Statistical Analysis Plan (SAP) for 'Evaluating a sustainable model of peer mentoring in traumatic brain injury: Randomised pragmatic waitlist trial with process evaluation' trial: a randomised controlled trial with cohort study of peer support after brain injury.

Short title: Peer Support After Brain Injury (PEER)

Trial registration number UTN: U1111-1224-0476

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1. Abstract

Background: There is little evidence about peer-mentoring interventions in traumatic brain injury (TBI). The PEER-TBI study is a randomised controlled trial of peer support after TBI, and an associated cohort study, that aims to evaluate the efficacy of peer support and longer-term outcomes in a sample of New Zealanders with TBI.

Objective: To pre-specify the statistical analysis plan to minimise reporting and other bias in the randomised controlled trial and cohort study of PEER-TBI.

Methods: This statistical analysis plan (SAP) takes into consideration aspects of trial design and reporting specific to non-pharmacological interventions and contains the plan for reporting and analysing the trial that also includes a pre-specified approach to missing data.

Results: The study protocol has a full description of the data collection (Kayes et al 2023)[1]. The SAP provides more detail of both the general principles for the planned study analysis, as well as the specific elements of the analysis. There are detailed descriptions for reporting of participant characteristics, trial outcomes, and process measures. The primary outcome is the Impact of Participation and Autonomy Outdoors Score. It will be analysed by intention-to-treat with a superiority approach. A sensitivity analysis will assess how potential confounding factors influence the assessment of treatment effect. Secondary outcomes will be analysed using traditional (two-sided) statistical methods.

Conclusion: The SAP for the PEER-TBI study is available in the public domain before completion of data collection to minimise the risk of analytic bias.

Trial registration: UTN: U1111-1224-0476

[1] Kayes N, Cummins C, Weatherall M, Smith G, Te Ao B, Elder H, Fadyl JK, Howard-Brown C, Foster A, Kersten P. Randomised pragmatic waitlist trial with process evaluation investigating the effectiveness of peer support after brain injury: protocol. BMJ Open. 2023 Feb 7;13(2):e069167. doi: 10.1136/bmjopen-2022-069167. PMID: 36750279; PMCID: PMC9906261.

2. Introduction

The burden of traumatic brain injury (TBI) on the individual, their whānau and society is significant and enduring. Existing service provison in Aotearoa New Zealand has been shown to be lacking and failing to address the ongoing needs of people with TBI and their whānau in the context of a social and relational process of learning to live with and adapt to life after TBI. Peer mentoring interventions have positive effects on health and social outcomes for both the mentee and mentor across a diversity of populations. Peer mentors are those who have successfully faced a particular experience and can provide good counsel and empathic understanding to help others faced with a similar experience. Our HRC feasibility study found peer mentoring after TBI is highly acceptable to both mentors and mentees and has the potential to impact health and wellbeing outcomes for both mentees and mentors.

We have received funding from the Health Research Council of New Zealand to proceed to a full trial of a tailored face-to-face peer support intervention. We have partnered with key health delivery partners (ABI Rehabilitation, Te Hiku Hauora) committed to working with us to produce actionable findings for ongoing service provision if trial findings are positive. This research will produce outcomes, process and economic data required for health delivery partners to determine benefit, utility, and affordability of peer mentoring.

The purpose of making the statistical analysis plan (SAP) available in the public domain before completion of data collection is to minimise the risk of analytic bias.

The aims, hypotheses and design of this study are described in detail in a protocol paper, written according to the 'SPIRIT' guidelines (Kayes et al 2023[2]). This SAP has a summary of trial design however the SAP focuses on the analysis and reporting of data summaries and analysis results.

[2] Kayes, N., Cummins, C., Weatherall, M., Smith, G., Te Ao, B., Elder, H., ... & Kersten, P. (2023). Protocol: Randomised pragmatic waitlist trial with process evaluation investigating the effectiveness of peer support after brain injury: protocol. *BMJ Open*, *13*(2).

3. Study design overview

A randomised pragmatic waitlist trial with process evaluation. The pragmatic trial design mimics likely future service provision if results are positive. The primary outcome point will be at 22 weeks (on completion of the five-month intervention period). A wait-list control design allows us to: 1) offer control participants subsequent access to the service; 2) test a rolling mentor recruitment approach; and 3) explore a range of secondary questions. Outcome data will be collected at baseline, 11 weeks, 22 weeks, 35 weeks, and 57 weeks (waitlist control only). The use of the wait-list control means that all participants who continue in the trial can be used as a cohort study to assess ongoing change in outcomes in addition to the effect of the randomised treatment. The process evaluation will primarily consist of qualitative data and site resource demands. The associated economic evaluation will be from a health funder perspective and consist primarily of assessment of health service resource use and service implementation costs. The trial is prospectively registered UTN: U1111-1224-0476, and the study protocol contains details of the participants, intervention, control, outcomes, and time course of the study.

4. Aims and hypotheses

4.1. Primary aims

- To test the effectiveness of a peer support intervention for improving participation, health, and well-being after TBI compared to usual care (waitlist control)

The associated null hypothesis for the primary aim is that a peer support intervention does not improve participation after TBI compared to usual care.

4.2. Secondary aims

- To explore longer-term outcomes for all participants who received peer support (including waitlist controls).
- To determine key process variables relating to intervention (e.g., mentor-mentee relationship, mentoring activities), context (e.g., location, living situation), and

implementation (e.g., service coordination, mentor training and support) to underpin an evidence-based framework for ongoing service provision.

- To explore mentor experiences and perceived impact of their involvement in the delivery of a peer support intervention on their well-being.
- To undertake an economic evaluation to determine the relative cost-effectiveness of a peer support intervention compared to usual care.

5. Participant description variables

Where specified in the SAP some participant characteristics will also be part of the sensitivity analyses: adjustment for confounding and effect modification.

5.1. Categorical participant descriptors

5.1.1. Gender

5.1.2. Ethnicity

Self-reported ethnicity data was collected at level one i.e. participants could choose as many level 1 ethnicity groupings that applied: Māori, Pacific Peoples, NZ European, Asian, MELLA, Other. If a participant identifies with more than one ethnicity, prioritised ethnicity will be used for randomisation and outcomes analysis i.e. if someone has selected identifies as Māori, they will be categorised as Māori as their primary ethnicity.

5.1.3. Injury severity

Mild, Moderate Severe

5.1.4. Employments status before injury

Full-time, part-time, unemployed, student, retired, unpaid work

5.1.5. Employment status at recruitment

Full-time, part-time, unemployed, student, retired, unpaid work

5.1.6. Current living arrangements

Living by myself, Living with partner or spouse, Living with my whānau/family, Living with people not related to me, Living in home that I own, Living in home owned by family member, Living in rental accommodation, Living in residential facility, Living in boarding house, Other.

