concealed. Once consent has been obtained by the local service coordinator, participants will complete a baseline assessment, as described below. The researcher will submit an online randomisation request to an independent data analyst within five working days following completion of the baseline assessment who will email group allocation to the local service coordinator. The local service coordinator will match participants randomised to peer support with a suitable mentor. Preferences and interests gathered during screening as well as mentor availability will guide matching decisions. Both mentor and mentee will be notified of the pairing within 5 days of randomisation, following which the service coordinator will set up a mutually convenient time for an initial session to make introductions, within 10 working days of randomisation. Mentees, mentors and local service coordinators will not be blinded to intervention allocation due to the nature of the intervention. They will not be involved in the collection and analysis of outcomes data. The assessors, data manager, statistician and remaining team members involved in analysis of outcomes data will be blinded to actual intervention allocation. Any instances of suspected unblinding will be recorded.

Data collection

Mentee outcomes data

There will be four assessment points for all mentee participants including at baseline, 11 weeks from date of randomisation (mid-intervention), 22 weeks from date of randomisation (completion of the 5-month intervention period), and 35 weeks (3-month follow-up). These are expected time frames with a maximum tolerance of a 3-week window which allows room for assessments to take place up to 1 week prior to scheduled assessment point and no more than 2 weeks after that time point. Waitlist controls will have an additional assessment point on completion of their 5-month intervention period. Given the potential for fatigue and cognitive impairment to contribute to mentees capacity to complete the full assessment at each time point,[26] (a) measures will be administered in order of priority and will always commence with the primary outcome, and (b) participants will be able to complete the assessment over two sessions if necessary and logistically viable.

Primary outcome

The primary outcome is mentee participation, measured by the IPA questionnaire[27 28] at 22 weeks. The IPA has

Table 3 Outcome measures

Variable	Measure	Items	Detail	Administration schedule
Participation	Impact on Participation and Autonomy[27 28]	39 in five domains	The IPA has excellent psychometric properties and has been used extensively in diverse populations, including acquired brain injury.[27–29]	*Mentees only:* Baseline 22 weeks 35 weeks 57 weeks (waitlist only)
Subjective well-being	The Short Warwick-Edinburgh Mental Well-Being Scale[34]	7	Good sensitivity and internal construct validity has been demonstrated using Rasch analysis.[35]	*Mentees:* Baseline 22 weeks 35 weeks 57 weeks (waitlist only) *Mentors:* On appointment On exit from their role as mentor
Life satisfaction	The Satisfaction with Life Scale[36 37]	5	Excellent internal consistency and able to measure change. Has been used in TBI.[17]	*Mentees only:* Baseline 22 weeks 35 weeks 57 weeks (waitlist only)
Hope	Herth Hope Index[38]	12	Measures globalised hope: temporality and future; positive readiness and expectancy; interconnectedness. Valid in people with cognitive impairment.[39]	*Mentees only:* Baseline 22 weeks 35 weeks 57 weeks (waitlist only)
Self-efficacy	General Self-Efficacy Scale[40]	10	Assesses personal agency, specifically an individual's belief in their ability to cope with a variety of life situations.	*Mentees only:* Baseline 22 weeks 35 weeks 57 weeks (Waitlist only)
Health status	EQ5D[41]	5 and a visual analogue scale	Valid in a range of health conditions including those with cognitive impairment.[42] The EQ5D will also be used to calculate quality–adjusted life years (QALY) for the cost utility analysis.	*Mentees only:* Baseline 22 weeks 35 weeks 57 weeks (waitlist only)
Productivity status	Self-report	2	Current occupational status (paid work, unpaid work (eg, homemaker, carer, volunteer), student, unemployed, retired, hours (eg, full/part time) and satisfaction with current status.[43]	*Mentees:* Baseline 22 weeks 35 weeks 57 weeks (waitlist only) *Mentors:* On appointment On exit from their role as mentor
Anxiety and depression	Hospital Anxiety and Depression Scale (HADS)[44]	14 in two domains	Strong internal validity in TBI with good concurrent and discriminant validity[45]	*Mentors only:* On appointment On exit from their role as mentor

IPA, Impact on Participation and Autonomy; TBI, traumatic brain injury.

excellent psychometric properties and has been used extensively in diverse populations, including acquired brain injury.[27–29] The IPA is unique. Rather than focusing solely on how much someone is participating (a common assumption in participation measurement is that more is better) it includes consideration of whether the individual is participating to the extent they wish to, and in the way they want to.

