



END OF PROJECT REPORT TEMPLATE

Project Reference	RfPPB-18-1502
Project Title	Group-based positive psychotherapy for people
	living with Acquired Brain Injury: A feasibility
	study
Lead Researcher	Professor Andrew Kemp
Host Institution	Swansea Bay University Health Board
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Main Messages (1-Page)

Traditional medical approaches often fall short of addressing the comprehensive needs of those living with acquired brain injury (ABI), emphasising physical recovery and neglecting broader psychological wellbeing. This gap highlights the necessity for innovative treatment approaches that encompass not just physical but also mental and social facets of recovery. Responding to this need, our research explored the feasibility of an innovative positive psychotherapy intervention designed for individuals with ABI on which a full-scale randomised controlled trial (RCT) would build.

Main Messages and Implications

- Quantitative Data: A high level of engagement suggests that people with ABI are willing and able to participate in research on positive psychotherapy, indicating feasibility for a future larger-scale RCT.
- Qualitative Data: The intervention was acceptable to individuals with ABI and perceived as beneficial, highlighting qualitative evaluation as a useful methodological approach.
- Psychophysiological Data: While data collection is feasible, a host of potentially confounding participant characteristics may impact on our capacity to draw objective conclusions in a full-scale trial.
- Health Economics: It is feasible to conduct health economic evaluations within the context of ABI psychotherapy research, providing insights into the cost implications of implementing such interventions in real-world settings. A future trial may benefit further from a full economic evaluation that provides a wider societal perspective.
- Service user-involvement significantly influenced the work, aligning with UK Standards for Public Involvement. Prioritising inclusivity, service users contributed to all aspects of our study, ensuring relevance and accessibility.

Conclusion: The study demonstrated successful recruitment, retention, and intervention adherence, indicating the feasibility of conducting a larger trial. Participant feedback was positive, endorsing satisfaction with the recruitment process, data collection, and the intervention. While the study was underpowered, findings are promising, showing improvements in some wellbeing measures.

Executive Summary (3-pages)

Context: Neurological conditions are a leading cause of global disability. The Science Evidence Advice report (2023) predicts a significant increase in neurological conditions in Wales by 2035, identifying them as having the highest level of social care need. Acquired brain injury (ABI) is one such neurological condition that has a devastating impact on individuals and their loved ones as well as costing the UK economy billions on an annual basis. Despite this, research indicates that only 31.4% of patients receive necessary rehabilitation support including psychological support. An overview of Cochrane systematic reviews (Young, 2022) highlighted a lack of high-quality evidence neurorehabilitation. Traditional regarding psychological interventions in neurorehabilitation models have primarily focused on reducing deficits and distress, yet emerging evidence suggests that wellbeing transcends the mere absence of illbeing. It is now understood that wellbeing is fostered through the management and acceptance of difficult emotions, the experience of positive emotions and meaning, and engagement in positive health behaviours. These are guided by core values and goaldirected activities that encourage connections with oneself, others, and nature. Our study introduces a novel positive psychotherapy intervention for individuals living with ABI. This intervention is designed to enhance wellbeing, drawing on core pillars identified in a broad range of theoretical frameworks, including our own research. Furthermore, it has been co-designed from the outset with people living with ABI.

Aims and Objectives: The aim of the study was to assess the feasibility of implementing our positive psychotherapy intervention for people living with ABI and to determine if such an intervention warrants a full-scale randomised controlled trial (RCT) compared to standard care. Our primary objective was to evaluate feasibility using standardised criteria, including recruitment rates, intervention compliance, and data collection procedures. Additionally, we aimed to explore participant experiences within the trial and gather feedback for potential improvements.

Project Summary: Individuals living with ABI in Wales were allocated to a Positive Psychology Intervention Group (PP) or a Treatment as Usual Group (TAU). Peer mentors were also recruited to facilitate the intervention alongside clinicians contributing their perspectives on lived experience. The PP intervention consisted of 8 sessions with each session lasting approximately 2.5 hours. The study was conducted across three health boards in Wales, ensuring relevance to the Welsh context and diversity among participants and geographical locations. Recruitment and

implementation occurred between October 2022 and October 2023, with ongoing analysis and follow-up extending beyond this period. In total, participants allocated to the TAU and PP were involved in the study for approximately 6.5 months. Data was collected at three time points (just before allocation to groups, immediately after the intervention and 3 months later). For more detailed information, readers can access the comprehensive 25-page report, which outlines the study's methodology, theoretical framework, and full analysis of findings as well as details about our intervention and its content.

Public and Patient Involvement and Engagement: Our work has been shaped by brain-injury survivors, in keeping with the UK Standards for Public Involvement. Central to our approach has been a commitment to inclusivity. Service users have played pivotal roles in shaping the development and execution of our wellbeing intervention and participant workbook and other facets of our study. For instance, service users were actively involved in associated governance structures, safeguarding the public interest. Their active involvement has ensured that our work remains finely attuned to the needs of its intended beneficiaries, fostering relevance, accessibility, and responsiveness throughout.

Key Findings

Feasibility of Positive Psychotherapy for ABI: The study demonstrated the practicality of implementing positive psychotherapy, with high participation and retention rates among ABI patients. Recruitment, retention, and intervention adherence exceeded expectations, indicating strong interest and perceived value among participants.

Psychological Wellbeing: Qualitative feedback highlighted the positive impact of the intervention on psychological wellbeing. Participants reported increased self-awareness, improved mood, and enhanced coping skills. By fostering a supportive group environment, the intervention facilitated social connections and reduced feelings of isolation among participants.

Economic Viability: Health economics showed that the average intervention cost aligned with traditional costs for rehabilitation interventions of similar durations. The clinical manual and workbooks supporting the intervention have now been developed and refined to an extent that any future study would be more cost effective, equating to around £176 per participant for an 8 week intervention. These findings are discussed in relation to value-based health care principles below.

Conclusion: The study demonstrated successful recruitment, retention, and intervention adherence, indicating the feasibility of conducting a larger trial. Participant feedback was positive, endorsing satisfaction with the process and the intervention itself. While sample sizes were too small to make definitive conclusions relating to efficacy, findings are promising.

Implications: The 'Healthier Wales' legislation set out the need for health services to adapt and meet the challenges posed by a population living longer with disabilities. Our approach was tailored specifically to address these challenges in the context of neurological conditions. A key aspect of the Welsh Government's vision for health and social care is to enhance value for patients by prioritising outcomes that matter most to individuals. The development of our approach and intervention has come from the feedback of our service users and has been developed and delivered alongside them. Although this was a feasibility trial, participant feedback very much confirmed that the intervention was needed and valued. In addition, health economic data demonstrated that it may provide a cost effective approach in keeping with the principles of Value Based Health Care. Our study marks the initial step in exploring the potential of holistic wellbeing approaches in ABI rehabilitation. By prioritising psychological wellbeing alongside conventional methods, we have the opportunity to unlock new avenues to recovery and enhance the overall quality of life for ABI patients. This could boost the effectiveness of traditional care approaches, leading to improved outcomes for the same cost. It also has the potential to reduce downstream expenses, comorbidities and poor mental health. Given the following factors: 1) the limited access to rehabilitation services for those with neurological conditions in Wales; 2) the limitations of care models that focus solely on diminishing ill-being; 3) the anticipated increase in neurological condition prevalence in Wales; and 4) the projection that these conditions will demand the highest level of social care, there's a critical need for investment in innovative, evidence-based, and co-created neurorehabilitation approaches. However, this can not be achieved without investment into high-quality research that can provide the backbone of evidence based practice and inform the type of innovation needed to navigate the major societal challenges ahead.

Scientific report (25 Pages)

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Abstract

Acquired brain injury (ABI) and other chronic conditions are placing unprecedented pressure on healthcare systems. As a result, there is an urgent need to adapt existing healthcare delivery differently to meet current and future increasing demands. A focus on wellbeing may provide an innovative opportunity to reduce the pressure on healthcare services, while also supporting patients to live more meaningful lives. The overarching aims of the study were to: 1) evaluate the feasibility of conducting a positive psychotherapy intervention for individuals with ABI, and 2) ascertain under what conditions such an intervention would merit a fully powered randomised controlled trial (RCT) compared to a standard control group. A randomised, two-arm feasibility trial involving allocation of patients to either a treatment group (positive psychotherapy (PP)) or control group (treatment as usual (TAU)) group, according to a 1:1 ratio. We recruited a total of 50 participants, across three sites. Assessments were conducted at baseline, on completion of the 8-week intervention and 3-month following the last session of the intervention. These included a range of questionnairebased measures, psychophysiology and qualitative outcomes focusing on feasibility outcomes and participant experience. This study was approved by the Wales Research Ethics Committee (IRAS project ID: 271251, REC reference: 19/WA/0336). Recruitment, retention, intervention adherence and data collection rates across all aspects of this study exceeded expectations demonstrating that the study was viable to conduct in practice. This was endorsed by participant experience evidencing satisfaction with the recruitment and data collection process and the intervention itself. Statistical analysis was successfully conducted across all areas of the trial, demonstrating feasibility to do so for a larger trial. Therefore, it was possible to conclude that a full RCT study would be practically feasible which was the primary aim of this study. This study also informed a number of potential refinements to the study design across each of the four study areas.

Trial registration number: ISRCTN12690685, registered 11th November 2020, https://doi.org/10.1186/ISRCTN12690685

Keywords: acquired brain injury; chronic conditions; randomised controlled trial; wellbeing; positive psychotherapy

Visual Abstract: Group-based positive psychotherapy for people living with Acquired Brain Injury: A feasibility study



Background and Rationale: Acquired brain injury (ABI) can lead to a wide range of physical, cognitive, psychological, and/or neurobehavioural difficulties that significantly affect psychological wellbeing and pose a significant barrier to rehabilitation (Vaghelo et al 2021). The impact of ABI is substantial, in the UK, 1.3 million people live with the effects of brain injury, costing the UK economy approximately £15 billion per year. This figure is equivalent to 10% of the annual NHS budget (Barber et al., 2018). Underpinning dominant western healthcare models is the insidious narrative that a person's condition may be 'fixed', yet ABI is a chronic condition that can require holistic long-term management (Wilson et al., 2019).

Models of healthcare for people living with chronic conditions including ABI, have tended to be overly focused on reducing deficits and psychological distress. This is despite compelling evidence that the absence of distress and ill-health is not synonymous with wellbeing (Kemp et al., 2022). This 'reduction of illbeing' approach is inefficient and reductionistic considering the evidence from population-based studies that good psychological wellbeing reduces the risk of morbidity and mortality, and that it remains possible to experience wellbeing despite suffering. For instance, Barak et al., (2009) noted that interventions to improve happiness can lead to improvements in patient status relating to a variety of diseases including Epilepsy, Huntington's disease, Multiple Sclerosis, Parkinson's disease, and Stroke. Positive Psychology is a distinctive field dedicated to uncovering human strengths and elements that contribute to a fulfilling life (Seligman, 2011). Central to Positive Psychology is the notion that leveraging strengths and virtues can cultivate wellbeing.

Promising controlled findings relating to ABI have been published with interventions focusing on use of signature strengths, reflection on positive events, volunteering, and goal setting (Andrewes et al., 2014; Wainman-Lefley et al., 2022; Payne et al., 2020; Cullen et al., 2016). Control comparison conditions in these studies included treatment as usual (TAU) (Andrewes et al., 2014; Wainman-Lefley et al., 2022; Cullen et al., 2016) or waitlist-control conditions (Payne et al., 2020). TAU included a variety of treatments including individual psychotherapy and group work, cognitive behavioural therapy, motivational interviewing, setting goals for rehabilitation, psychoeducation focused on brain injury, social skills and meal planning, and pharmacological psychiatric treatments for mood disorders. The content of usual care is not typically standardised and depends on services available and participant needs.