5.1.7. Intervention allocation

5.2. Scale participant descriptors

5.2.1. Age
5.2.2. Time since injury
5.2.3. Length of post-acute inpatient rehabilitation
5.2.4. Multi-morbidity index scores (Functional Comorbidity Index)

5.3. Outcome variables

5.3.1. Impact of participation and autonomy scores

Total, Autonomy outdoors (primary), Autonomy indoors, Family role, Social life and relationships, Work and education.

5.3.2. Short Warwick-Edinburgh Mental Well Being Scale
5.3.3. Satisfaction with Life survey score
5.3.4. Hearth Hope Index
5.3.5. General Self-efficacy scale
5.3.6. EQ5D-3L Health Utility Score
5.3.7. EQ5D Visual Analog Scale
5.3.8. Employment status

Full-time, part-time, unemployed, student, retired, unpaid work, satisfaction with current work status. The priority interest will be in proportion of people in paid work pre-injury, at baseline and at post intervention periods, together with satisfaction with current work status.

5.3.9. Serious Adverse events

Individual adverse events and total per participant

5.4. Trial process variables

5.4.1. Recruitment flow

Total potential participants, assessed for eligibility, ineligible, eligible but no consent, randomised and into which group.

5.4.2. Non-missing data by assessment time

5.4.3. Intervention completion by session

Including count of those attending all sessions and withdrawal count

5.4.4. Reasons for withdrawal

5.4.5. Protocol violations

5.4.6. Time between randomisation and initiation of intervention

5.4.7. Times between scheduled and actual assessments

6. Mentor description variables

As for participants above unless specified otherwise.

6.1.1. Gender

6.1.2. Ethnicity

6.1.3. Injury severity

6.1.4. Employments status before injury

6.1.5. Employment status at recruitment

6.1.6. Current living arrangements

6.2.Scale mentor descriptors

6.2.1. Age

6.2.2. Time since injury

6.2.3. Length of post-acute inpatient rehabilitation

6.3.Outcome variables

6.3.1. Short Warwick-Edinburgh Mental Well Being Scale

6.3.2. Hospital Anxiety and Depression Scale (HADS) Questionnaire
Anxiety and depression subscales

6.3.3. Employment status

6.4.Trial process variables

6.4.1. Recruitment flow

Total potential mentors, assessed for eligibility, ineligible, eligible but no consent, employed, and allocated to mentee

6.4.2. Intervention completion by session by mentee

Including count of those completing all sessions and withdrawal count, and the number of mentees worked with

6.4.3. Reasons for withdrawal

6.4.4. Protocol violations

6.4.5. Duration of actual vs planned intervention periods

7. Analysis

7.1. General principles

Analysis of the RCT will be by intention-to-treat; participants categorised as from the particular randomised group regardless of whether they actually received the allocated treatment.

In a secondary analysis, and because all participants will eventually receive the peer-support intervention, the total study group will be analysed as a cohort study design with a particular focus in change-from-baseline for outcome variables.

It is very unlikely that participants in the wait-list control group will receive any form or peer-mentoring but should this occur the participants will still be treated as randomised initially. There is no plan to analyse participants 'per-protocol' although should participants not receive their randomised treatment this will be enumerated. The missing data approach is outlined in a separate section.

Study inference is for the primary outcome variable and primary analysis approach. Control of type I error for the study is only for this variable, the Impact of Participation and Autonomy (outdoors) score, and analysis.

All other analyses will be reported as point estimates and 95% confidence intervals, with implied type I error of 0.05, and reported P-values, however no formal control of type I error inflation will be used and these analyses should be regarded as exploratory. This particularly applies for the Cohort Study of all participants as the sample size for this part of the study is determined both by the initial sample size calculation, the loss of potential participants due to COVID-related disruptions, and attrition. The width of confidence intervals in relation to clinically meaningful changes will be part of the discussion of the findings, as part of discussion of weaknesses in relation to type II error.

Where appropriate, for scale variables using ANOVA and related general linear models, normality assumptions based on residuals will be evaluated.

Reporting of data summaries will follow CONSORT-guideline principles; namely that readers should be able to replicate analyses based on summary data. If normal distribution assumptions for general linear models are not met, relevant data summaries will still be reported. In general for all data summaries all of mean and standard deviation (SD), median and inter-quartile range, and minimum and maximum; will be reported for scale variables. Counts, both numerators and denominators, and proportions, as percentages, will be reported for categorical variables. Reporting of ordinal variables will use both approaches.

Relevant plots for scale variables will be box-plots, frequency histograms, and figures of summary values by time with means and error bars, using standard deviations.

This trial is mixed methods by design and we anticipate that findings from the qualitative data may suggest statistical analysis other than those planned a priori here. If this is the case, then we will specify a further limited set of quantitative analyses (limiting type I error).

7.2. Randomisation

This will use computerised randomisation by a statistician using random block sizes (range 2 and 4), to ensure allocation in equal proportions to peer support and wait-list control; the latter receiving mentoring after their 35-week assessment, the three-month follow-up time point. Stratification will be by site and prioritised ethnicity (ie Māori vs Other) at the point of randomisation. The allocation sequence will remain concealed. 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.

7.3. Correlated measures

7.3.1. Non-time related correlated measures

These will constitute outcome measurements at a single time-point e.g. the primary outcome measurement, the Impact of Participation and Autonomy

(outdoors) score, 22 weeks after randomisation; where Mentees will receive the Peer-support intervention from the same Mentor. In this case, Mentors will be treated as a 'random effect' to allow for correlation between measurements made on participants receiving the intervention from the same Mentor.

7.3.2. Time-related correlated measurements

For those outcome measurements made on repeated occasions an important secondary analysis will be to use a mixed linear model to explicitly model correlated measures and explore time-associated changes, both treating time as a categorical co-variate, and as a continuous co-variate. In the former, absence of a time-by-treatment interaction suggests that effect sizes are the same at every measurement time. In the latter patterns of change with time can be explored. In both cases the baseline measurement will be used as a continuous co-variate; rather than as a part of the multi-variate time-associated vector of measurements.

7.4. Missing data approach

For the key inferential outcome in the RCT very little missing data is anticipated. Overall, the approach will be to present a 'complete case' analysis. However, if the missing data rate is important for the primary outcome, we plan a multiple imputation approach for the key inferential outcome. This will assume a missing at random approach and use baseline variables to impute the outcome variable. The approach will be to generate a set of imputed data sets and combine these to form a sensitivity analysis of likely primary outcome variable differences by randomised groups. Missing data is more likely in the cohort study, however as this is non-inferential, and exploratory, this will be analysed using mixed-linear models; but without imputation, as this method is robust to some missingness.