Additional measures

Age and injury severity will be collected at screening. Demographic data including gender, ethnicity, pre-injury occupational status and pre-injury living situation will be collected at baseline. Table 3 provides an overview of additional measures collected at each assessment point. Selection of secondary outcomes was informed by findings from the feasibility study and aim to capture outcomes identified as important to mentees and mentors in that feasibility work.

Mentor outcomes data

Mentor outcomes data will be collected at two assessment points including at the time of their recruitment into the role and then again at the end of their involvement in the research. Demographic data including age, gender and ethnicity will be collected when they are first appointed. Current occupational status and current living situation

will be collected at both assessment points. Table 3 includes an overview of measures collected for mentors.

Process evaluation data

The purpose of the process evaluation is to determine key process variables relating to intervention, context and implementation relevant for future service delivery.

Intervention-related data

As noted above, mentors will keep intervention records of the number, frequency and nature of their contacts for example, phone contact/face-to-face sessions/mentor-supported activities. Service coordinators will also have regular informal debriefing conversations with mentors following each intervention session and will maintain field notes as a supplement to mentor notes.

Debrief with mentees

All mentee and family members, where applicable, will be invited to share their experiences of peer support including their reasons for taking part, their perspectives on key intervention components (e.g. mentor match, content, frequency, timing), whether peer support meets their expectations, and any perceived impact. These debriefing sessions will be carried out with a researcher not otherwise involved in service delivery and/or blinded assessments at the end of the intervention period. These sessions will be primarily by telephone but may be in person if preferred. They will be audio recorded and transcribed verbatim.

Reflective journals

Both mentors and service coordinators will keep a reflective journal, written or audio depending on preference, to capture their reflections and experiences throughout the research process. They will be encouraged to share any reflections on their role, challenges they have faced and positive or negative impacts they have experienced or observed.

Group debrief with mentors

As noted, group debriefing sessions will be carried out with mentors during active mentoring periods on a quarterly basis. They will be audio recorded and transcribed verbatim.

In-depth interviews

Mentors and service coordinators will be invited to take part in an in-depth interview on study completion to explore their experiences and perspectives regarding peer support after brain injury, their role as mentor or service coordinator, reflections on key aspects of the mentoring training and process, service structures and design, and their recommendations for future service delivery.

Economic evaluation data

Intervention-related costs

Cost of peer support programme will be estimated by the number of mentees and the length of time they have participated in the programme. Intervention-related resources will be recorded to estimate costs of the peer support programme, including time commitment for service coordinators and mentors, including time for travel, training, administration, mentoring sessions, debriefing; travel costs; expenses associated with mentor-supported activities; and training materials.

Health service utilisation

Health service utilisation data will initially be captured by self-report using a resource-use and cost questionnaire completed by mentees, at baseline and 35 weeks. Questions will seek details of health and social service utilisation, medication and home care. Self-reported service utilisation data will be supplemented by electronic medical records (hospital) obtained with participant consent. Only data relevant to the study period and injury-related health use will be extracted.

Sample size

Our target sample size is 46, based on a Minimal Clinically Important Difference (MCID) for the primary outcome variable of 1.6, an SD of 1.44[27] and assuming a 30% attrition rate, giving over 80% power to detect the MCID. In detail: the primary outcome is the IPA 'Autonomy Outdoors' subscale completed at 22 weeks from randomisation (completion of the 5-month intervention period). This subscale captures autonomy, the key focus of this research, across a diversity of participatory activities: visiting relatives/friends, going on trips/holidays, leisure and social activities and more broadly 'living life the way I want to'. The chosen MCID for this variable is 1.6, reported by Cardol and colleagues.[27] In our feasibility study, in a very similar sample to the one we will recruit, the estimated SD was 0.91 (95% CI 0.67 to 1.44). In the sample size calculation, we used a conservative approach by using the upper confidence limit of the estimated SD.