Our study differed from past research and adds value to the literature in several novel ways. Firstly, we had developed an innovative positive psychotherapy intervention for ABI (Fisher et al., 2022, 2023) that seeks to promote wellbeing in service users in a more comprehensive way, focused on the promotion of individual, collective, and planetary wellbeing, and based on our own theoretical model. Our intervention makes use of positive psychological techniques, but is broader in scope, drawing on the wider evidence base on how to promote wellbeing (Kemp et al., 2017; Mead et al., 2021; Wilkie et al, 2022). Secondly, our study adopted a mixed method approach encompassing a range of measures including quantitative and qualitative measures, psychophysiological measures of wellbeing as well as a health economic component, providing a more holistic perspective and the foundation on which deeper insights may be realised.

Research Aims and Objectives: The overarching aims of the study were to: 1) evaluate the feasibility of conducting a positive psychotherapy (PP) intervention for individuals with ABI, and 2) ascertain under what conditions, if any, such an intervention would merit a fully powered randomised controlled trial (RCT) compared to a standard control group (TAU).

Our primary objective was to assess the feasibility of the research using the standardised ACCEPT checklist, which encompassed areas like recruitment rate, compliance with the intervention, randomisation process, data collection and analysis procedures, and research governance and trial management. We also delved into participants' experiences within the trial, focusing on the acceptability of procedures and their engagement with the intervention, while also collecting feedback for potential refinements. Additionally, by analysing our comprehensive dataset that included quantitative, qualitative, psychophysiological, and health economic data, we sought to identify early indications of the intervention's impacts.

Method

Trial Design: This study is based on a study protocol (Version 7) which has been refined and published (Fisher et al, 2024). The study is a mixed-methods feasibility RCT with participants randomly allocated to a treatment (PP intervention) or control (TAU) group. There are three research sites; Swansea Bay University (SBUHB), Hywel Dda University (HDUHB) and Cardiff and Vale University (CVUHB) healthboard. Data collection took place at each of the three healthcare sites, capturing a diverse representation of patients and enhancing the generalizability of the findings beyond a single site. Quantitative measures included questionnaire-based measures, psychophysiological measures and a health economic evaluation for the PP and TAU groups. Qualitative measures analysed focus group data of participant experience for PP group only. Participant recruitment and data collection began in October 2022, and the last patient visit took place at the end of October 2023.

Monitoring and Audit: An independent Trial Steering Committee (TSC) and Data Monitoring Committee inclusive of public patient involvement (PPI) oversaw trial monitoring and management. Full NHS ethical approval was obtained from the Wales Research Ethics Committee on January 6th, 2020 (IRAS project ID: 271251, REC reference: 19/WA/0336). The study adhered to ethical guidelines set by the NHS to protect participants' welfare and a risk-adaptive approach was employed for monitoring and oversight. Following recruitment, medium-intensity monitoring included electronic self-reviews of the Investigator Site File, scrutiny of completed data on case report forms, and annual monitoring visits by the trial manager who inspected 10-20% of source data. These measures ensured adherence to ethical standards and regulatory requirements, safeguarding participants' rights and wellbeing.

Recruitment procedures: A site Principal Investigator (PI) was identified at each site prior to starting the trial. The site PI and clinical staff acted as referrers for the trial to facilitate the identification of potential patients. Full lists of active patients were reviewed against the study inclusion and exclusion criteria (see participant section). Initial discussions regarding participation were initiated by a treating clinician known to the patient. Potentially interested patients were provided with a detailed participant information sheet (PIS) with full details of the research activities and commitments. Patients had a one-to-one telephone conversation with the PI, Clinical Trial Coordinator (CTC) or Research Assistant (RA) for an in-depth explanation of the study, to answer any questions, and to book a consent appointment. Consenting participants

and mentors were screened to ensure that they were suitable for inclusion. This involved cross referencing against the eligibility criteria and a brief standardised cognitive assessment including the Repeatable Battery for Assessment of Neuropsychological Status (RBANS) and the St Andrews-Swansea neurobehavioral outcome scale (SASNOS). Any participants deemed ineligible were contacted by the PI and given an explanation.

Participants: Participants were included in the study if they were 18 or over and able to provide informed consent with a confirmed diagnosis of ABI. Participants needed to be able to actively engage in the intervention (determined by their neuropsychological assessment and treating clinician) and they had to be living in the community and in the catchment area of one of the participating health boards. All participants needed to have sustained their brain injury at least three-months before recruitment, allowing time for spontaneous recovery and for the person to develop an awareness of their difficulties. Participants were excluded if they had receptive or expressive language difficulties, or extremely low memory function to the extent that this precluded meaningful engagement in the intervention or research. They were also excluded if they were deemed too risky from a medical or psycho-social perspective (based on risk assessment by the referring clinician). Finally, participants were excluded if their treating clinicians felt their participation would potentially be disruptive to other group members. In this study, 73 patients with a confirmed diagnosis of ABI were approached of whom 55 provided informed consent. Nineteen participants were male, 40% had suffered a stroke, approximately one-third had a traumatic brain injury (TBI) and ranged in age from 21 to 68 years.

Mentors: In addition to participants, two mentors were recruited per site to help facilitate the intervention alongside clinicians and provide their lived experiences. Mentors were subject to the same inclusion criteria as participants plus additional inclusion criteria which stipulated that they were known to and recommended by their referring clinical team; they had good interpersonal skills with the ability to be responsive and sensitive to the needs of others as determined by the treating clinician and that they were willing and able to commit to training as well as attending each session of the intervention. Six mentors, aged between 30 and 66 years, were recruited to support intervention delivery alongside clinicians providing their lived experience. Table One provides a condensed overview of the key participant and mentor characteristics. More detailed and comprehensive tables of all participants and mentor

characteristics will be included in the supplementary materials published alongside the final manuscript.

	Participants (All)	Mentors
Injury type	Intracerebral stroke 14%	Intracerebral stroke 33%
	Extracerebral haemorrhage 28%	Extracerebral haemorrhage 17%
	TBI 34%	TBI 33%
	Other* 24%	Other*17%
Sex (% Male)	38%	50%
Age (at consent)	Median = 46.5	Median = 51
	Range = 21 to 68	Range = 30 to 66
Time since injury	Median = 3.9	Median = 7.4
(years)	Range = 0.3 to 11	Range = 0.9 to 26
Antidepressants (%)	44%	50%

Table 1: A condensed overview of the key participant and mentor characteristics

*'Other is made up of brain tumour, vascular malformation, hypoxia, neuroinflammation etc.

Figure One visually illustrates the flow of participants and mentors from recruitment through to analysis. It provides a summary of participant enrollment, allocation, follow-up, and analysis across the study, in keeping with the CONSORT (Consolidated Standards of Reporting Trials) guidelines.

Figure 1: CONSORT Flow chart illustrating the flow of participants and mentors from recruitment through to analysis



Public and patient involvement: With reference to the UK Standards for Public Involvement, we have created 'Inclusive Opportunities' for service users to contribute to the development and facilitation of the positive psychotherapy intervention and all aspects of research study. We have also sought to 'Work Together' by including service users in the development of our research proposal and subsequent research study as integral members of our team. Their contributions have shaped the direction, content and accessibility of our work. Our participant workbook has undergone multiple revisions based on user feedback and includes editing contributions and stories from several service users. With regards 'Support & Learning', we have endeavoured to empower service users to contribute confidently to clinical and research activities enhancing their skills in public involvement. With respect to 'Communications', service users have provided valuable feedback on participant-facing materials, research design and contributed to press releases, presentations and publications. Regarding 'Impact', the decisions taken during the trial (e.g., exclusion of the DASS as an inclusion criterion), underscore key changes that have been made to the trial on the

basis of service user feedback. Insights shared by one of our service users during the final Trial Steering Committee prompted us to reassess potential measures for future trials, ensuring they not only capture changes in wellbeing (and illbeing) but also in regards to 'acceptance'. Finally, with regards to 'Governance', service users were actively involved in governance structures, including the Trial Management Group and Trial Steering Committee, ensuring that decisions promoted and protected the public interest.

Randomisation: Participants were randomly allocated to the PP intervention or TAU. The randomisation schedule was created using REDCap. The randomisation algorithm was designed to ensure that sample size of the groups were balanced. Randomisation was conducted within each of the three sites and stratified by antidepressant use (i.e., number of participants prescribed antidepressants within a site were evenly distributed across groups).

Treatment as usual: Treatment as usual involved assessment and case management from different members of the multidisciplinary team. Person-centred treatment goals were set to guide neurorehabilitation efforts, and depending on an individual's needs, a variety of treatments were offered, either individually or in group settings. See Appendix 1 for further details.

The PP intervention: Over the last few years, we have developed a PP intervention involving a two-hour session per week over an 8-week period. Our treatment manual has been continuously enhanced based on our prior clinical experience of running this group, as well as user feedback and developments in wellbeing science. The present study has informed further refinements to our intervention and materials including a clinician manual and participant workbook. Please see Appendix 1 for an overview of session-by-session content.

Procedure: The study involved the following key stages: referral, consent, eligibility, baseline measures, randomisation, treatment, post-intervention data collection and three-month follow-up. Please see Appendix 2 and Figure 1 for more details.

Measures: Once participant eligibility was confirmed, cognitive assessment data, questionnaire-based measures, psychophysiology and qualitative experience related data was collected from participants. Please see Appendix 4 for more detail.

Analysis

Quantitative data: Quantitative analysis included descriptive statistics to summarise participant demographics and clinical measures, focusing on assessing the feasibility, adherence, and preliminary outcomes of the PP versus TAU. An exploratory split-plot ANOVA was conducted to assess changes in psychological measures over time, including the DASS and the PERMA Profiler. Stata 17.0 SE was used for analysis.

Qualitative data: Reflexive thematic analysis (RTA) was used to explore, interpret and draw patterns of meaning from participant experience while embracing insights generated by the knowledge, experience and perspectives of the researchers (Braun & Clarke, 2021). To contextualise how people with brain injury experienced the PP intervention through the lens of wellbeing theory, a critical realist approach was adopted (Archer et al., 2020; Pilgrim, 2019). Beginning with reading the transcripts alongside the audio recording to familiarise themselves with the data Braun and Clarke (2006, 2019) six phases of RTA were followed in a non-linear fashion. The flexibility of RTA enabled coding of data to be tailored to the type of experience being shared, for example, commentary relating to feasibility, like in relation to travel distances and fatigue, were coded semantically whereas reflections about self-identity were coded latently (Braun, 2022). Similarly, coding was both inductive, deriving meaning from what participants shared, and deductive, by integrating data with insights from wellbeing theory (Braun, 2022). To supplement written notes and bring structure to the coding process ATLAS.TI was used. The software enabled visualisation of the codes within candidate themes, grouped initially based on similar content, and moved around as themes evolved. As part of the reflexive process, a thematic map displaying thematic interrelations and key quotations was discussed with research team members including those on the TMG, which contributed to the development of the final themes.