7.5. Sample size

The target sample size was 46, based on a Minimal Clinically Important Difference (MCID) for the primary outcome variable of 1.6, an SD of 1.44, 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 five-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. 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.

7.6. Interim analyses

There are no planned interim analyses.

8. Statistical analysis

8.1. Trial profile

The flow of patients through the study will be shown in a Consolidated Standards of Reporting Trials (CONSORT) diagram. A similar diagram will be created for mentors.

8.2. Characteristics of participants and baseline comparisons

The characteristics outlined in sections 5 will be summarised as discussed in section 7.1These will be reported by randomised group and combined summaries for both groups will also be reported. No analysis of baseline 'comparability' will be done, unless subsequently requested after review after a manuscript submission. The description of the cohort study at baseline will be that reported for the total participants.

8.3. Outcome variable analyses

General data descriptions for outcome variables will be as outlined in section 7.1.

8.3.1. Randomised controlled trial

Variable	**Analysis**
Primary outcome variable primary analysis	
Impact of Participation and Autonomy (outdoors) score 22 weeks after randomisation	ANCOVA with baseline score as a continuous co-variate and randomised treatment as the key categorical predictor. Key plots: Boxplot of score 22 weeks after randomisation, change from baseline score 22 weeks after randomisation, and histograms of the same
Primary outcome variable secondary analyses	
Impact of Participation and Autonomy (outdoors) score 22 weeks after randomisation	Mixed linear model with same co-variates as for the primary analysis but with the addition of a random effect for Mentor. Note that if the random effect has an estimate of zero this will be equivalent to the primary analysis Additional confounders: Ethnicity (Māori versus non- Māori), Gender Key plots: Boxplot of score 22 weeks after randomisation in relation to Ethnicity and Gender and change from baseline score 22 weeks after randomisation, and histograms of the same
Secondary outcomes[1]	

EQ5D-3L Health Utility Score*	ANCOVA with baseline score as a continuous co-variate and randomised treatment as the key categorical predictor.
EQ5D Visual Analog Scale*	ANCOVA with baseline score as a continuous co-variate and randomised treatment as the key categorical predictor.
Short Warwick-Edinburgh Mental Well Being Scale* Note: Both mentees and mentors, treated separately	ANCOVA with baseline score as a continuous co-variate and randomised treatment as the key categorical predictor.
Satisfaction with Life survey score*	ANCOVA with baseline score as a continuous co-variate and randomised treatment as the key categorical predictor.
Employment status*	Paired contingency table analysis
Employment status * Note: Mentors	Paired contingency table analysis
HADS anxiety and depression scores* Note: Mentors	ANCOVA with baseline score as a continuous co-variate and randomised treatment as the key categorical predictor.
Hearth Hope Index	ANCOVA with baseline score as a continuous co-variate and randomised treatment as the key categorical predictor.
General Self-efficacy scale	ANCOVA with baseline score as a continuous co-variate and randomised treatment as the key categorical predictor.
Total Impact of participation and Autonomy score and Impact of participation and Autonomy subscale scores:- Autonomy	ANCOVA with baseline score as a continuous co-variate and randomised treatment as the key categorical predictor.

indoors, Family role, Social life and relationships, Work and education	
Serious Adverse events	
Individual	Comparison of proportions by an exact method
Total count	Poisson regression

[1]Secondary outcomes ordered in terms of priority.

*Secondary outcomes prioritised for reporting in the primary paper. The intention would be to include all other outcomes in supplementary materials.

8.4. Cohort study

Variable	**Analysis**
Impact of Participation and Autonomy (outdoors) score	Summarise cohort study data as described in section 7.1., but also include change from baseline data summaries. Mixed linear model with baseline score as a part of the response vector. In this case will still be a categorical predictor, but the main interest will be on modelling the change from baseline. This will be achieved by modelling correlated repeated measures by an exponential spatial model (correlation depends on distance apart measurements are using an exponential structure) and primarily by treating time as a categorical variable, and estimating the difference between nominated measurement times and baseline time. A robust smoother (cubic spline) will be used to visualise change in time semi-parametrically. Key plots: Boxplot of change scores with time, scatter plot smoother of outcomes with time
Other variables[1]	
EQ5D-3L Index*	
EQ5D Visual Analog Scale*	
Short Warwick-Edinburgh Mental Well Being Scale*	
Satisfaction with Life survey score*	

Employment status*	
Hearth Hope Index	
General Self-efficacy scale	
Total Impact of participation and Autonomy score and other Impact of participation and Autonomy subscale scores:- Autonomy indoors, Family role, Social life and relationships, Work and education	
Serious Adverse events	
Individual	
Total count	

[1]Secondary outcomes ordered in terms of priority.

*Secondary outcomes prioritised for reporting in the primary paper. The intention would be to include all other outcomes in supplementary materials.

8.5.Mentors

Mentors completed baseline questionnaires which were repeated on completion of employment.
Secondary hypothesis - 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.

Details included in Randomised control trial tables.

8.6. Sensitivity analyses

8.6.1. Confounding variables

The main confounding variables will be ethnicity and gender. The main other sensitivity analysis will include Mentor as a random effect.

8.6.2. Effect modification variables (sub-groups)

There will be no effect modification (sub-group) analyses because of the lower than planned recruitment.

9. Conclusions

We propose that this pre-specified SAP accords with high quality standards of internal validity and should minimise future analysis bias.

10. Health Economic Analysis Plan

10.1. Health economic objective

The *evaluating a sustainable model of peer monitoring in traumatic brain injury* trial objectives, inclusion criteria, sample size, end points and analysis plan are described within the study protocol.

This document describes the planned cost-effectiveness analysis, where the objectives is to establish the relative cost-effectiveness of a peer mentoring program for people with traumatic brain injury using incremental cost and cost-effectiveness using disease specific clinical outcomes and quality of life measures.

Objective 3: Undertake an economic evaluation to determine the relative cost-effectiveness of a peer support intervention compared with usual care.

10.2. Health economic Analysis plan

The objective of this analysis plan is to describe the cost-effectiveness analyses to be carried out for the *evaluating a sustainable model of peer monitoring in traumatic brain injury* randomised controlled trial for the final analyses. It does not address the trial analysis set out in the Statistical Analysis Plan (SAP) above.