Data safety and monitoring

Data completeness will be monitored continuously, and quality checks will be conducted on a quarterly basis by the data manager. Adverse events will be recorded and reported to the principal investigator, steering committee and ethics committee as per a predefined protocol. An independent data monitoring committee (DMC) will meet 6 months to review trial security and monitor adverse events. The trial will be suspended if a serious adverse event (including death, life threatening event, permanently disabling or incapacitating event, hospitalisation, significant physical or emotional harm) is deemed to have a high probability of relatedness to study conduct or intervention. In this instance, the steering committee will conduct a safety review which will be submitted to the DMC for review and discussion. The trial will resume

only after the steering committee (under guidance of the DMC and in discussion with the Health and Disability Ethics Committee) are satisfied that all reasonable steps are in place to prevent a similar event. If not, the trial will be terminated.

Data analysis

Primary analysis

The primary analysis of the continuous variables will be analysis of covariance with baseline measurement as a covariate and randomised treatment as the main explanatory predictor variable after 22 weeks. Use of the baseline measurement as a continuous covariate is likely to increase statistical power compared with the change from baseline SD used in the sample size calculation.

Secondary analyses

Secondary analyses will include modelling mentors as a random effect in a mixed linear model to determine if there is a strong element of correlated data within mentors and if so to estimate the relevant intraclass correlation coefficient. If this correlation is present, this will widen CIs but make the estimates more generalisable. Other secondary analyses will be to model centres as fixed effects and use mixed linear models for estimating differences across all the timed measurements. Categorical variables will be modelled by Poisson regression (for multiple category variables such as productivity status). Although we feel the sample size is robustly estimated, it is still relatively small, so there may be maldistribution of possibly influential covariates. As another secondary analysis we will model the covariates of mentee ethnicity (noting that we have already stratified randomisation by ethnicity) and gender, as main effects, to explore if the conclusions from the primary analysis are robust. Additional secondary analyses will explore change from before and after peer mentoring in the waitlist control group. This will explore whether there is evidence for a treatment effect at a longer time post-injury.

Process evaluation

Process evaluation analyses will include the following: (a) synthesis of data relevant to key intervention parameters, (b) analysis of mentee and mentor experiences and perspectives of peer support and (c) production of in-depth case examples. These analyses will be synthesised to inform the development of a service framework for ongoing service provision.

Intervention parameters

Predetermined codes relating to intervention parameters of interest will be developed. Intervention parameters include for example mentor training and support, mentoring sessions and activities, the mentoring relationship, intervention timing/frequency/length, rolling mentor process and family involvement. Additional topics may be identified during debriefing sessions with mentees and mentors. Directed content analysis[30] will be used initially to code data relevant to key intervention parameters. Data coded within each parameter will then be inductively analysed to generate insights relevant to each parameter.

Experience and perspectives of peer support

Reflexive thematic analysis[31] will be used to examine the experiences and perspectives of mentees, mentors and service coordinators. Primary data sources for this analysis will be the mentee and mentor debriefing sessions, and in-depth interviews with mentors and service coordinators. Initially, data from each participant type (mentees, mentors and service coordinators) will be analysed separately to explore patterns that may be unique to each group, and then together to construct themes across the data set.

Case examples

In-depth case examples will be developed from a purposeful sample of mentees (at least n=6). Mentees will be sampled for diversity with respect to age, ethnicity, injury severity, timing of peer support and service location. Data sources will include all outcomes and process data relevant to each mentee. A summary narrative will be constructed for each individual case. A cross-case analysis will draw on realist principles[32] to develop a deeper understanding of what works, for whom and in what circumstances.