Psychophysiological data: Raw R-R interval data, measuring timing between heartbeats, was processed in Kubios Premium. Artefact correction threshold was adjusted individually, the optimal threshold was identified by choosing the lowest correction level that identified all artefacts (R-R intervals that fell outside of the 600–1200 ms range), but without identifying too many normal RR intervals as artefacts (<5% of all beats removed). The mean number of beats which were removed was 0.58 (0.16%). See Appendix 3 for definitions of the psychophysiological measures that were calculated and used for analysis. Statistical analysis included split-plot ANOVAs, with

group assignment (intervention vs. control) serving as the between-subjects factor, and time (pre vs. two follow-up assessments) as the within-subjects factor.

Health Economic Evaluation: Feasibility assessment focused on a United Kingdom (UK) National Health Service (NHS), and was framed by a personal social services (PSS) perspective. Economic outcome measures (resource use, health-related quality of life and wellbeing) were collected as part of the study. A description of the resource use and costs associated with the implementation of the PPT intervention compared to TAU was obtained. Descriptive analyses were undertaken in Microsoft Excel 2016 (Microsoft 365) and STATA 16.0 (StataCorp LLC). Study notes and discussions with the trial team were used to explore data availability and estimate the resources required to provide the intervention to calculate intervention cost. The feasibility of collecting patient-participant level healthcare usage was tested using an adapted Client Service Receipt Inventory (CSRI) healthcare resource use questionnaire, which required participants to indicate social care contacts, group activities and medication (Beecham and Knapp, 1990). Healthcare use and costs were calculated using the CSRI data and relevant published unit cost and medication cost data detailed in Appendix 7 (NHS England, 2023; Jones et al., 2023; Joint Formulary Committee, 2024). Total cost per group, mean cost per patient and SDs for each data collection point were supplemented by median and interquartile ranges due to inherent skewness in cost data (Mihaylova et al., 2011). The feasibility of collecting health-related quality of life (utility) data using EQ-5D-5L questionnaire and capability/wellbeing data using ICECAP-A was tested (Herdman et al., 2011; Al-Janabi et al., 2012) and scores calculated. Mean utility and capability scores (and SD) as well as median costs and interquartile ranges were reported for the two groups (PP, TAU) at each data collection point and mapped according to validated and appropriate scoring systems (NICE, 2022; Hernández Alava et al., 2023; Mitchell et al. 2017; University of Bristol, 2024).

Results

Results: Quantitative data

Recruitment and Retention: The study team approached 73 individuals across all sites and consented 75.3% (55/73) of approached individuals. Reasons for individuals' decline were: commitment issues for example work or childcare (n=10), not interested in the study (n=3), illness (n=2), and felt it was too early to consider group work (n=3). Recruitment rate was defined as the number of eligible individuals to participate in the

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study randomised to an allocation. The overall recruitment rate was 90.9% (50/55) and varied from 77.3% to 100% within sites. This passed the ACCEPT criteria of \geq 50% of eligible individuals being randomised. Reasons for ineligibility were due to the DASS-42 eligibility criteria at the Swansea site (n=5). Twenty seven participants were assigned to TAU, and 23 were assigned to the PP group. Randomisation was a 1:1 allocation, the imbalance in arms is due to block randomisation and stratification variables.

Randomisation process: The study passed the ACCEPT criteria. However, one patient was withdrawn due to misunderstanding their allocation and one mentor was mistakenly randomised after which the database was amended to prevent this happening in future.

Intervention Adherence: Intervention adherence, defined as attending at least six of eight group meetings, was achieved by 21 of 23 (91.3%) participants. For the assigned 'homework' tasks, patient completion was high (87%) for both assignments, facilitated by flexible deadlines and reminders from the study management team. Intervention adherence was therefore ≥75% and so passed ACCEPT criteria.

Data Collection: Data collection for the study was highly successful, with 94.6% of patient's forms being collected, which exceeded the ACCEPT target of 70%. Attrition affected data collection, as there were four patients from whom data could not be collected at a follow-up time point due to withdrawal.

Attrition: The attrition rate for patients was 8% (4/50). This was below the ACCEPT criteria attrition rate of 40%. Participant withdrawals occurred due to various reasons; in the TAU group one participant was withdrawn by the Trial team due to a misunderstanding of their allocation, another was lost to follow-up and a third withdrew before the three-month follow-up. The PP group saw only one withdrawal, attributed to commitment issues prior to the post-intervention follow-up. The attrition rate for mentors was 16.7% (1/6). A single mentor withdrew because of commitment issues related to group meeting attendance.

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Baseline Characteristics: Table Two shows a condensed version of key baseline participant characteristics as a function of the allocated group (TAU or PP) and Mentor characteristics. More detailed tables will be included in supplementary materials published alongside the final manuscript.

Participant demographics	TAU	PP	Mentor
Injury type	Intracerebral stroke 22% TBI 30% Extracerebral haemorrhage 37% Neuroinflammatory 7% Other* 4%	Intracerebral stroke 4% TBI 39% Extracerebral haemorrhage 17% Brain tumour 9% Vascular malformations 9% Hypoxia 9% Other* 13%	Intracerebral stroke 33% Extracerebral haemorrhage 17% TBI 33% Other*17%
Sex (% Male)	43%	44%	50%
Age (at consent)	Median = 47	Median = 46	Median = 51
	Range = 21 to 68	Range =22 to 64	Range = 30 to 66
Time since injury	Median = 3.9	Median = 3.9	Median = 7.4
(years)	Range = 0.4 to 10	Range = 0.3 to 11	Range = 0.9 to 26
Employed pre-injury	89%	78%	50%

44%

14

48%

(12; 15)

50%

14

50%

(11; 19)

Table 2: Key baseline participant characteristics as a function of those allocatedTAU or PP groups. Characteristics of Mentors are also displayed.

*Other made up of brain tumour, vascular malformations, hypoxia, neuroinflammatory etc.

Statistical Analysis: ANOVA and pairwise comparisons were succesfully conducted across both DASS and PERMA quantitative measures. The results are detailed in Appendix 5. The findings for all key measures moved in the predicted direction. However, no significant overall omnibus findings were observed or expected because the study was conducted for feasibility purposes and was underpowered.

Results: Qualitative data

Employed currently

Education (years)

(25th; 75th percentile)

Antidepressants (%)

(%)

Median

22%

13

41%

(11; 16)

The PP groups were invited to attend focus groups immediately following the final PP session. Of the 23 participants invited, 20 attended either one of the three focus groups

or a one-to-one interview. Table three describes a condensed overview related to the characteristics of participants who were allocated to the PP group and whose data was included in the qualitative analysis. Detailed tables will be included in supplementary materials published alongside the final manuscript.

Table 3: Characteristics of those allocated to the PP group and whose data wa
included in the qualitative analysis.

	Participants (PP only)
Injury type	Intracerebral Stroke 5%; TBI 30%; Extracerebral haemorrhage 20%; Brain tumour 10%; Vascular malformations 10%; Hypoxia 10%; Other* 15%
Sex (% Male)	45%
Age (at consent)	Median = 47; Range = 22 to 64
Time since injury (years)	Median = 3.9; Range = 0.3 to 11
Antidepressants (%)	50%

*'Other' categorisation is made up of neuroinflammation, abscess, lead toxicity etc.

Figure Two below shows a thematic map presenting the feasibility themes, their implications for future studies and key illustrative participant quotations.



Figure 2: Thematic map presenting the feasibility themes, their implications for future studies and key illustrative participant quotations.

Key themes related to feasibility included; 'A really good referral group'; 'Wanted entry, details unnecessary'; Practical matters, matter'; 'Extent of fatigue impacted data collection experience'; 'Laying the groundwork for successful group dynamics'; 'Successfully delivered valuable content' and a 'Workbook for life'.

A 'Really good referral group' reflected consensus that the intervention was universally beneficial especially in regard to providing much needed help following medical discharge. 'Desired entry, details unnecessary' captured the view that overall, the participants were satisfied with the introduction they received albeit noting it was lengthy and difficult to fully absorb. 'Practical matters, matter' emphasised the importance of getting factors like travel, location and session timing right, to enable participation. 'Extent of fatigue moderated data collection experience' captured general contentment with the data collection process, noting that it was typically tiring, and for some, too tiring, with travel suggested to be a contributing factor. 'Laying the groundwork for effective group dynamics' reflected factors like group size, clarifying expectations and managing participation, as key enablers for fostering group dynamics. Participants were largely content with group size which ranged from 8 to 10 and was within the typical range for similar studies. Most importantly they felt safe to share and that they would make 'time for each other'. Participants also valued the important roles of the facilitators and mentors. 'Successfully delivered beneficial content' captured undisputed appreciation for the quality of the intervention across all three sites with variation in the aspects that were considered most beneficial. The balance of the sessions, ensuring ample time for sharing experiences, variety of taught content and an emphasis on explaining 'why', resulted in them feeling like engaged learners, although some participants felt that each session covered too much content. 'Workbook 'a plan for life" reflected the universal agreement on the value of the workbook which served as a 'plan of action' for future reference boosting the longevity of their learning. It plugged gaps, like missed sessions, and those created by common challenges after brain injury, like memory and focus.



Figure 3: Thematic map, with key participant quotations, demonstrating the relationship between the themes and their contribution to building blocks for participant wellbeing

'Cultivating a safe space through mutual understanding' captured how the environment - aided by shared experience and nurturing facilitation - enabled participants to share, explore and test limits. 'Virtuous cycle of shared experience' reflected how sameness through shared experience fostered an immediate connection between participants, creating a sense of belonging and acceptance, free from judgement, which established trust. This deepened sharing and created a cycle of shared experience that normalised living with brain injury and provided respite from the misunderstanding of the outside world. 'Fostering a personalised experience whilst nurturing group dynamics' denoted how the facilitators - supported by the mentors' lived experience - effectively balanced support and encouragement to provide a personalised experience within a group setting. 'Holistic appreciation of the science of wellbeing' covered how the comprehensive nature of the wellbeing content and the depth of teaching, critically explaining 'why, what, and how', resulted in participants feeling respected as capable learners, empowered to make informed choices about when and how to put their learning into practice. Facilitated by the content of the themes described above, 'empowerment through psychosocial boosting', underpinned by four sub-themes, captured participants demonstration, in both sentiment and language, that they felt 'boosted' with the capability, motivation, self-belief and positive mood to improve their own wellbeing. 'Building a customised 'toolbox' for enhanced capability' reflected the breadth of skills and techniques participants had built up through learning and practice, giving them the knowledge to take charge of their wellbeing. 'Expanding comfort zone – finding comfort in discomfort' captured how participants practised, within the safety of the group, being outside their comfort zone, testing, trying, exploring, and through this building resilience and motivation to do so in the outside world. 'Mindset shift through self-acceptance' encapsulated how comparing and contrasting shared experience enabled participants to embrace different aspects of themselves, shifting perspective and leading to self-acceptance. They demonstrated a sense of autonomy for their role in 'making the most of life' and self-efficacy, a belief in their ability to succeed. 'Connecting with others – 'social boost'', captured the sustained improved mood felt by participants through connecting, learning, and supporting one another.

Psychophysiological data

Descriptive Statistics: Table Four provides a condensed overview of key participant variables relevant to the interpretation of physiological data (HRV) as a function of group allocation (TAU, PP). Detailed tables will be included in supplementary materials published alongside the final manuscript.