10.3. Analysis

10.3.1. Study perspective

All analysis will be at the patient level, by intention to treat and will take a New Zealand health funder perspective

10.3.2. Contributory outcomes

10.3.2.1. Health services resource usage

Resource use is recorded by asking participants to recall:- GP visits, occupational therapists, physiotherapist, speech/language therapist, psychology, psychiatrist, medical specialist, outpatient visit. Resources assessments occur at 22 weeks, 35 weeks. Health services resource use will be costed using current market prices or published national

references costs. Patient level costs will be estimated as the sum of the resources used weighted by their current market price. The self-reported resource use questionnaire will be used at follow up to document costs (e.g., health/social service utilisation, medication, home care and out of pocket expenses) among mentees. Self-reported service utilisation will be supplemented by electronic medical records (hospital) obtained with consent. Effect of treatment on resource use and cost will be estimated using student t-test for unpaired data and bootstrapping.

10.3.2.2. Quality of life

The trial includes the use of EQ-5D-3L (1) a generic measure of health consisting of 5 items and a visual analogue scale, valid in a range of health conditions including those with cognitive impairment (2). It will be used to calculate quality adjusted life years (QALYs) for the cost-utility analysis. EQ-5D-3L will be completed at baseline, 11, 22 and 35 weeks. Repeated scores over time will be used to construct area under curve estimates for each participant using average EQ-5D value over the period of the trial.

10.3.3. Economic analysis

Cost of peer mentoring program will be estimated by the number of mentees and the length of time they have participated in the program and the recruitment and training of mentors. Health care and community services utilisation will be assessed using self-reported resource use questionnaires. (3, 4) Cost of resource consumption will be estimated using a resource-based costing approach. Costs (NZD 2023 value) required to provide health services will be calculated using national or market prices per service use multiplied by the frequency of reported unmet need for health services. Cost analysis will include direct health care costs (i.e. rehabilitation services, prescription charges), indirect costs (lost productivity will be assessed by changes in employment), and out of pocket expenses associated with the peer mentoring program compared with usual care. Additional information on health care and community service utilisation obtained from self-reported questionnaires will be supplemented with electronic medical records matched by patient identifiers and cost information from the previous BIONIC study in Hamilton/Waikato if required.(7) The primary outcome, mentee participation, measured by the *Impact on Participation and Autonomy (IPA)* will be determined for each

individual over the trial period. EQ5D is the most commonly used preference based outcome measure(8) in economic evaluations to estimate quality of life and will be used to calculate quality–adjusted life years (QALY) for the cost utility analysis.

10.3.4. Cost effectiveness 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 (CHEERS) (9) to examine the likely impacts of the *peer mentoring relative to usual care* aimed at improving outcomes after having a TBI. An incremental cost effectiveness ratio will be calculated to compare additional costs and health benefits associated with *peer* mentoring. Patient level data and quality of life data will be bootstrapped (sampled with replacement, n=10,000) to populate incremental cost effectiveness (ICER planes, to estimate average (median) cost effectiveness and pseudo 95% confidence intervals (2.5 and 97.5 centile). Additional analysis will determine any cost offsets by cost savings generated from reduced need for health service utilization and increased productivity during follow-up. Findings will be visualised by generating cost-effectiveness acceptability curves. The economic evaluation will be supplemented by a re-analysis of unmet needs to identify any cost or quality of life differences associated with unmet need. Further, threshold analysis will be performed, informed by input from an expert advisory group (healthcare funders and planners) to: (i) reflect the combined implication and uncertainty in the model parameters, illustrated using cost effectiveness acceptability curves; and (ii) to identify under what conditions peer mentoring could be cost effective and yield cost savings.

10.4. References

1. Cheung, K., M. Oemar, M. Oppe, R. Rabin, on behalf of the Euroqol Group. *EQ-5D. User Guide. Basic information on how to use the EQ-5D. Version 2.0*. 2009; Available from: http://www.euroqol.org/.
2. Payakachat, N., M.M. Ali, and J.M. Tilford, *Can The EQ-5D Detect Meaningful Change? A Systematic Review.* PHARMACOECONOMICS, 2015. **33**(11): p. 1137-1154.
3. Marques, E., E.C. Johnson, R. Gooberman-Hill, A.W. Blom, and S. Noble, *Using resource use logs to reduce the amount of missing data in economic evaluations alongside trials.* Value Health, 2013. **16**(1): p. 195-201.

4. Thorn, J.C., J. Coast, D. Cohen, W. Hollingworth, M. Knapp, S.M. Noble, C. Ridyard, S.Wordsworth, and D. Hughes. *Resource-use measurement based on patient recall: issues andchallenges for economic evaluation.* Appl Health Econ Health Policy, 2013. **11**(3): p. 155-61.
5. Wilkinson-myers, L., P. Brown, C. McLean, and N. Kerse, *Met and unmet need for personal assistance among community-dwelling New Zealanders 75 years and over.* Health and SocialCare, 2013. **22**(3): p. 317-27.
6. Andelic, N., H. Soberg, S. Berntsen, S. Sigurdardottir, and C. Roe, *Self-perceived healthcare needs and delivery of health care services 5 years after moderate to severe traumatic braininjury.* Physical Medicine and Rehabilitation, 2014. **6**(11): p. 1013-21.
7. Te Ao, B., K. Jones, V.L. Feigin, P. Brown, M. Tobias, S. Ameratunga, S. Barker-Collo, A. Theadom, K. McPherson, N. Starkey, A. Dowell, on behalf of the BIONIC Study Group. Costof traumatic brain injury in New Zealand: Evidence from a population-based study. Neurology,2014. 83(18): p. 1645-1652.
8. Greenberg, D. and J.S. Pliskin, *Preference-based outcome measures in cost-utility analyses:A 20-year overview.* International Journal of Technology Assessment in Health Care, 2002.**18**(3): p. 461-6.
9. Husereau, D., M. Drummond, S. Petrou, C. Carswell, D. Moher, D. Greenberg, F.Augustovski, A.H. Briggs, J. Mauskopf, and E. Loder. *Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement.* Value in Health, 2013. **16**(2): p. e1.