Economic evaluation

Cost analysis

Cost analysis will include (a) cost of peer support programme, (b) direct healthcare costs, that is, rehabilitation services, prescription charges; (c) indirect costs (lost productivity will be assessed by changes in productivity status) and (d) out of pocket expenses associated with peer support compared with usual care. Cost will be measured using New Zealand dollars 2023 value. The per person cost of peer mentoring will be estimated drawing on data regarding the number of mentees, their hourly rate, time commitment (including travel, mentoring sessions, training, support and administration), intervention costs (including travel, mentor-supported activities and training materials) and number of mentees. *Hospitalisations* will be confirmed by International Classification of Diseases, 10th Revision (ICD-10), codes. The cost will be taken from assessed hospital charges recorded in the National Minimum Dataset. Hospitalisation costs will be determined using weighted discharge value known as the weighted inlier equivalent separations for all NMDS events by the Ministry of Health. We will use NZ dollars 2022/2023 financial year prices for inpatient admitted and non-admitted care events. Direct healthcare costs will be estimated using a resource-based costing approach. Self-reported health and social service use information completed by mentees, at baseline and 35 weeks, detailing the frequency of health service usage. Costs required to provide health services will be calculated using national or market prices per service. *Indirect costs*

will estimate the loss of income in the workplace resulting from injury for time off work to attend inpatient admitted or non-admitted care. Median daily income sourced from the New Zealand Statistics data will be used to estimate productivity loss.

Cost effectiveness and cost utility analysis

A cost effectiveness and cost utility analysis will be conducted alongside the clinical trial in accordance with the Consolidated Health Economic Evaluation Reporting Guidelines[33] to examine the likely impacts of peer support relative to usual care. An incremental cost effectiveness ratio will be calculated to compare additional costs and health benefits associated with peer support using the primary outcome. If peer support is proven cost-effective, then further, threshold analysis will be performed to: (i) reflect the combined implication and uncertainty in the model parameters, illustrated using cost effectiveness acceptability curves; and (ii) identify under what conditions peer support could be cost effective and yield cost savings. The EQ5D will be used to calculate quality–adjusted life years for the cost utility analysis.

ETHICS AND DISSEMINATION

Ethics approval for this trial has been obtained from the New Zealand Health and Disability Ethics Committee (19/NBT/82) and the Auckland University of Technology Ethics Committee (19/345). Dissemination of findings will be via traditional academic routes including publication in internationally recognised peer-reviewed journals and presentation at professional conferences. Three planned papers will report: (1) primary trial findings, (2) implementation of peer support after brain injury and (3) mentor experiences and perspectives of peer support. In addition to these traditional academic routes, we will share findings with key localities and communities involved in the research. Furthermore, a primary outcome of this research will be the development of a service framework to underpin ongoing service provision by third-party providers for immediate implementation which will be shared with rehabilitation funders and providers.

CONCLUSION

This research will produce outcomes, process and economic data required for health funders, policymakers and providers to determine benefit, utility and affordability of a peer support intervention after TBI. We will (a) establish TBI peer support services in three regions in Aotearoa New Zealand; (b) test effectiveness for improving participation, health and well-being and (c) determine service parameters for optimal impact and cost-effective delivery. These findings will inform the development of a service framework to underpin ongoing service provision by third-party providers for immediate implementation.

Author affiliations
[1]Centre for Person Centred Research, Faculty of Health and Environmental Sciences, Auckland University of Technology, Auckland, New Zealand
[2]Rehabilitation Teaching and Research Unit, University of Otago Wellington, Wellington, New Zealand
[3]School of Population Health, Faculty of Medical and Health Sciences, University of Auckland, Auckland, New Zealand
[4]He Tapu Te Upoko, Auckland, New Zealand
[5]ABI Rehabilitation New Zealand Ltd, Wellington, New Zealand
[6]Foster Medical Communications, Auckland, New Zealand
[7]Faculty of Medicine, Health and Social Care, Canterbury Christ Church University, Canterbury, UK

Twitter Nicola Kayes @nickayes4 and Paula Kersten @paula_kersten

Contributors NK is principal investigator. NK, PK and CC conceived of the study. NK, PK, CC and GS initiated the study design and all authors contributed to refining the design. All authors are named investigators on the grant. CC is the project manager and will oversee day-to-day running of the trial. GS provides experience in clinical trial administration and is responsible for data management. MW provided statistical expertise in clinical trial design and is conducting the statistical analysis. BTA provided economic evaluation expertise and is leading the economic evaluation. JF, CHB and AF provide experience in TBI and will support process evaluation and the development of a service framework for future implementation. HE provides clinical experience of working in TBI and leads Māori engagement. All authors contributed to refinement of the study protocol and approved the final manuscript. All investigators will be invited to contribute to further publications arising from this work.