Participant	TAU	PP	Chi-square	Mentor
demographics				
Engaged in moderate	52%	57%		67%
to vigorous exercise				
Blood Pressure	44%	26.%		17%
Conditions				
Chronic Heart or	11%	17.4%		0%
Respiratory				
conditions				
Current smokers	19%	22%		17%
Consuming alcohol				
- 2-3 times a week	11%	17%		0%
- 4+ times per week	11%	4%		17%

 Table 4: Condensed overview of key participant variables relevant to the interpretation of HRV data as a function of group allocation (TAU, PP)

50 participants completed baseline characteristics, 27 in the TAU group and 23 in the PP group (see Figure 1), of which 9 were removed due to measurement error (n=4) and abnormal respiratory rates (n=5). A total of 43 participants were included in the final HRV analysis at time 1 and 2, and 42 participants at time 2. Blood pressure

conditions were prevalent, with 36.0% of participants overall reporting such conditions. Chronic heart issues or respiratory conditions were reported by 14.0% of participants. 20% were current smokers and alcohol consumption was moderate on average. Calculated means and standard deviations of psychophysiological measures are presented in Table 5 below as a function of group, at each time point.

Table 5: Means and standard deviations of psychophysiological measures as a	3
function of group, at each of the three study time points.	

Variable	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean	Mean
	Baseline	Baseline	Post TAU	Post PP	(SD) 3	(SD) 3
	TAU	PP			month	month
					post TAU	post PP
Heart	71.1 (7.5)	73.0 (12.6)	71.6 (11.4)	73.68	71.7 (8.6)	77.4 (11.9)
Rate, Mean (SD)				(12.6)		
RMSSD.	23.0 (10.6)	20.7	23.2 (13.0)	20.36	16.0 (5.1)	16.2 (7.2)
Mean (SD)		(12.28)		(10.9)		
SDNN.	25.9(11.6)	27.1 (12.5)	27.4 (12.7)	24.84	19.9 (7.1)	22.3
Mean (SD)				(11.2)		(10.8)
HF HRV	40.8 (14.9)	29.3 (20.2)	35.0 (14.3)	29.31	35.9	27.9
(n.u), Mean (SD)				(13.11)	(18.0)	(14.4)
HF HRV	268.7	198.4	278.3	173.5	106.1	112.7
(abs), Mean (SD)	(261.5)	(270.2)	(373.7)	(180.7)	(72.5)	(88.6)
LF/HF.	1.87 (1.3)	4.90 (4.75)	2.65 (2.68)	3.14 (1.89)	2.63	4.02
Mean (SD)					(2.29)	(3.49)

* Definitions of the psychophysiological measures presented in the variable column can be found in Appendix 3.

Feasibility Outcomes for Psychophysiology Data Collection: Regarding feasibility, there were some challenges associated with HRV measurement and analysis. Nearly half the sample were taking antidepressant medications, which have a notable impact on HRV. In addition, five participants were identified as having abnormal respiratory rates outside of the HF band, indicating abnormal breathing patterns, the influence of external factors, or potential measurement errors in the data. Of these participants, one had a chronic heart condition, one was taking medication known to affect respiratory rate, two were likely impacted by lifestyle factors as they reported drinking alcohol and undertaking intensive physical activity in 24 hours prior to data collection.

One participant had no obvious issues relating to lifestyle, health, or medication so it is not clear what was impacting respiratory rate. Four additional participant data points had to be removed due to measurement error. This is likely due to sensor contact issues such as improper strap placement or excessive movement.

Statistical Analysis: ANOVA and pairwise comparisons were succesfully conducted across all HRV measures (See Appendix 6). The findings varied in terms of both effect size and direction. No statistically significant findings were expected because the study was conducted for feasibility purposes and was underpowered.

Health Economic Evaluation

The health economic evaluation was conducted for all 50 participants, 23 of which were in the PP group and 27 in the TAU group. There were four components to the health economics results: 1) calculation of the implementation cost of the PPT intervention; 2) feasibility of health data collection for a future trial; 3) comparison of healthcare and PSS resource use, and 4) costs for PP and TAU group and comparison of utility and capability results for PP and TAU group.

Intervention costs: Intervention costs totalled £23,565, two-thirds of which related to development costs which included creation of clinician and participant manuals, presentation slides, and audio-visual aids. Delivery and training costs primarily related to clinician time in training, preparing, and delivering the interventions and were similar across all three sites. Average cost per participant was £1,164, excluding development costs this would fall to £176. See details in Appendix 7.

Feasibility of data collection for a future trial: Table Four shows the health economic evaluation of feasibility in relation to the ACCEPT checklist.

Table 4: Health economic evaluation of feasibility based on study ACCEPT

checklist.

Criteria	FAIL	PASS
Data collection from participants	<70%	≥ 70%
Availability and access to intervention implementation costs		100%. All relevant intervention resource use could be obtained with unit costs available from the study team and published sources (e.g. NHS Employers, 2022)
Availability and access healthcare and PSS costs:		Overall, CSRI completion rates were high between 92% and 100%.
Availability, <u>feasibility</u> and acceptability of patient-reported outcome measures (EQ-5D-5L and ICECAP-A):		All participants completed both questionnaires at baseline, with 8.0% missing questionnaires at the two follow- up points. All questionnaires were complete and could be scored.

As the table shows, data collection rates were high, ranging from 92% to 100%, across both healthcare costs and participant health care data, which exceeded the study criteria of 70%.

Healthcare resource use and cost: Means, medians and interquartile ranges were successfully calculated for both the TAU and PP groups. Over the study period, median costs and number of contacts reduced for both groups. See Appendix 7 for details.

Comparison of healthcare outcomes: Means, medians and interquartile ranges were successfully calculated for both the TAU and PP groups across utility measures (EQ-5D-5L and EQ-VAS) and capability measures (ICECAP-A). The results for both utility measures showed a slight improvement for both TAU and PP groups across the study period. The capability measure showed a slight improvement in the TAU group and a slight deterioration in the PP group over the period. Please see Appendix 9 for further details.

Discussion

Summary of main findings and recommendations

A focus on quantitative, qualitative, psychophysiological, and health economic evaluations contributed unique insights into the feasibility of the intervention. A summary of overall findings and recommendations are provided in Figure 4 and additional discussion on each of the evaluations is provided in Appendix 9.

Figure 4: Summary of feasibility findings relative to the ACCEPT Checklist.

Component of tri	al	Assessment (Result)	Status	Recommendation
Trial design		Good balance between scientific/ practical		To consider the pros and cons of a wait list control design
Sample size		Recruitment target achieved		A priori vs post hoc considerations, and issues relating to sensitivity of outcome measures for detecting change
Interventions	Clinical governance	100% compliance with training (clinical and research)		
	Intervention fidelity	Intervention adherence > 80% (92%)		Consider recording treatment sessions to confirm adherence to manual
Participants	Recruitment strategy	Recruitment rate > 50% (91%)		
	Eligibility criteria	Recruitment rate > 50% (78%)		DASS removed as eligibility criteria
Consent procedures	Participant information sheet	Qualitative participant feedback		Format to be amended to shorten / video
	Taking informed consent	100% Consented, no issues		
Randomisation process		<2 randomisation errors (0)		
Data	Data collection	>70% (95%)		Consider adding WEMWBS plus PERMA
	Data management	Feedback trial team, amendment made to database		Some minor amendments needed to study database (an option to indicate no change to medication etc)
	Quality	High data collection/completion rate		
Research governance	Research protocol adherence	Amendments to inc. feasibility		
	Adverse events	Procedures tested, protocol amended		
	Health & Safety	Followed NHS procedures & NIHR guidelines		
Data analysis		Minor amendments to protocol (SAP)		Consider pros and cons of HRV
Trial management		Feedback trial team		Clearer roles & responsibilities with dedicated project management

Key: Green = PASS; Orange = Pass with Amendments; Red = FAIL

Quantitatively, the study not only met but exceeded expectations in participant recruitment, retention, and intervention adherence, with statistical analyses indicating promising directions in key measures of wellbeing. Qualitatively, participant feedback underscored the effectiveness of the recruitment and data collection processes, revealing valuable insights for refining the intervention, such as enhancing introductory materials and addressing practical considerations like travel and session timing to improve the participant experience in rural sites. This feedback also highlighted the positive impact of the intervention on participants' ability to manage emotions and

enhance personal relationships, suggesting its potential for broadening collective wellbeing. The psychophysiological data, while offering valuable insights into vagal function - a psychophysiological index of wellbeing indicated by HRV - revealed challenges due to the ABI population's diverse medical conditions and medication use, indicating need for further reflection on whether this component should be included in a future trial. Meanwhile, the health economic evaluation demonstrated the feasibility of collecting cost-related data and although there was a variable pattern in healthcare usage post-intervention, there was an indication of cost effectiveness. While the average cost per participant was £1,164, exclusion of development costs substantially reduces this cost. The average cost of £1,164 per patient aligned with typical costs for rehabilitation interventions of similar duration (e.g., CBT interventions, Richards et al., 2017). However, the clinical manual and workbooks supporting the intervention have now been developed and refined to an extent that any future study would be more cost effective, and restricted to delivery and training. Ongoing intervention costs, excluding development costs, therefore equated to around £176 per participant, in line with around three sessions of counselling or appointments with a clinical psychologist (NHS, 2023). Together, these findings indicate that a full RCT study is practically feasible. The study also informed a number of potential refinements that will be made to the study methodology. As the study was designed to determine feasibility (Figure 4) it was underpowered. Nevertheless, it is interesting and promising to observe that findings related to primarily quantitative measures (e.g., DASS and PERMA) were in the predicted direction (Appendix 5). Participant experience indicated that participants felt empowered and equipped with capability, intrinsic motivation and self-belief to master their own wellbeing.

Potential benefits: The 'Healthier Wales' legislation sets out the need for health services to adapt and meet the challenges posed by a population living longer with disabilities. Our approach was tailored specifically to address these challenges in the context of neurological conditions. A key aspect of the Welsh Government's vision for health and social care is to enhance value for patients by prioritising outcomes that matter most to individuals. The development of our approach and intervention has come from the feedback of our service users and has been developed and delivered alongside them. Although this was a feasibility trial, participant feedback very much confirmed that the intervention was needed and valued. In addition, health economic data demonstrated that it may provide a cost effective approach in keeping with the principles of Value Based Health Care. Our study marks the initial step in exploring the

potential of holistic wellbeing approaches in ABI rehabilitation. By prioritising psychological wellbeing alongside conventional methods, we have the opportunity to unlock new avenues to recovery and enhance the overall guality of life for ABI patients. This could boost the effectiveness of traditional care approaches, leading to improved outcomes for the same cost. It also has the potential to reduce downstream expenses, comorbidities and poor mental health. Given the following factors: 1) the limited access to rehabilitation services for those with neurological conditions in Wales; 2) the limitations of care models that focus solely on diminishing ill-being; 3) the anticipated increase in neurological condition prevalence in Wales; and 4) the projection that these conditions will demand the highest level of social care, there's a critical need for investment in innovative, evidence-based, and co-created neurorehabilitation approaches. However, this cannot be achieved without investment into high-quality research that can provide the backbone of evidence based practice and inform the type of innovation needed to navigate the major societal challenges ahead. In pursuit of that goal research should be embedded and integrated into clinical systems and tailored to address urgent clinical challenges.