11. Appendices

11.1. Table templates for publication

11.1.1. Data description (Mentees)

	Mean (SD)		
Variable (continuous)	**Randomisation**		**All**
	Treatment **N=TT[1]**	**Control** **N=CC[1]**	 **N=AA[1]**
Age	XX (XX)	XX (XX)	XX (XX)
Time since injury (days)	XX (XX)	XX (XX)	XX (XX)
Length of post-acute inpatient rehabilitation (days)	XX (XX)	XX (XX)	XX (XX)
Multi-morbidity index scores (Functional Comorbidity Index)	XX (XX)	XX (XX)	XX (XX)
Outcome Variable (continuous)			
Impact of participation and autonomy scores Total Autonomy outdoors (primary) Autonomy indoors Family role Social life and relationships Work and education.	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)
Short Warwick-Edinburgh Mental Well Being Scale	XX (XX)	XX (XX)	XX (XX)
Satisfaction with Life survey score	XX (XX)	XX (XX)	XX (XX)
Hearth Hope Index	XX (XX)	XX (XX)	XX (XX)
General Self-efficacy scale	XX (XX)	XX (XX)	XX (XX)
EQ5D-3L Index (Utility)	XX (XX)	XX (XX)	XX (XX)
EQ5D VAS	XX (XX)	XX (XX)	XX (XX)

Variables (categorical)	**N/TT[1] (%)**	**N/CC[1] (%)**	**N/AA[1] (%)**
Gender			
Female	XX (XX)	XX (XX)	XX (XX)
Male	XX (XX)	XX (XX)	XX (XX)
Self described	XX (XX)	XX (XX)	XX (XX)
Ethnicity			
Māori	XX (XX)	XX (XX)	XX (XX)
Pacific	XX (XX)	XX (XX)	XX (XX)
NZ European	XX (XX)	XX (XX)	XX (XX)
Asian	XX (XX)	XX (XX)	XX (XX)
MELLA	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)
Region			
Auckland	XX (XX)	XX (XX)	XX (XX)
Gisborne	XX (XX)	XX (XX)	XX (XX)
Northland	XX (XX)	XX (XX)	XX (XX)
Injury severity			
Mild	XX (XX)	XX (XX)	XX (XX)
Moderate severe	XX (XX)	XX (XX)	XX (XX)
Highest education qualification			
None,	XX (XX)	XX (XX)	XX (XX)
High School	XX (XX)	XX (XX)	XX (XX)
Tertiary	XX (XX)	XX (XX)	XX (XX)
Employment status prior to injury			
Paid employment	XX (XX)	XX (XX)	XX (XX)
Satisfied with employment status	XX (XX)	XX (XX)	XX (XX)
Employment status at recruitment			
Paid employment	XX (XX)	XX (XX)	XX (XX)
Satisfied with employment status	XX (XX)	XX (XX)	XX (XX)
Current living arrangements at recruitment			
Living by myself	XX (XX)	XX (XX)	XX (XX)
Living with partner or spouse	XX (XX)	XX (XX)	XX (XX)
Living with my whānau/family	XX (XX)	XX (XX)	XX (XX)
Living with people not related to me	XX (XX)	XX (XX)	XX (XX)
Living in home that I own	XX (XX)	XX (XX)	XX (XX)
Living in home owned by family member	XX (XX)	XX (XX)	XX (XX)
Living in rental accommodation	XX (XX)	XX (XX)	XX (XX)
Living in residential facility	XX (XX)	XX (XX)	XX (XX)
Living in boarding house	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)

[1]Unless specified.

11.1.2. Data description (Mentors)

	Mean (SD)
Variable (continuous)	**All**
Age	XX (XX)
Time since injury (days)	XX (XX)
Length of post-acute inpatient rehabilitation (days)	XX (XX)
Multi-morbidity index scores (Functional Comorbidity Index)	XX (XX)
Outcome Variable (continuous)	
Short Warwick-Edinburgh Mental Well Being Scale	XX (XX)
Hospital Anxiety and depression Score Anxiety depression	 XX (XX) XX (XX)
Variables (categorical)	**N/AA[1] (%)**
Gender Female Male Self described	 XX (XX) XX (XX) XX (XX)
Ethnicity Māori Pacific NZ European Asian MELLA Other	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)
Region Auckland Gisborne Northland	 XX (XX) XX (XX) XX (XX)
Injury severity Mild Moderate severe	 XX (XX) XX (XX)

Highest education qualification	
None,	XX (XX)
High School	XX (XX)
Tertiary	XX (XX)
Employment status prior to injury	
Paid employment	XX (XX)
Satisfied with employment status	XX (XX)
Employment status at recruitment	
Paid employment	XX (XX)
Satisfied with employment status	XX (XX)
Current living arrangements at recruitment	
Living by myself	XX (XX)
Living with partner or spouse	XX (XX)
Living with my whānau/family	XX (XX)
Living with people not related to me	XX (XX)
Living in home that I own	XX (XX)
Living in home owned by family member	XX (XX)
Living in rental accommodation	XX (XX)
Living in residential facility	XX (XX)
Living in boarding house	XX (XX)
Other	XX (XX)

11.1.3. Trial process reporting tables for publication

	Mean (SD)		
Variable (continuous)	**Randomisation**		**All**
	Treatment **N=TT[1]**	**Control** **N=CC[1]**	**N=AA[1]**
Time between randomisation and initiation of intervention (days)	XX (XX)	XX (XX)	XX (XX)
Times between scheduled and actual assessments (days)	XX (XX)	XX (XX)	XX (XX)
Variables (categorical)	**N/TT[1] (%)**	**N/CC[1] (%)**	**N/AA[1] (%)**
Recruitment variables Total potential participants Assessed for eligibility Ineligible Eligible but no consent Randomised	 XX	 XX	 XX (100%) XX (XX) XX (XX) XX (XX) XX (XX)
Non-missing data by assessment *time (ie completed assessments)* Baseline 11 week 22 week	 XX (XX) XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX) XX (XX)

35 week 57 week	XX (XX)	XX (XX)	XX (XX)
Intervention completion Session 1 Session 2 Session 3 Session 4 Session 5 Session 6 Session 7 Session 8 # attending all allocated sessions # withdrawn	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)
Reasons for withdrawal A …. B…. C…. etc	 XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX)
Protocol violations A …. B…. C…. etc	 XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX)
Number of mentors[3] Mentors with 1 mentee Mentors with 2 mentees Mentors with 3 mentees Mentors with no mentees			XX X X X X

[3] Also to include a timeline of mentee-mentor diad activity to illustrate any overlap

11.1.4. Analysis reporting tables for publication

	ANCOVA		**Adjusted[1]**	
Treatment minus control	**Estimate (95% CI)**	**P**	**Estimate (95% CI)**	**P**
Impact of Participation and Autonomy (outdoors) score 22 weeks after randomisation ***[Mixed linear model]***	XX (XX to XX)	XX	XX (XX to XX)	XX
Primary outcome variable secondary analyses				
Impact of Participation and Autonomy (outdoors) score 22 weeks after randomisation	XX (XX to XX)	XX	XX (XX to XX)	XX
Secondary outcomes				
Other Impact of participation and Autonomy scores	XX (XX to XX)	XX	XX (XX to XX)	XX
Autonomy outdoors (primary)	XX (XX to XX)	XX	XX (XX to XX)	XX
Autonomy indoors	XX (XX to XX)	XX	XX (XX to XX)	XX
Family role	XX (XX to XX)	XX	XX (XX to XX)	XX
Social life and relationships	XX (XX to XX)	XX	XX (XX to XX)	XX