Funding This work was supported by Health Research Council of New Zealand 18/311. The funder had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data or decision to submit results.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Nicola Kayes http://orcid.org/0000-0002-2747-667X
Joanna Kirstin Fadyl http://orcid.org/0000-0001-7678-9122

REFERENCES

1 Hyder AA, Wunderlich CA, Puvanachandra P, *et al*. The impact of traumatic brain injuries: a global perspective. *NeuroRehabilitation* 2007;22:341–53.
2 Sendroy-Terrill M, Whiteneck GG, Brooks CA. Aging with traumatic brain injury: cross-sectional follow-up of people receiving inpatient rehabilitation over more than 3 decades. *Arch Phys Med Rehabil* 2010;91:489–97.
3 Hoofien D, Gilboa A, Vakil E, *et al*. Traumatic brain injury (TBI) 10-20 years later: a comprehensive outcome study of psychiatric symptomatology, cognitive abilities and psychosocial functioning. *Brain Inj* 2001;15:189–209.
4 Colantonio A, Ratcliff G, Chase S, *et al*. Long-term outcomes after moderate to severe traumatic brain injury. *Disabil Rehabil* 2004;26:253–61.
5 Olver JH, Ponsford JL, Curran CA. Outcome following traumatic brain injury: a comparison between 2 and 5 years after injury. *Brain Inj* 1996;10:841–8.
6 Lorenz LS, Doonan M. Value and cost savings from access to multidisciplinary rehabilitation services after severe acquired brain injury. *Front Public Health* 2021;9:753447.