Limitations: The study design was potentially compromised by a waitlist control group in which the TAU group was informed that they would be able to attend the intervention once the trial was completed if they wanted to. Although this was done for ethical reasons, it may have influenced their engagement and the study's outcomes and this needs further reflection when designing a larger RCT. A broader health economic evaluation to capture the intervention's societal benefits including participant engagement in their communities would have been desirable given that the design of the intervention was developed to encourage this. Preliminary results hint at the intervention's potential for sustained wellbeing improvements but it may have been useful to gain some qualitative feedback from participants (3 months post intervention). Data collection challenges, notably in HRV measurement, underscore the need to refine methodologies in subsequent research. There is also a need for reflection as to whether additional measures may be more useful in detecting theorised changes (i.e. a measure of acceptance which was a strong theme in the qualitative analysis and discussion at the recent trial steering committee).

Future plans: As we prepare for a full-scale RCT, our immediate priority is to determine the necessary sample size, guided by ongoing discussions with the trial management group and trial steering committee. This critical step, informed by insights from service user experiences, including reflections from a participant member of the

trial steering committee, will help us identify the most appropriate measures of clinically meaningful change, which could include one of the administered measures or another measure such as the 7-item measure of the Warwick Edinburgh Mental Wellbeing Scale, or a measure of self-acceptance. Alongside this, we are committed to enhancing the intervention's accessibility and readability, as indicated by the evaluation of collected qualitative data, by refining the participant manual. This endeavour will be complemented by a feedback event in June for all our stakeholders, aimed at disseminating the feasibility findings and fostering a dialogue on future directions. Integral to our approach is the publication of these findings in a peer-reviewed manuscript, ensuring the transparency of our research and the opportunity to contribute valuable knowledge to the field. We expect that this publication will include a service user as a co-author, honouring their contributions and embedding their perspectives within academic discourse. This comprehensive process, from refining study materials to engaging with our community and sharing our findings publicly, sets a solid foundation for the planned future RCT. It also underscores our commitment to a research journey that is not only scientifically rigorous but also deeply collaborative, marking the beginning of a continued effort to improve the wellbeing of people living with ABI.

Conclusion: The study demonstrated successful recruitment, retention, and intervention adherence, indicating the feasibility of conducting a larger trial. Participant feedback was positive, endorsing satisfaction with study procedures and the intervention itself. While sample sizes were too small to make definitive conclusions relating to efficacy, findings are promising.

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Appendix Section

Appendix 1: Treatment As Usual and Intervention.

Treatment As Usual (TAU)

Treatment as usual was tailored to individual needs, with a range of strategies including:

a) Strategies to compensate for or ameliorate cognitive, physical, or communication challenges,

b) Psychological therapies, such as cognitive behavioural therapy, acceptance and commitment therapy and mindfulness,

c) Vocational rehabilitation and engagement in meaningful activities, or

d) Groups designed to support reintegration into local communities.

Positive Psychology (PP) Group Intervention

Session name (No.)	Summary of session content
(1) Living with difficult emotions	Before focusing on positive emotions and wellbeing, it is important to acknowledge the role and value of difficult emotions and thoughts. Following a major life event, the experience of difficult thoughts and emotions are both understandable and common. It is important to recognise this and point out that the aim of the course is not to 'get rid' of negative thoughts and emotions but recognise their value where possible and to learn skills to make room for these experiences when they become overwhelming. The techniques outlined in this session are informed by Acceptance and Commitment 14 Therapy, Mindfulness and Compassion Focused Therapy, drawing on the work of Harris, Hayes and Kabat-Zinn.
(2) Identifying & living using Character Strengths	Identifying one's character strengths is the foundation to 'building on what is strong, rather than fixing what is wrong'. In this session, group members introduce themselves by their character strengths and provide examples of how they use their strengths. We discuss new ways to use character strengths and making positive statements based on participants strengths, talents and values. Niemiec's work provides a solid foundation in this regard.

(3) Building Positive Emotions	Positive emotions are fundamental to theories of hedonic wellbeing. Barbara Fredrickson's 'Broaden and Build Model' is a major focus of this section as well Seligman's and Dieners work. A core feature of positive psychology is to promote task engagement by facilitating 'psychological flow' as coined by Csíkszentmihályi. In this session, we explore and practice several evidence-based techniques to build and savour positive emotions and experiences including flow, gratitude and optimism.
(4) Connection between Body and Mind	In this session, we emphasise the importance of building positive health behaviours to facilitate vagal function which in turn positively impacts on wellbeing. This session is influenced by our own GENIAL model, and the work of Porges, Dana and Thayer. In this session, we teach participants about the mechanisms that underpin the connection between the mind and the body, emphasising the regulatory role of the vagus nerve (as indexed by heart rate variability). Participants learn about techniques/lifestyle factors that have been shown to improve heart rate variability including diet, exercise, sleep, meditation etc. To maximise engagement in the session, participants explore the acute impact of different activities on their own HRV, through engagement in a variety of exercises.
(5) Connection to others and the Natural Environment	In part one of this session, we explore the importance of social connection to health and wellbeing outcomes. We practice techniques shown to facilitate social connection (and social relational emotions) including 'Acts of Kindness and 'Gratitude' exercises. We talk in more detail about the positive emotion of love in keeping with Fredrickson's work on Positivity Resonance. We learn about techniques to elicit feelings of love including 'Loving Kindness Meditation'. We talk about the importance of connection with our communities and explore how disconnection, following brain injury, may impact one's sense of identity. This section is influenced by the theoretical work of Tajfel and Haslam. Finally, we talk about the importance of nature connectedness for health and wellbeing drawing on key theories such as ecological systems theory, biophilia, stress reduction theory and attention restoration theory, inspired by the work of Wilson, Kaplan, Ulrich and O'Brien.
(6) Meaning & Purpose	Meaning and purpose in life are major components to eudemonic wellbeing. The theoretical work by Ryff, Frankl and Wong are particularly influential in this regard. We argue that meaning and purpose in life might be enhanced and facilitated through a combination of interventions that focus on the individual, community, and environment. In this session we explore photos that represent areas of meaning for participants (inspired by the work of Steger) and link these areas of meaning to each participant's values using a values clarification exercise. We talk about meaning as providing a sense 15 of direction in life and values as a Global Positioning System (GPS) to help us move in the right direction.

(7) Translating Values into Action	In this session, we recap on each participant's strengths, values and areas of meaning. We explore the extent to which participants are living a values-based life or 'acting out their values'. Participants identify and share areas where they are acting out their values and areas where they could better connect with their values. Using a 'goal setting' framework, participants set goals that support them to reconnect with some of their values in the coming months. We explore some of the challenges and opportunities for growth that participants might encounter whilst trying to achieve their goals. This session is inspired by Acceptance and Commitment Therapy, Positive Psychology as it relates to the Human Values System, inspired by the work of Bojanowska and the theoretical work of Schwartz related to Values and the Basic Human Needs System
(8) Behaviour Change and Managing Ups and Downs	In this session, we recap on each participant's strengths, values and areas of meaning. We explore the extent to which participants are living a values-based life or 'acting out their values'. Participants identify and share areas where they are acting out their values and areas where they could better connect with their values. Using a 'goal setting' framework, participants set goals that support them to reconnect with some of their values in the coming months. We explore some of the challenges and opportunities for growth that participants might encounter whilst trying to achieve their goals. This session is inspired by Acceptance and Commitment Therapy, Positive Psychology as it relates to the Human Values System, inspired by the work of Bojanowska and the theoretical work of Schwartz related to Values and the Basic Human Needs System

Appendix 2: Procedure.

- 1. **Referral**: Potential participants and mentors asked whether they would like to participate in the study and given the participant or mentor information sheet as appropriate.
- 2. **Consent:** Potential participants and mentors meet a member of the research team to discuss the study and provide consent.
- 3. **Eligibility**: Potential participants and mentors met with the RA (under the supervision of a clinical psychologist) to determine eligibility for the study. If participants are deemed ineligible, they are followed up by the PI and an explanation given.
- 4. **Baseline measures**: Eligible participants and mentors meet with the RA to complete baseline measures (see below for detailed description of methods).
- 5. **Randomisation**: Participants randomly assigned to the TAU control group or the PP group. Two mentors assigned to each of the three groups based on availability and proximity.
- 6. **Treatment:** Participants and mentors attended the 8-week PP group or TAU control.
- 7. Post-intervention data collection: All participants met the RA to repeat quantitative measures over a two-week period following the final session of the intervention. PP Group attendees and mentors were also invited to take part in participant and mentor focus groups, respectively, to gather data for qualitative analysis.
- 8. **Three-month follow-up:** All participants meet the research assistant to repeat quantitative measures a final time, three months following the final session for the intervention.

Psychophysiological Measure	Definition		
Heart Rate (HR)	Number of times the heart beats per minute		
	(bpm).		
Root Mean Square Of	Time domain measure of HRV that quantifies		
Successive Differences	the variability in the time intervals between		
Between Normal Heartbeats	successive normal heartbeats		
(RMSSD)			
Standard Deviation of All	Another time domain HRV measure which		
Normal RR (SDNN)	represents the variability in the time between		
	consecutive normal heartbeats		
High Frequency Heart Rate	Frequency-domain measure of HRV. Represent		
Variability Normalised Units	the relative power of high-frequency HRV		
(HF HRV n.u)	compared to total power, expressed as a		
	percentage.		
High Frequency Heart Rate	Frequency-domain measure of HRV. Quantifies		
Variability Absolute Power (HF	the raw power in the high-frequency range of		
HRV abs)	HRV, between 0.15 and 0.4 Hz.		
Ratio of LF to HF Power (LF/HF	Frequency-domain measure of HRV. Compares		
ratio)	the power of low-frequency (LF) HRV to high-		
	frequency (HF) HRV. LF HRV is associated with		
	sympathetic nervous system activity, while HF		
	HRV reflects parasympathetic activity. The		
	LF/HF ratio is used as an index of		
	sympathovagal balance.		

Appendix 3: Definitions of Psychophysiological Measures Used.

Appendix 4: Information about Measurement Tools.

- Cognitive assessment: Participants completed paper-based standardised cognitive assessments: (a) the RBANS (Randolph et al., 1998), a neuropsychological screening tool, commonly employed in ABI populations, that yield scores across five cognitive domains including immediate memory, visuospatial ability, language, attention, and delayed memory; and (b) SASNOS (Alderman et al., 2011), a 49-item measure relating to a broad range of neurobehavioural difficulties people face when living with an ABI and measured on a 7-point scale ranging from 'never' to 'always'. Response forms were scored on paper, and index scores, confidence intervals and percentiles were entered into dedicated case report forms (CRFs) on the REDCap database.
- Questionnaire-based measures: Participants completed а battery of questionnaires by verbally conveying their responses to a researcher who typed the participant's response directly into the REDCap database. Questionnaires included: (a) the Depression, Anxiety and Stress Scales (DASS-42) (Lovibond et al., 1995), a 42-item measure of the severity/frequency of negative affective symptoms that are rated on a 4-point scale ranging from 'never' to 'almost always'; (b) the EuroQual of life scale (EQ-5D-5L) (Herdman et al., 2011), which measures five dimensions of health status including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression across five levels ranging from 'no problems" to 'unable/extreme problems', alongside a Visual Analogue Scale to provide a self-report of individual health status; (c) the ICECAP measure for Adults (ICECAP-A) (Al-Janabi et al., 2012), which assesses five capabilities relevant to wellbeing including stability, attachment, autonomy, achievement and enjoyment; (d) the Positive emotion, Engagement, Relationships, Meaning, and Accomplishment (PERMA) profiler (Butler et al., 2016), a 23-item measure to assess flourishing across 5 domains (PERMA) as well as health, negative emotion, loneliness, and overall happiness on a 11-point scale ranging from not at all/never to completely/always; and (e) an adapted version of the Client Service Receipt Inventory (CSRI) – Mental Health Version (Beecham et al., 1992), which captures individual health service usage data.
- *Psychophysiology:* a Polar H10 heart rate sensor was attached to a chest strap, placed around the chest wall, and positioned below the pectoral muscles. The

participant was then placed in a seated position and left alone for 10-minutes while heart rate variability (HRV) data was collected. The sensor was connected to the Elite HRV application (Gambassi et al., 2020), and the data exported as a plain text file. The data file contained only millisecond timings between heartbeats and the unique study identification number with no personal information. Prior to data collection, participants were asked some lifestyle questions regarding physical activity, meal and alcohol intake, smoking status, sleep, height and weight. Prior work has demonstrated that the data collected from the Polar H10 devices are highly correlated with the hospital-grade electrocardiogram (r=0.997) (Gilgen-Ammann et al., 2019).