Work and education	XX (XX to XX	XX	XX (XX to XX	XX
Short Warwick-Edinburgh Mental Well Being Scale	XX (XX to XX)	XX	XX (XX to XX)	XX
Satisfaction with Life survey score	XX (XX to XX)	XX	XX (XX to XX)	XX
Hearth Hope Index	XX (XX to XX)	XX	XX (XX to XX)	XX
General Self-efficacy scale	XX (XX to XX)	XX	XX (XX to XX)	XX
EQ5D-3L Index	XX (XX to XX)	XX	XX (XX to XX)	XX
EQ5D Visual Analog Scale	XX (XX to XX)	XX	XX (XX to XX)	XX
Paid employment status *[Paired contingency table analysis]*	XX (XX to XX)	XX	XX (XX to XX)	XX
Satisfaction with current work status *[Paired contingency table analysis]*	XX (XX to XX)	XX	XX (XX to XX)	XX
Serious Adverse events Individual ***[Comparison of proportions by an exact method]***	XX (XX to XX)	XX	XX (XX to XX)	XX

Total count ***[Poisson regression]***	XX (XX to XX)	XX	XX (XX to XX)	XX

[1]Mentor as a random effect

11.1.5. Data description – Summary table changes from baseline

	Mean (SD)								
	Treatment **N=TT[1]**			Control N=CC[1]				All N=AA[1]	
Variable (continuous)	Baseline	Change from baseline at Week 22 (post intervention)	Change from baseline at Week 35	Baseline	Change from baseline at Week 22	Change from baseline at Week 35	Change from baseline at Post intervention	Baseline	Change from baseline to Post intervention (22 or 57wk assessment points)
Age	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Time since injury (days)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)

Length of post-acute inpatient rehabilitation (days)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Multi-morbidity index scores (Functional Comorbidity Index)	XX (XX)	N/A	N/A	N/A	XX (XX)	N/A	N/A	N/A	N/A
Outcome Variable (continuous)									
Impact of participation and autonomy scores Total Autonomy outdoors (primary) Autonomy indoors Family role Social life and relationships Work and education.	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Short Warwick-Edinburgh Mental Well Being Scale	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Satisfaction with Life survey score	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Hearth Hope Index	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)

General Self-efficacy scale	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
EQ5D-3L Index (Utility)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
EQ5D VAS	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Variables (categorical)	**N/TT[1] (%)**			**N/CC[1] (%)**				**N/AA[1] (%)**	
Employment status Proportion of people in paid work	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Proportion full time	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Proportion part time	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Satisfaction with current work status work	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Current living arrangements at recruitment									
Living by myself	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living with partner or spouse	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living with my whānau/family	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living with people not related to me	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in home that I own	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in home owned by family member	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)

Living in rental accommodation	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in residential facility	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in boarding house	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)

11.1.6. Cohort analysis table

	All N=AA[1]				
	Mean (SD)			**Mixed linear models**	
Outcome Variable (continuous)	Baseline	Post intervention	Post intervention - baseline	**Estimate (95% CI)**	**P value**
Impact of participation and autonomy scores					
Total	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Autonomy outdoors (primary)	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Autonomy indoors	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Family role	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Social life and relationships	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Work and education.	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Short Warwick-Edinburgh Mental Well Being Scale	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Satisfaction with Life survey score	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Hearth Hope Index	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
General Self-efficacy scale	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
EQ5D-3L Index (Utility)	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
EQ5D VAS	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Variables (categorical)	**N/AA[1] (%)**			Difference in proportions	P
Employment status *[Paired contingency table analysis]*					

Proportion of people in paid work	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Proportion full time	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Proportion part time	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Satisfaction with current work status work	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Current living arrangements at recruitment					
Living by myself	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living with partner or spouse	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living with my whānau/family	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living with people not related to me	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living in home that I own	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living in home owned by family member	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living in rental accommodation	XX (XX)	XX (XX)		XX (XX to XX)	X
Living in residential facility	XX (XX)	XX (XX)		XX (XX to XX)	X
Living in boarding house	XX (XX)	XX (XX)		XX (XX to XX)	X
Other	XX (XX)	XX (XX)		XX (XX to XX)	X

11.1.7. Mentors analysis table

	All N= All mentors				
	Mean (SD)			**Mixed linear models**	
Outcome Variable (continuous)	Baseline	Post mentor activity period	Post intervention - baseline	**Estimate (95% CI)**	**P value**
HADS anxiety and depression scores Anxiety Depression	XX (XX) XX (XX)	XX (XX) XX (XX)	XX (XX) XX (XX)	XX (XX to XX) XX (XX to XX)	X X
Short Warwick-Edinburgh Mental Well Being Scale	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Variables (categorical)	**N/AA[1] (%)**			Difference in proportions	P
Employment status *[Paired contingency table analysis]* Proportion of people in paid work	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Proportion full time	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Proportion part time	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Satisfaction with current work status work	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X

11.2. Table templates for Statistical Analysis Report

11.2.1. Data description (Mentees and mentors)

Variable (continuous)			
Age	**Mean (SD)**	**Median (IQR)**	**Min to Max**

Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
All N=AA	XX (XX)	XX (XX to XX)	XX to XX
Mentors	XX (XX)	XX (XX to XX)	XX to XX
Time since injury (days)	**Mean (SD)**	**Median (IQR)**	**Min to Max**
Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
All N=AA	XX (XX)	XX (XX to XX)	XX to XX
Mentors	XX (XX)	XX (XX to XX)	XX to XX
Length of post-acute inpatient rehabilitation (days)	**Mean (SD)**	**Median (IQR)**	**Min to Max**
Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
All N=AA	XX (XX)	XX (XX to XX)	XX to XX

Mentors	XX (XX)	XX (XX to XX)	XX to XX
Multi-morbidity index scores (Functional Comorbidity Index)	**Mean (SD)**	**Median (IQR)**	**Min to Max**
Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
All N=AA	XX (XX)	XX (XX to XX)	XX to XX