7 Levack WMM, Kayes NM, Fadyl JK. Experience of recovery and outcome following traumatic brain injury: a metasynthesis of qualitative research. *Disabil Rehabil* 2010;32:986–99.
8 Fadyl JK, Theadom A, Channon A, *et al*. Recovery and adaptation after traumatic brain injury in New Zealand: longitudinal qualitative findings over the first two years *Neuropsychol Rehabil* 2019;29:1095–112.
9 McPherson K, Fadyl J, Theadom A, *et al*. Living life after traumatic brain injury: phase 1 of a longitudinal qualitative study. *J Head Trauma Rehabil* 2018;33:E44–52.
10 Dennis C-L. Peer support within a health care context: a concept analysis. *Int J Nurs Stud* 2003;40:321–32.
11 Campbell HS, Phaneuf MR, Deane K. Cancer peer support programs-do they work? *Patient Educ Couns* 2004;55:3–15.
12 Dale JR, Williams SM, Bowyer V. What is the effect of peer support on diabetes outcomes in adults? A systematic review. *Diabet Med* 2012;29:1361–77.
13 Repper J, Carter T. A review of the literature on peer support in mental health services. *J Ment Health* 2011;20:392–411.
14 Kolakowsky-Hayner SA, Wright J, Shem K, *et al*. An effective community-based mentoring program for return to work and school after brain and spinal cord injury. *NeuroRehabilitation* 2012;31:63–73.
15 Sherman JE, DeVinney DJ, Sperling KB. Social support and adjustment after spinal cord injury: influence of past peer-mentoring experiences and current live-in partner. *Rehabilitation Psychology* 2004;49:140–9.
16 Hibbard MR, Cantor J, Charatz H, *et al*. Peer support in the community: initial findings of a mentoring program for individuals with traumatic brain injury and their families. *J Head Trauma Rehabil* 2002;17:112–31.
17 Struchen MA, Davis LC, Bogaards JA, *et al*. Making connections after brain injury: development and evaluation of a social peer-mentoring program for persons with traumatic brain injury. *J Head Trauma Rehabil* 2011;26:4–19.
18 Hanks RA, Rapport LJ, Wertheimer J, *et al*. Randomized controlled trial of peer mentoring for individuals with traumatic brain injury and their significant others. *Arch Phys Med Rehabil* 2012;93:1297–304.
19 Sveen U, Guldager R, Soberg HL, *et al*. Rehabilitation interventions after traumatic brain injury: a scoping review. *Disabil Rehabil* 2022;44:653–60.
20 Kersten P, Kayes NM, Cummins C, *et al*. Peer mentoring after traumatic brain injury (TBI) – a valuable experience for mentees and mentors. *Arch Phys Med Rehabil*2015;96:e87.
21 Lau SKC, Luong D, Sweet SN, *et al*. Using an integrated knowledge translation approach to inform a pilot feasibility randomized controlled trial on peer support for individuals with traumatic brain injury: a qualitative descriptive study. *PLOS ONE* 2021;16:e0256650.
22 Gagnon ML. Moving knowledge to action through dissemination and exchange. *J Clin Epidemiol* 2011;64:25–31.
23 Elder H. Te Waka Kuaka and Te Waka Oranga. Working with whanau to improve outcomes. *Aust N Z J Fam Ther* 2017;38:27–42.
24 Kelly EH. Community competence and violently acquired spinal cord injury: employment as a peer role model. *Rehabil Psychol* 2007;52:226–35.
25 Haas BM, Price L, Freeman JA. Qualitative evaluation of a community peer support service for people with spinal cord injury. *Spinal Cord* 2013;51:295–9.
26 Greenwood A, Theadom A, Kersten P, *et al*. Exploring researchers' experiences of working with people with acquired brain injury. *Brain Inj* 2015;29:592–600.
27 Cardol M, Beelen A, van den Bos GA, *et al*. Responsiveness of the impact on participation and autonomy questionnaire. *Arch Phys Med Rehabil* 2002;83:1524–9.
28 Cardol M, de Haan RJ, de Jong BA, *et al*. Psychometric properties of the impact on participation and autonomy questionnaire. *Arch Phys Med Rehabil* 2001;82:210–6.
29 Kersten P, Cardol M, George S, *et al*. Validity of the impact on participation and autonomy questionnaire: a comparison between two countries. *Disabil Rehabil* 2007;29:1502–9.
30 Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res* 2005;15:1277–88.
31 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.
32 Pawson R, Tilley N. *Realistic evaluation*. SAGE Publications, 1997.
33 Husereau D, Drummond M, Petrou S, *et al*. Consolidated health economic evaluation reporting standards (cheers) statement. *Value Health* 2013;16:e1–5.
34 Tennant R, Hiller L, Fishwick R, *et al*. The warwick-edinburgh mental well-being scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes* 2007;5:63.
35 Stewart-Brown S, Tennant A, Tennant R, *et al*. Internal construct validity of the warwick-edinburgh mental well-being scale (WEMWBS): a Rasch analysis using data from the Scottish health education population survey. *Health Qual Life Outcomes* 2009;7:15.
36 Diener E, Emmons RA, Larsen RJ, *et al*. The satisfaction with life scale. *J Pers Assess* 1985;49:71–5.
37 Corrigan JD, Kolakowsky-Hayner S, Wright J, *et al*. The satisfaction with life scale. *J Head Trauma Rehabil* 2013;28:489–91.
38 Herth K. Abbreviated instrument to measure hope: development and psychometric evaluation. *J Adv Nurs* 1992;17:1251–9.
39 Hunsaker AE, Terhorst L, Gentry A, *et al*. Measuring hope among families impacted by cognitive impairment. *Dementia (London)* 2016;15:596–608.
40 Luszczynska A, Scholz U, Schwarzer R. The general self-efficacy scale: multicultural validation studies. *J Psychol* 2005;139:439–57.
41 Cheung K, Oemar M, Oppe M, *et al*. EQ-5D. User Guide. Basic information on how to use the EQ-5D. Version 2.0. 2009. Available: http://www.euroqol.org/
42 Payakachat N, Ali MM, Tilford JM. Can the EQ-5D detect meaningful change? A systematic review. *Pharmacoeconomics* 2015;33:1137–54.
43 Young AE, Roessler RT, Wasiak R, *et al*. A developmental conceptualization of return to work. *J Occup Rehabil* 2005;15:557–68.
44 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361–70.
45 Dahm J, Wong D, Ponsford J. Validity of the depression anxiety stress scales in assessing depression and anxiety following traumatic brain injury. *J Affect Disord* 2013;151:392–6.