 Qualitative data collection: Focus groups, led by a female CTC with post-graduate experience in psychology were conducted with participants allocated to the PP group to facilitate a better understanding of study acceptability and participants' experiences of the trial procedures and of the wellbeing intervention itself. A semistructured interview schedule covered topics including recruitment and data collection procedures, as well as experiences of participating in the group. The interviewer used open-ended questions and encouraged group discussion, seeking alternate and confirmatory views from participants and inviting quieter participants to engage. To ensure accuracy, all interviews and focus groups were recorded and transcribed using an orthographic approach excluding names and locations to safeguard anonymity.

Appendix 5: Quantitative Statistical Analysis.

DASS (Depression, Anxiety and Stress Scale)

ANOVA Transformed (ln(1+x)) DASS-42 Stress score

Source	df	MS	F	Prob>F
Model	61	0.60	4.49	< 0.001
Group treatment allocated	1	1.80	2.76	0.104
Site	2	1.79	2.74	0.076
Group treatment allocated # Site	2	0.70	1.08	0.350
Time	2	0.23	0.35	0.704
Group treatment allocated # Time	2	0.42	0.64	0.534
Site # Time	4	0.23	0.35	0.842
Group treatment allocated # Site # Time	4	0.28	0.42	0.791
Patient Site Group treatment allocated	44	0.65		
Residual	80	0.13		
Total	141	0.34		

| Symbol indicates nesting.

Symbol indicates interaction.



Transformed DASS-42 Stress	Treatment as usual	Positive psychology group	
score	Mean [95% CI]	meetings Mean [95% Cl]	
Baseline	2.8 [2.7, 3.0]	2.9 [2.7, 3.0]	
Post meetings	2.8 [2.7, 3.0]	2.6 [2.4, 2.7]	
3 months post meetings	2.8 [2.7, 3.0]	2.7 [2.5, 2.8]	

ANOVA Transformed	(ln(1+x)) DASS-42	Anxiety score
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Source	df	MS	F	Prob>F
Model	61	1.07	6.46	< 0.001
Group treatment allocated	1	1.31	1.09	0.301
Site	2	3.49	2.92	0.064
Group treatment allocated # Site	2	0.79	0.66	0.523
Time	2	0.72	0.60	0.553
Group treatment allocated # Time	2	0.80	0.67	0.516
Site # Time	4	0.46	0.38	0.819
Group treatment allocated # Site # Time	4	0.18	0.15	0.960
Patient Site Group treatment allocated	44	1.19		
Residual	80	0.17		
Total	141	0.56		

| Symbol indicates nesting.

Symbol indicates interaction.



ANOVA Transformed (ln(1+x)) DASS-42 Depression score

Source	df	MS	F	Prob>F
Model	61	1.40	7.16	<0.001
Group treatment allocated	1	1.64	1.10	0.301
Site	2	4.37	2.93	0.064
Group treatment allocated # Site	2	1.27	0.85	0.435
Time	2	1.15	0.77	0.469
Group treatment allocated # Time	2	1.37	0.92	0.406
Site # Time	4	0.28	0.19	0.944
Group treatment allocated # Site # Time	4	0.50	0.33	0.855
Patient Site Group treatment allocated	44	1.49		
Residual	80	0.20		
Total	141	0.72		

Symbol indicates nesting.

3 months post meetings

Symbol indicates interaction.



2.5 [2.3, 2.6]

2.4 [2.2, 2.5]

ANOVA Transformed (ln(1+x)) PERMA Overall score

Source	df	MS	F	Prob>F
Model	61	0.15	7.44	< 0.001
Group treatment allocated	1	0.27	1.53	0.223
Site	2	0.45	2.59	0.086
Group treatment allocated # Site	2	0.02	0.12	0.886
Time	2	0.11	0.61	0.549
Group treatment allocated # Time	2	0.03	0.16	0.852
Site # Time	4	0.04	0.21	0.930
Group treatment allocated # Site # Time	4	0.03	0.18	0.946
Patient Site Group treatment allocated	44	0.18		
Residual	80	0.02		
Total	141	0.08		

| Symbol indicates nesting.

Symbol indicates interaction.



		· · · · · · · · · · · · · · · · · · ·
score	Mean [95% CI]	meetings Mean [95% CI]
Baseline	1.8 [1.8, 1.9]	1.8 [1.8, 1.9]
Post meetings	1.8 [1.8, 1.9]	1.9 [1.9, 2.0]
3 months post meetings	1.9 [1.8, 1.9]	2.0 [1.9, 2.0]

ANOVA Transformed (ln(1+x)) PERMA Meaning score

Source	df	MS	F	Prob>F
Model	61	0.31	5.81	< 0.001
Group treatment allocated	1	1.26	3.76	0.059
Site	2	1.00	2.99	0.061
Group treatment allocated # Site	2	0.04	0.12	0.889
Time	2	0.06	0.17	0.848
Group treatment allocated # Time	2	0.09	0.26	0.769
Site # Time	4	0.12	0.36	0.836
Group treatment allocated # Site # Time	4	0.06	0.18	0.947
Patient Site Group treatment allocated	44	0.34		
Residual	80	0.05		
Total	141	0.16		

| Symbol indicates nesting.

3 months post meetings

Symbol indicates interaction.



1.7 [1.6, 1.8]

1.9 [1.8, 2.0]

Inferential Statistics Summary

For the DASS measure, no significant main or interaction effects were observed on any of the three DASS subscales. However, significant differences were observed for depression, anxiety and stress for those participants allocated to the PP group, and these findings were in the expected direction. No significant differences were observed for any such pairwise comparison in TAU. A reduction in depression score was observed from T1 to T2 (p<0.001, d=0.65), with a small significant rise in depression score was observed at T3 relative to T2 (p=0.007, d=-.032). Note however, that the depression score at T3 remained significantly less than T1 (p=0.034, d=0.33). See above figure illustrating changes in the depression DASS score across time in those allocated to the PP group. For anxiety, a significant reduction was observed from T1 to T2 (p<0.001, d=0.40), although this finding was reversed at T3 (T3 v T2, p=0.004, d=-0.38). There was no difference between T1 and T3 indicating that anxiety had returned to baseline 3-months following the end of the intervention. For stress, again a significant reduction was observed from T1 to T2 (p=0.005, d=0.54) and this reduction was retained at T3 (T1 v T3, p=0.060, d=0.29). There was no change from T2 to T3 (T2 v T3 p=0.318, d=-0.14).

Similarly, for the PERMA measure, no significant changes in overall omnibus ANOVAs. Further examination of pairwise comparisons revealed significant findings in predicted directions for those allocated to the PP group while no significant changes were observed for those in the control group. For the overall PERMA score, there was improvement from T1 to T2 (p=0.038, d=0.26) and this effect was maintained at T3 (T1 vs T3, p=0.002, d=0.43), although there was no significant change from T2 to T3 (p=0.291, d=0.20) in those allocated to the PP group (see Fig 2). Similarly, for the positive emotion score, there was improvement from T1 to T2 (p=0.028, d=0.28) and this effect was maintained at T3 (T1 vs T3, p=0.004, d=0.50), although there was no significant change from T2 to T3 (p=0.456, d=0.17). This trend was also observed for the happiness score, which also displayed improvement from T1 to T2 (p=0.036, d=0.26) and this effect was maintained at T3 (T1 vs T3, p=0.035, d=0.26), although there was no significant change from T2 to T3 (p=0.456, d=0.17). This trend was also observed for the happiness score, which also displayed improvement from T1 to T2 (p=0.036, d=0.26) and this effect was maintained at T3 (T1 vs T3, p=0.035, d=0.26), although there was no significant change from T2 to T3 (p=0.994, d=0.01). Findings for engagement, relationships, meaning, accomplishment and negative emotion were more equivocal.

Appendix 6: Psychophysiological statistical analysis.

Measure 1	Measure 2	Intervention Group:	Effect Size	Control Group:	Effect Size
		Cohen's d		Cohen's d	
Baseline	Post HR	-0.172	Negligible	-0.127	Negligible
Mean HR		(-0.601; 0.261)		(-0.589; 0.339)	
Baseline	FU HR	-0.418	Small	-0.388	Small
Mean HR		(-0.841; 0.013)		(-0.877; 0.111)	
Post HR	FU HR	-0.324	Small	-0.003	Negligible
		(-0.760; 0.119)		(-0.465; 0.459)	
Baseline	Post	-0.030	Negligible	-0.031	Negligible
RMSSD	RMSSD	(-0.457; 0.398)		(-0.493; 0.431)	
Baseline	FU	0.377	Small	0.654	Medium
RMSSD	RMSSD	(-0.050; 0.797)		(0.120; 1.171)	
Post	FU	0.471 (0.014; 0.918)	Small	0.500	Medium
RMSSD	RMSSD			(0.002; 0.984)	
Baseline	Post SDNN	0.066	Negligible	-0.180	Negligible
SDNN		(-0.363; 0.493)		(0.643; 0.289)	
Baseline	FU SDNN	0.421	Small	0.396	Small
SDNN		(-0.011; 0.843)		(-0.104; 0.885)	
Post SDNN	FU SDNN	0.509	Medium	0.478	Small
		(0.048; 0.959)		(-0.017; 0.961)	
Baseline HF	Post HF	-0.042	Negligible	0.365	Small
(n.u)	n.u	(-0.496; 0.387)		(-0.118; 0.838)	
Baseline HF	FU HF n.u	0.070	Negligible	0.274	Small
(n.u)		(-0.340; 0.479)		(-0.215; 0.754)	
Post HF	FU HF n.u	0.032	Negligible	-0.106	Negligible
(n.u)		(-0.396; 0.460)		(-0.567; 0.359)	
Baseline HF	Post HF	0.005	Negligible	-0.094	Negligible
(ms2)	abs	(-0.423; 0.432)		(-0.556; 0.370)	
Baseline HF	FU HF abs	0.320	Small	0.566	Medium
(ms2)		(-0.103; 0.736)		(0.045; 1.072)	
Post HF abs	FU HF abs	0.393	Small	0.459	Small
		(-0.056; 0.832)		(-0.034; 0.939)	
Baseline	Post LF/HF	0.368	Small	-0.264	Small
LF/HF		(-0.079; 0.806)		(-0.731; 0.210)	
Baseline	FU LF/HF	0.194	Small	-0.379 (-867; 0.119)	Small
LF/HF		(-0.221; 0.605)			
Post LF/HF	FU LF/HF	-0.235	Small	0.020	Negligible
		(-0.666; 0.201)		(-0.442; 0.482)	

Pairwise comparisons for psychophysiological metrics across each time interval.