Outcome Variable (continuous) – repeated for baseline, week 22, wk35 and week 57 assessment points				
Impact of participation and autonomy scores		**Mean (SD)**	**Median (IQR)**	**Min to Max**
Autonomy outdoors (primary)	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
Total score		**Mean (SD)**	**Median (IQR)**	**Min to Max**
	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX

	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
Autonomy indoors		**Mean (SD)**	**Median (IQR)**	**Min to Max**
	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
Family role		**Mean (SD)**	**Median (IQR)**	**Min to Max**
	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
Social life and relationships		**Mean (SD)**	**Median (IQR)**	**Min to Max**
	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX

Work and education.		**Mean (SD)**	**Median (IQR)**	**Min to Max**
	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
Short Warwick-Edinburgh Mental Well Being Scale		**Mean (SD)**	**Median (IQR)**	**Min to Max**
	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
	Mentors	XX (XX)	XX (XX to XX)	XX to XX
Satisfaction with Life survey score		**Mean (SD)**	**Median (IQR)**	**Min to Max**
	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX

Hearth Hope Index		**Mean (SD)**	**Median (IQR)**	**Min to Max**
	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
General Self-efficacy scale		**Mean (SD)**	**Median (IQR)**	**Min to Max**
	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
EQ5D-3L		**Mean (SD)**	**Median (IQR)**	**Min to Max**
Utility	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
		Mean (SD)	**Median (IQR)**	**Min to Max**

VAS	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
Productivity status		**Mean (SD)**	**Median (IQR)**	**Min to Max**
Paid hours/week prior to injury	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
	Mentors	XX (XX)	XX (XX to XX)	XX to XX
		Mean (SD)	**Median (IQR)**	**Min to Max**
Paid hours per week at recruitment	Treatment N=TT	XX (XX)	XX (XX to XX)	XX to XX
	Control N=CC	XX (XX)	XX (XX to XX)	XX to XX
	All N=AA	XX (XX)	XX (XX to XX)	XX to XX
	Mentors	XX (XX)	XX (XX to XX)	XX to XX
		Mean (SD)	**Median (IQR)**	**Min to Max**

HADS Depression	Mentors	XX (XX)	XX (XX to XX)	XX to XX
Anxiety	Mentors	XX (XX)	XX (XX to XX)	XX to XX
Variables (categorical)	**N/TT[1] (%)**	**N/CC[1] (%)**	**N/AA[1] (%)**	**Mentors**
Gender				
Female	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Male	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Self described	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Ethnicity				
Māori	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Pacific	XX (XX)	XX (XX)	XX (XX)	XX (XX)
NZ European	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Asian	XX (XX)	XX (XX)	XX (XX)	XX (XX)
MELLA	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Region				
Auckland	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Gisborne	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Northland	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Injury severity				
Mild	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Moderate severe	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Employment status prior to injury				
Full time	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Part time	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Unemployed	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Student	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Retired	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Unpaid work	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Number in paid work	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Satisfied with current work status	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Employment status at recruitment				
Full time	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Part time	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Unemployed	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Student	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Retired	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Unpaid work	XX (XX)	XX (XX)	XX (XX)	XX (XX)

Other	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Number in paid work	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Satisfied with current work status	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Current living arrangements at recruitment				
Living by myself	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living with partner or spouse	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living with my whānau/family	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living with people not related to me	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in home that I own	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in home owned by family member	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in rental accommodation	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in residential facility	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in boarding house	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)	XX (XX)

[1]Unless specified

11.2.1. Process reporting tables for statistical analysis report (Mentee related)

	Mean (SD)		
Variable (continuous)	**Randomisation**		**All**
Time between randomisation and initiation of intervention (days)	**Mean (SD)**	**Median (IQR)**	**Min to max**
Treatment N=TT	XX (XX)	XX (XX)	XX (XX)
Control N=CC	XX (XX)	XX (XX)	XX (XX)
All N=AA	XX (XX)	XX (XX)	XX (XX)
Times between scheduled and actual assessments (days)	**Mean (SD)**	**Median (IQR)**	**Min to max**
Treatment N=TT	XX (XX)	XX (XX)	XX (XX)
Control N=CC	XX (XX)	XX (XX)	XX (XX)
All N=AA	XX (XX)	XX (XX)	XX (XX)
Variables (categorical)	**N/TT[1] (%)**	**N/CC[1] (%)**	**N/AA[1] (%)**
Recruitment variables (mentees) Total potential participants Assessed for eligibility Ineligible Eligible but no consent Randomised	 XX	 XX	 XX (100%) XX (XX) XX (XX) XX (XX) XX (XX)
Non-missing data by assessment *time (ie completed assessments)* Baseline 11 week 22 week 35 week 57 weel	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)
Intervention completion Session 1 Session 2 Session 3 Session 4 Session 5 Session 6 Session 7 Session 8 # attending all allocated sessions # withdrawn	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX) XX (XX)

Reasons for withdrawal A …. B…. C…. etc	 XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX)
Protocol violations A …. B…. C…. etc	 XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX)	 XX (XX) XX (XX) XX (XX)

11.2.1. Process reporting tables for statistical analysis report (Mentor related)

	N (%)
Recruitment variables	
Total potential participants	XX (100%)
Assessed for eligibility	XX (XX)
Ineligible	XX (XX)
Eligible but no consent	XX (XX)
Employed	XX (XX)
Matched with mentee	XX(XX)
Reasons for withdrawal	
A ….	XX (XX)
B….	XX (XX)
C….	XX (XX)
etc	
Protocol violations	
A ….	XX (XX)
B….	XX (XX)
C….	XX (XX)
etc	

11.2.2. Mentor activity reporting table

Mentor (N)	Number of mentees		
	Treatment N/TT (%)	Control N/CC (%)	All N/AA (%)
M1 …. M2 ….. etc	X (%) X (%) X (%)	X (%) X (%) X (%)	X (%) X (%) X (%)

Timeline of mentee-mentor diad activity to illustrate any overlap from data below

Mentor	Mentee	Date start	Date stop	Intervention duration (wks)
M1	E1 E2 etc	dd/mm/yy dd/mm/yy	dd/mm/yy dd/mm/yy	X X
M2 etc				

11.2.3. Analysis reporting tables

As for publication tables except for inclusion of all variables ...