Inferential Statistics

ANOVA tests revealed that no HRV measures showed statistically significant between group effects. However, the study was designed to test feasibility, not to detect effects or differences, so significant p-values were not expected. Effect sizes ranged from negligible to medium (see table below).

F	p value (tv tailed)	wo η²	Effect size	
1.236	0.274	0.028	Small	
0.422	0.520	0.007	Very Small	
0.002	0.963	<0.000	Negligible	
3.648	0.065	0.064	Medium	
0.563	0.458	0.008	Small	
3.714	0.062	0.054	Medium	
	F 1.236 0.422 0.002 3.648 0.563 3.714	F p value (trailed) 1.236 0.274 0.422 0.520 0.002 0.963 3.648 0.065 0.563 0.458 3.714 0.062	F p value (two n² tailed) 1.236 0.274 0.028 0.422 0.520 0.007 0.002 0.963 <0.000	Fp value (two n²Effect size1.2360.2740.028Small0.4220.5200.007Very Small0.0020.963<0.000

ANOVA between subjects effects

Pairwise Comparisons

Pairwise comparisons were performed for each psychophysiological metric across different time intervals. To assess the potential impact of the intervention, effect sizes were calculated, providing insight into the strength of the intervention's effects on each measure. For both the PP and TAU groups, changes in mean HR from baseline to post-intervention and follow-up were small. Time domain HRV measures RMSSD and SDNN showed small to medium effects from baseline to follow-up in both groups. Frequency domain HRV metrics, including HF (n.u) and LF/HF ratios, generally showed negligible to small changes. Overall time domain HRV indices appeared to have the most pronounced changes.

Appendix 7: Health Economics

Site/Activity	Staff	Materials	Other	Total (%)	Per patient (n=22)	Per clinician (n=6)
				16,812		
Development	16,812	-	-	(66)	764	2,802
Training & Delivery:						
Swansea Bay				2 900		
UHB	2,160	739	-	(11)	322	1,450
- Cardiff and Vale	2 200	500		2,700	450	4.050
UHB	2,200	500	-	(11)	450	1,350
				3,201		
 Hywel Dda UHB 	2,393	580	228	(13)	457	1,601
	23,565	1,820	228	25,613		
Overall (%)	(92)	(7.1)	(0.9)	(100)	1,164	4,269

Intervention costs, cost comparisons & healthcare and medication unit costs.

Notes:

No discounting was applied as the study time horizon did not exceed 12 months

• The feasibility assessment only included patients; mentors were not considered at this point.

• As it was provided in addition to TAU, implementation costs did not take into account TAU.

Healthcare costs across study period for TAU and PP groups: The chart below shows the median per participant healthcare costs and number of healthcare contacts for the PP and TAU group at the three measurement points. For the PP group, median health and social care costs increased post-intervention, driven by a number of planned and emergency surgeries, and reverted to slightly below baseline level by 3 months post-intervention, whilst number of contacts declined at each time point. For the TAU group, median costs reduced slightly from baseline to post-intervention to three months post-intervention.



Figure above shows healthcare cost/usage comparison PP vs TAU

Comparison of healthcare outcomes based on utility and capabilities questionnaires

The results for the two utility measures, the descriptive measure (EQ-5D-5L) and the visual measure (EQ-VAS) showed a slight improvement for both TAU and PP group across the study period. The capability measure, assessed using ICECAP-A questionnaire, showed a slight improvement in the TAU group and a slight deterioration in the PP group over the period.



Figure above shows utility measured using EQ-5D-5L



Figure above shows 'utility' measured using EQ-VAS



Figure above shows 'capability' as measured using ICECAP-A

Table below shows unit costs applied for costing of healthcare resource use

Healthcare contact	Unit cost	Notes
Primary and social care	-	
GP visit in surgery	£41.00*	With qualifications and direct care staff
GP by phone	£15.50*	GP-led triage including other costs
GP home visit	£132.50*	30 minutes assumed; £265/h of patient contact
Nurse visit in surgery	£13.00*	15 minutes assumed; £52/h Band 5 practice nurse
Nurse by phone	£8.69*	Nurse-led triage including other costs
Nurse visit at home	£53.74¶	District Nurse, Adult, Face to face; N02AF
Personal assistant/carer	£46.00*	2 hours assumed based on £23 hourly rate
Social worker	£50.00*	1 hour assumed at £50 hourly rate
Out-of-hours visit	£198.75*	1.5 times salary assumed; GP
Out-of-hours phone call	£23.25*	1.5 times salary assumed; GP
Rehabilitation coach	£42.00*	1 hour assumed at £42 hourly rate (Band 5)
Clinical psychologist	£66.00*	1 hour assumed at £66 hourly rate (Band 7)
Occupational therapist	£42.00*	1 hour assumed at £42 hourly rate (Band 5)
Group activities	£104.00*	Social prescribing cost of £416 per person per year
Counsellor	£66.00*	1 hour assumed at £66 hourly rate (Band 7)
Specialist nurse	£75.58 [¶]	Other Specialist Nursing, Adult, Face to face; N29AF
Pharmacist	£13.75*	15 minutes assumed at £55 hourly rate (Band 6)
Secondary care		
Emergency care		

A&E visit	£246.24¶	Weighted average of all speech and language options
Minor injury unit	£110.99 [¶]	Weighted average of all minor injury unit options
Inpatient care	1	
Angiogram - inpatient	£2,584.48¶	Arteriography; YR25Z; elective inpatient
Elective eye surgery	£3,490.56 [¶]	Weighted average of all elective eye procedures
Elective surgery	£5,850.54¶	Weighted average of all elective procedures
Kidney stones emergency admission	£6,530.13 [¶]	Weighted average of all long-stay kidney procedure options
Seizures emergency admission	£607.24¶	Weighted average of all short stay epilepsy options
Outpatient care		
Angiogram - outpatient	£1,301.09¶	Weighted average of all arteriography options
Audiology	£125.93 [¶]	Weighted average of all audiology options
Blood test	£7.04¶	Weighted average of all DAPS options + phlebotomy
Clinical pharmacology	£282.29¶	Weighted average of all clinical pharmacology options
Clinical psychology	£252.53¶	Weighted average of all clinical psychology options
Diabetes service	£183.19¶	Weighted average of all diabetes service options
ENT	£155.17¶	Weighted average of all speech ang language options
Eye surgeon	£146.75¶	Weighted average of all CL ophthalmology services

General medicine	£146.02¶	Weighted average of all general internal medicine
Intensive care medicine	£197.88¶	Weighted average of all intensive care medicine
Maxillofacial surgery	£184.88¶	Weighted average of all maxillofacial surgery options
MRI scan	£208.17¶	Weighted average of all MRI scan options
Music therapy	£14.59¶	Music Therapy Service, WF01A
Neurology	£213.50¶	Weighted average of all neurology service options
Neurorehabilitation	£145.32¶	Weighted average of all specialist rehab services
Neurosurgeon	£227.00¶	Weighted average of all CL neurosurgical services
Occupational therapy	£106.10¶	Weighted average of all occupational therapy options
Oncology	£160.43¶	Weighted average of all clinical oncology options
Ophthalmology	£141.97 [¶]	Weighted average of all ophthalmology OP options
Pain management	£204.36¶	Weighted average of all pain management services
Physiotherapy	£100.47¶	Weighted average of all physiotherapy options
Psychotherapy	£341.97¶	Weighted average of all medical psychotherapy
Radiographer	£97.38¶	Weighted average of all NCL interventional radiology
Speech and language therapy	£188.29¶	Weighted average of all speech ang language options
Spinal consultation	£197.00¶	Weighted average of all spinal surgery options

Stroke medicine service	£302.14¶	Weighted average of all Stroke medicine services
Urology	£137.74	Weighted average of all urology service options

* Source: Unit Costs of Health and Social Care 2022

[¶] Source: National Cost Collection Data 2021/22

Name	Strength	Pack size	Unit cost
Amitriptyline	10mg	28	£0.65
Amitriptyline	25mg	28	£0.86
Amlodipine	5mg	28	£0.66
Amlodipine	10mg	28	£0.71
Aspirin	75mg	28	£0.68
Atorvastatin	20mg	28	£1.03
Atorvastatin	40mg	28	£0.95
Baclofen	10mg	84	£1.51
Bendroflumethiazide	2 5mg	28	£0.62
Biuwa (astradial with progesterone)	2.5119	20	20.02
- HRT	1mg/100mg	28	£8.14
Bisoprolol fumarate	1.25mg	28	£0.70
Bisoprolol fumarate	2.5mg	28	£1.13
Buccolam (Midazolam)	5mg/1ml	4	£85.50
Carbamazepine	100mg	84	£2.07
Citalopram	20mg	28	£1.03

Table A2: Medication costs

Clobazam	10mg	30	£6.47
Clopidogrel	75mg	28	£1.16
Codeine phosphate	30mg	28	£0.99
CPD oil (Sativex oromucosal spray)	2.5mg/dose	270	£300.00
Cyclizine	50mg	100	£3.47
Dapagliflozile (Forxiga)	10mg	28	£36.59
Duloxetine	90mg	28	£16.59
Eplerenone	25mg	28	£2.80
Fluoxetine	40mg	30	£2.50
Gabapentin	100mg	100	£2.36
Gabapentin	600mg	100	£14.99
Glucophage (metformin hydrochloride)	500mg	86	£2.88
Hydroxychloroquine	200mg	60	£3.90
Ibuprofen	600mg	86	£4.93
Keppra (levetirazetam)	250mg	60	£28.01
Lamictal (lamotrigine)	50mg	56	£40.02
Lamotrigine	50mg	56	£1.73
Lamotrigine	200mg	56	£2.07
Lansoprazole	15mg	28	£2.76
Levetirazetam	250mg	60	£1.97
Levetirazetam	500mg	60	£3.01
Levothyroxine	75mcg	28	£2.96
Melatonin	2mg	30	£5.32
Methadone hydrochloride	1mg/ml	2500ml	£23.75

Mirtazapine	15mg	28	£1.01
Morphine (Sevredol)	10mg	56	£5.31
Naproxen	250mg	28	£0.94
Naproxen	500mg	28	£1.38
Omeprazole	20mg	28	£6.13
Paracetamol	500mg	100	£2.34
Phenergan (promethazine hydrochloride)	25mg	56	£29.30
Pregabalin	25mg	56	£3.99
Pregabalin	150mg	56	£5.59
Propranolol hydrochloride	80mg	56	£1.40
Ramipril	1.25mg	28	£1.17
Ramipril	2.5mg	28	£1.00
Ramipril	5mg	28	£1.06
Ramipril	10mg	28	£1.22
Rosuvastatin	20mg	28	£1.29
Sacubitril (Entresto)	49mg/51mg	56	£91.56
Sertraline	50mg	28	£0.96
Sertraline	100mg	28	£1.11
Simvastatin	40mg	28	£0.80
Sumatriptane	50mg	6	£1.05
Tegretol	400mg	56	£5.02
Thiamine	50mg	28	£1.05
Venlafaxine	75mg	56	£10.57
Zapain - co-codamol	30/500mg	100	£3.11

Zopiclone	7.5mg	28	£1.44

Source: British National Formulary, 2024

Appendix 8: Reflection on limitations.