	ANCOVA		**Adjusted[1]**	
Treatment minus control	**Estimate (95% CI)**	**P**	**Estimate (95% CI)**	**P**
Impact of Participation and Autonomy (outdoors) score 22 weeks after randomisation ***[Mixed linear model]***	XX (XX to XX)	XX	XX (XX to XX)	XX
Primary outcome variable secondary analyses				
Impact of Participation and Autonomy (outdoors) score 22 weeks after randomisation	XX (XX to XX)	XX	XX (XX to XX)	XX
Secondary outcomes				
Other Impact of participation and Autonomy scores				
Autonomy outdoors (primary)	XX (XX to XX)	XX	XX (XX to XX)	XX
Autonomy indoors	XX (XX to XX)	XX	XX (XX to XX)	XX
Family role	XX (XX to XX)	XX	XX (XX to XX)	XX

Social life and relationships	XX (XX to XX)	XX	XX (XX to XX)	XX
Work and education	XX (XX to XX)	XX	XX (XX to XX)	XX
Total score	XX (XX to XX	XX	XX (XX to XX	XX
Short Warwick-Edinburgh Mental Well Being Scale	XX (XX to XX)	XX	XX (XX to XX)	XX
Satisfaction with Life survey score	XX (XX to XX)	XX	XX (XX to XX)	XX
Hearth Hope Index	XX (XX to XX)	XX	XX (XX to XX)	XX
General Self-efficacy scale	XX (XX to XX)	XX	XX (XX to XX)	XX
EQ5D-3L Index	XX (XX to XX)	XX	XX (XX to XX)	XX
EQ5D Visual Analog Scale	XX (XX to XX)	XX	XX (XX to XX)	XX
Employment status *[Paired contingency table analysis]*				
Paid employment	XX (XX to XX)	XX	XX (XX to XX)	XX
Full time - paid	XX (XX to XX)	XX	XX (XX to XX)	XX
Part time -paid	XX (XX to XX)	XX	XX (XX to XX)	XX
Unemployed	XX (XX to XX)	XX	XX (XX to XX)	XX
Student	XX (XX to XX)	XX	XX (XX to XX)	XX
Retired	XX (XX to XX)	XX	XX (XX to XX)	XX
Unpaid work	XX (XX to XX)	XX	XX (XX to XX)	XX
Number in paid work	XX (XX to XX)	XX	XX (XX to XX)	XX
Other	XX (XX to XX)	XX	XX (XX to XX)	XX
Satisfaction with current work status *[Paired contingency table analysis]*	XX (XX to XX)	XX	XX (XX to XX)	XX
Serious Adverse events				
Individual ***[Comparison of proportions by an exact method]***	XX (XX to XX)	XX	XX (XX to XX)	XX
Total count ***[Poisson regression]***	XX (XX to XX)	XX	XX (XX to XX)	XX

11.2.4. Data description – Summary table changes from baseline for statistical report

	Mean (SD)								
	Treatment **N=TT[1]**			Control N=CC[1]				All N=AA[1]	
Variable (continuous)	Baseline	Change from baseline at Week 22 (post intervention)	Change from baseline at Week 35	Baseline	Change from baseline at Week 22	Change from baseline at Week 35	Change from baseline at Post intervention	Baseline	Change from baseline to Post intervention (22 or 57wk assessment points)
Age	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Time since injury (days)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Length of post-acute inpatient rehabilitation (days)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)

Multi-morbidity index scores (Functional Comorbidity Index)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Outcome Variable (continuous)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Impact of participation and autonomy scores Autonomy outdoors (primary) Autonomy indoors Family role Social life and relationships Work and education.	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Short Warwick-Edinburgh Mental Well Being Scale	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Satisfaction with Life survey score	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Hearth Hope Index	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
General Self-efficacy scale	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
EQ5D-3L Index (Utility)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
EQ5D VAS	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)

Variables (categorical)	**N/TT[1] (%)**			**N/CC[1] (%)**				**N/AA[1] (%)**	
Employment status Proportion of people in paid work	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Proportion full time	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Proportion part time	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Unemployed	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Student	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Retired	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Unpaid work	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Satisfaction with current work status work	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Current living arrangements at recruitment									
Living by myself	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living with partner or spouse	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living with my whānau/family	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living with people not related to me	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in home that I own	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in home owned by family member	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in rental accommodation	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)

Living in residential facility	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Living in boarding house	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)

11.2.5. Cohort analysis table for statistical report

	All N=AA[1]				
	Mean (SD)			**Mixed linear models**	
Outcome Variable (continuous)	Baseline	Post intervention	Post intervention - baseline	**Estimate (95% CI)**	**P value**
Impact of participation and autonomy scores					
Autonomy outdoors	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
(primary)	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Autonomy indoors	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Family role	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Social life and relationships	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Work and education.	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Short Warwick-Edinburgh Mental Well Being Scale	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Satisfaction with Life survey score	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Hearth Hope Index	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
General Self-efficacy scale	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
EQ5D-3L Index (Utility)	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
EQ5D VAS	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Variables (categorical)	**N/AA[1] (%)**			Difference in proportions	P
Employment status *[Paired contingency table analysis]*					
Proportion of people in paid work	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
full time				XX (XX to XX)	X

part time	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Unemployed	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Student	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Retired	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Unpaid work	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Other	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
	XX (XX)	XX (XX)	XX (XX)		
Satisfaction with current work status work	XX (XX)	XX (XX	XX (XX	XX (XX to XX)	X
Current living arrangements at recruitment					
Living by myself	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living with partner or spouse	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living with my whānau/family	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living with people not related to me	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living in home that I own	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living in home owned by family member	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Living in rental accommodation	XX (XX)	XX (XX)		XX (XX to XX)	X
Living in residential facility	XX (XX)	XX (XX)		XX (XX to XX)	X
Living in boarding house	XX (XX)	XX (XX)		XX (XX to XX)	X
Other	XX (XX)	XX (XX)		XX (XX to XX)	X

11.2.6. Mentors analysis table

	All N= All mentors				
	Mean (SD)			**Mixed linear models**	
Outcome Variable (continuous)	Baseline	Post Mentor activity period	Post intervention - baseline	**Estimate (95% CI)**	**P value**
HADS anxiety and depression scores Anxiety Depression	 XX (XX) XX (XX)	 XX (XX) XX (XX)	 XX (XX) XX (XX)	 XX (XX to XX) XX (XX to XX)	 X X
Short Warwick-Edinburgh Mental Well Being Scale	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Variables (categorical)	**N/AA[1] (%)**			Difference in proportions	P
Employment status *[Paired contingency table analysis]* Proportion of people in paid work	 XX (XX)	 XX (XX)	 XX (XX)	 XX (XX to XX)	 X
Proportion full time	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Proportion part time	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X
Satisfaction with current work status work	XX (XX)	XX (XX)	XX (XX)	XX (XX to XX)	X

12. Table of amendments to SAP

Version	Date of amendments	Summary of changes
Version 1	10/8/2023	-
Version 2	16/8/2023	Addition of Economic analysis plan to document