Whilst the study was established as a control group design, during the onboarding process, participants in the TAU group were informed that they would be invited to participate in the intervention after completion of the study. This altered the design of the study and may have impacted some of the quantitative and health economics results. For example, participants in the TAU group may have been less inclined to subscribe to alternative groups / interventions during the study period because they were aware that they would be offered the PP intervention at the end of the period.

There were two study aims in relation to mentor participation, the first was about increasing meaning for the mentors themselves and the second was to provide hope and inspiration for the participants. The first aim has not been analysed as part of the study because to date the mentor data qualitative, quantitative or health economics data was not analysed by the study team. Extending the quantitative analysis specifically through looking at PERMA-meaning score would be valuable in evaluating the first study aim in relation to mentors. In hindsight some of the data collected for mentors, for example, DASS, was not necessary and would not be collected in future studies. The health economic evaluation focused purely on healthcare and medication costs and did not consider wide societal perspectives. With a number of participants sharing, in the focus groups, examples of putting into practice what they had learned in the outside world, like volunteering, a broader evaluation would have enabled these benefits to be captured. The quantitative measures of wellbeing adopted in the health economic evaluation, on reflection, were not in line with the aims of the intervention e.g. capturing factors like activity levels, pain and mobility (Herdman et al., 2023). These measures were selected because they had corresponding healthcare cost reduction estimates available to support the evaluation. Today, the Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS), which is a more reflective measure of the expected impact of the intervention, also has cost reduction estimates available based on recent research studies (Santini et al., 2021). The qualitative themes demonstrated that participants were at the beginning of their wellbeing journey, equipped with the building blocks to develop what they had achieved through the intervention. Quantitative findings showed that PERMA continued to increase after the intervention period to the three-month follow-up which is promising in terms of evidencing that this may have been happening in practice. A longer follow-up period, for both quantitative and qualitative analysis would have enabled this theme to be explored. A longer period

for analysing health economics would also have been beneficial to capture the full effects of the intervention in terms of how they evolved over time. With regards to HRV, whilst the data collection rate exceeded the study criteria, almost 20% of the data could not be included in the analysis due to a combination of measurement error and measurements outside normal ranges. This reduced the data set that could be analysed and improving this in future trials would involve practical challenges like requiring participants to moderate lifestyle factors, like alcohol intake, before the measurements are taken and conducting the measurements with greater precision.

Appendix 9: Detailed discussion on evaluations conducted

Quantitative data: The study exceeded expectations in terms of recruitment and retention of participants (Fisher et al., 2024; Swift et al., 2012; Cullen et al., 2016; Payne et al., 2020). Similarly, intervention adherence, including participation in the sessions and completion of homework, exceeded expectations and experience of similar studies (Fisher et al., 2024; Cullen et al., 2016). Data collection rates, aided by high attrition. also exceeded expectations determined at baseline (Fisher et al., 2024). The quality and quantity of data collected enabled statistical analysis. While the purpose of the study was to determine feasibility, the effects showed promise with all key measures, across both PERMA and DASS, moving in the predicted direction from baseline to post-intervention.

Qualitative data: Participant feedback reflected effective recruitment and data collection processes evidenced by comparatively low attrition rates (Swift & Greenberg, 2012; Charlesworth et al., 2013). Eligibility criteria proved effective, consistent with comparable studies (Cullen et al., 2018; Karagiorgou et al., 2018). Participants shared valuable feedback which would inform improvements to introductory material to make it more digestible (Eliav et al., 2024; Zimmermann et al., 2015, Charlesworth et al., 2013). Fatigue was amplified by travel distance and afternoon sessions, and this negatively impacted participant experience (Belmont et al., 2006). Participant reflections demonstrated the value of practical factors like session timing, travel, and location to inform future interventions including a need for straightforward travel, sufficient breaks, and a welcoming 'non-medical' location (Kotzur et al., 2023; Norris et al., 2013; Hansen et al., 2019; Charlesworth et al., 2013). Both content and delivery were universally valued and the workbook was appreciated as a means of supplementing and extending learning. The participants at each site differed in their appreciation of various aspects of the intervention, indicating potential to tweak content and delivery to broaden benefit for future participants through an update to the clinicians manual to capture specific enhancements (Gracey et al., 2009; Kotzur et al., 2023).

Through learning and connecting, participants demonstrated how they felt equipped and empowered with the capability, motivation, self-belief, and positive mood to master their own wellbeing (Aterman et al., 2023, Salas et al., 2021). Consistent with

psychological boosting, evidenced through reflections shared, the intervention educated participants with holistic knowledge and skills of wellbeing which they successfully adapted and employed in a variety of contexts (Fabian & Pykett, 2022; Hertwig & Grüne-Yanoff, 2017). Through techniques like reframing, gratitude and savouring, they exemplified their ability to navigate difficult emotions and savour positive emotions, core aspects of wellbeing theories, which improved their mood and personal relationships (Diener, 1984; Fredrickson, 2001; Seligman, 2011). They shared how the practice of testing their comfort zone inspired intrinsic motivation to find and take opportunities to put their skills into practice, consistent with psychological boosting (Fabian & Pykett, 2022; Hertwig & Grüne-Yanoff, 2017; Heyman & Dweck, 1992). In reflecting on their achievements, they showed an appreciation of the impact of setting meaningful goals and presented experiences of personal growth (Seligman, 2011; Ryff & Keyes, 1995; Wainman-Lefley et al., 2022). Their experience evidenced self-acceptance - a key component of eudaimonic wellbeing - presented a more positive view of the present situation, demonstrating pronounced life satisfaction and hope for a positive future consistent with aspects of hedonic and PERMA wellbeing theories (Seligman, 2011; Diener, 1984). Their language indicated a sense of autonomy and self-belief for their role in enabling a positive future both of which are considered enablers of successful and sustainable rehabilitation (Jones & Riazi, 2011; Jones et al., 2013; Nott et al., 2021; Ryff & Keyes, 1995). The positive relationships they had built with one another boosted and sustained mood, consistent with PERMA wellbeing theory (Seligman, 2011) and particularly important for people with acquired brain injury as social isolation is a common contributor to long-term challenges (Bay et al., 2002; Bombardier et al., 2010; Lau et al., 2021). They attached meaning and purpose to the support they were giving to one another which demonstrated that they were starting to extend their practice of wellbeing beyond themselves (Seligman, 2011; Ryff & Keyes, 1995). Whilst the taught content extended beyond individual wellbeing, encompassing collective and planetary wellbeing, the participant experience focused on the former (Kemp & Fisher, 2022), highlighting how a focus on the self, others and nature promote individual wellbeing (Corral-Verdugo et al., 2021;, Fisher et al., 2019). Participant experience demonstrated that as individual wellbeing improve, attention begins to shift outwards to other people and the planet. Although the natural environment did not feature in their feedback there is potential for this to develop in the future as they put into practice what they have learnt with the aid of the workbook. This study focused on feedback immediately after the intervention itself and therefore,

qualitative data was not available to determine whether the building blocks had been used and further developed overtime. Future studies could capture feedback both at the intervention stage and at a follow-up some months later. No qualitative feedback was obtained from the control group and therefore, it is not possible to compare the experience of those who attended the intervention to those that had treatment as usual.

Psychophysiological data: Considering the psychophysiological findings, the feasibility of collecting HRV data in future studies warrants a nuanced discussion. On one hand, HRV is a valuable marker for assessing vagal function and has the potential to yield insightful data on the physiological impacts of interventions (Wilkie et al., 2022; Arakaki et al., 2023). On the other hand, the low effect sizes observed in this study, coupled with the complexities inherent to the ABI population, present significant challenges. The diverse medical conditions, medication use, and comorbidities of participants may impact on HRV (Shaffer & Ginsberb, 2017). Some recommendations for a full scale RCT follow. Firstly, the rigorous participant screening for health conditions and medication that was followed in the present study would need to continue in a future trial. This information was essential for interpretation of data and is especially true given that many respiratory rates fell outside the HF HRV band due to individual medical conditions and lifestyle behaviours. Given the impact of lifestyle factors on HRV, it is advisable to provide participants with pre-data collection instructions that aim to standardise their physiological state as much as possible. For example, avoiding alcohol, strenuous exercise, and caffeine before measurements would help mitigate their transient effects on HRV. Additionally, scheduling data collection consistently in the morning hours, as opposed to varied throughout the day, could control circadian influences on HRV and promote adherence to fasting. Finally, it is recommended that sensor placement is improved. A demonstration video that details the correct fitting of the HRV measurement equipment and outlines the do's and don'ts during data collection could be beneficial to send to participants prior to their appointment. However, implementing these recommendations requires resources and may still not fully address the variability introduced by the underlying health status of participants with ABI and associated high prevalence of antidepressant medication use. Therefore, while it is possible to collect HRV data, the question remains whether the potential benefits outweigh the logistical and resource-related burdens.

Health economic evaluation: Data collection of health economic information was feasible. Average cost, of £1,164 per patient, aligned with typical costs for rehabilitation interventions of similar duration for example CBT interventions (Richards et al., 2017). The clinical manual and workbooks supporting the intervention have now been developed and refined to an extent that any future study would be more cost effective. and restricted to delivery and training. Ongoing intervention costs, excluding development costs, equated to around £176 per participant, in line with around three sessions of counselling or appointments with a clinical psychologist (NHS, 2023). The results relating to healthcare costs and impact of intervention on health outcomes showed a variable pattern of results. Healthcare usage increased post-intervention for the PP group, driven primarily by a number of planned and emergency surgeries, and then dropped slightly below baseline level 3 months post-intervention. Changes in both utility and capability measures for the PP and TAU groups were marginal over the study period. A full economic evaluation would include a wider societal perspective to capture fuller extent of costs and effects of intervention versus control to people living with ABI over a longer timeframe. The baseline costs for PP and control group were imbalanced, a difference that would likely disappear with a larger sample size. With regards to the utility outcome measures, the questionnaires did not capture the type of improvements that would be expected from this type of intervention. The Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS) may be more reflective of the impact that would be anticipated through a positive psychology intervention and therefore, will be considered for future studies, alongside or instead of the measures in the current feasibility study. Recent research utilising WEMWBS has estimated the reduction in healthcare and sickness costs associated with increasing WEMWBS (Santini et al., 2021), findings that could be built on by utilising this measure in a full scale RCT in an ABI population. Revisions would also be made to the data collection procedures to improve timeliness and recall accuracy.

Monitoring Checklist (to be completed by researcher for

Health and Care Research Wales internal monitoring purposes only)

What journal articles are planned?	Mixed methods paper that integrates all four datasets
When will you know if the journal articles have been accepted? Will it be Open Access?	Date: TBA Yes
Do you have dissemination / knowledge transfer plan to promote awareness of your findings?	Yes
If yes, is the plan aimed at both academic and non-academic audiences?	Yes
Does your research include examples of successful public and patient involvement and engagement?	Yes
If yes, can we contact you for further information?	Yes
Did you register your project with the Health and Care Research Wales Clinical Research Portfolio, or equivalent and other publically accessible registers or registries?	Yes
If yes, have you already updated the register/registry following completion of the study?	No (this will be done once the scientific report is finalised and submitted)
Would you be willing to provide a case study/story of success to be included in Health and Care Research Wales publicity?	Yes
Have you submitted project outputs on to ResearchFish?	Yes
Is the data from your study being added to the SAIL database? Will your data be available to other researchers on request?	No Yes

Lead researcher signature:	
	A
Name:	Andrew Kemp
Date:	28 March 2024

Please email your report in Word format to: <u>Healthandcareresearchgrants@gov.wales</u> (no hard copies are required).