A NATURE-BASED INTERVENTION TO IMPROVE MENTAL HEALTH: EFFICACY OF AN ANGLING INTERVENTION FOR MILITARY VETERANS AND EMERGENCY SERVICE PERSONNEL WITH POST-TRAUMATIC STRESS DISORDER (PTSD)

RESEARCH PROTOCOL

1. BACKGROUND

This project addresses the critical issue of post-traumatic stress disorder (PTSD) within the community, focusing on veterans and emergency service personnel. PTSD, characterized by trauma-induced symptoms, often results in impaired functioning and comorbid conditions such as depression and anxiety (Murphy et al., 2017; Rytwinski et al., 2013). Existing psychotherapeutic treatments create significant barriers for veterans and others, including delayed help-seeking, lengthy waiting times, and a lack of military-specific knowledge among healthcare professionals (Mellotte & Murphy, 2017). In response to these challenges, the study proposes a nature-based angling intervention as a novel approach, leveraging the potential benefits of nature-based interventions (NBIs) for mental health.

The need for innovative treatments is underscored by the limitations and reduced effectiveness of current therapies for veterans (Bryant et al., 2003; Gros et al., 2011). The proposed angling intervention, developed over seven years, aims to provide a local, cost-efficient, and accessible solution. Previous trials indicated significant improvements in PTSD, anxiety, and depression following a single 2-day intervention, with peer-supported angling proving particularly effective (Wheeler et al., 2020). The study's expansion to include emergency service personnel acknowledges their elevated risk of PTSD and seeks to provide much-needed evidence for NBIs in this understudied population.

The choice of angling as the intervention is justified by its broad appeal, accessibility, and potential for year-round engagement. The intervention's delivery is facilitated by a not-for-profit community interest company (iCARP CIC), emphasizing collaboration with military veterans and aligning with broader initiatives that promote angling for well-being. The research aims to contribute robust experimental evidence to support the integration of NBIs into mental health care policy, potentially reducing the social and economic costs of untreated PTSD within the community.

This study represents a significant step towards addressing the mental health needs of veterans and emergency service personnel, offering a promising alternative to conventional treatments. The outcomes may not only improve the well-being of these populations but also inform broader mental health policies, emphasizing the role of nature-based interventions in promoting mental health and resilience.

Main Study Aims:

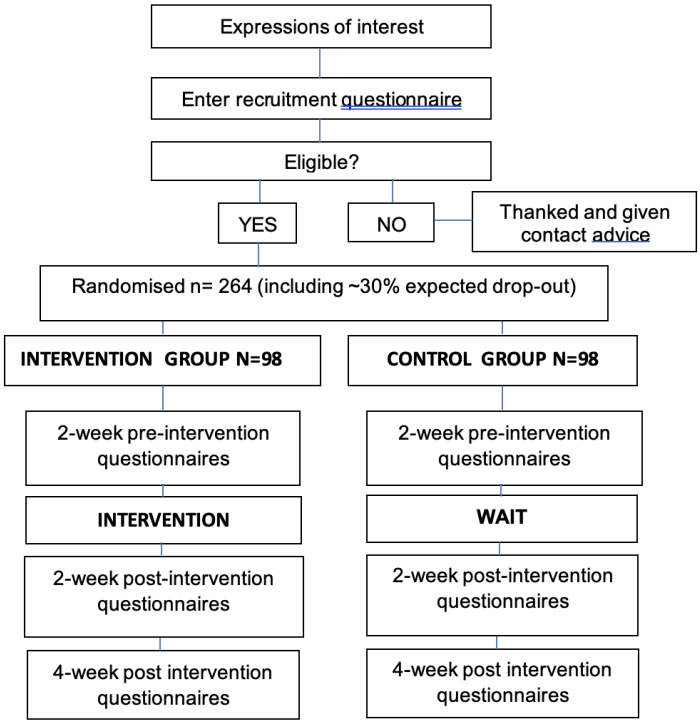
- To conduct a full-scale randomised controlled study powered to provide definitive evidence of the efficacy of the nature-based, group angling intervention for military veterans and emergency service personnel with PTSD.
- To collect measures of the effects of the intervention at 6-months and 1-year after the intervention for the active (angling) group.

2. METHOD

2.1 Study Design and Setting

A randomised waitlist-controlled study with a four-week follow-up. The primary outcome will be assessed at 2-weeks and 4-weeks post-intervention and compared with the waitlist control group. The intervention will be run by iCARP CIC at their 'Lifted Lakes' mental health and wellbeing centre in Great Oakley, Essex.

Figure 1. Flowchart for RCT



2.2 Inclusion Criteria

UK armed forces veterans or emergency service personnel (current or former).

2.3 Exclusion Criteria

Not a military veteran or member of the emergency services (current or former).

2.4 Planned Sample Size

2.4.1 Power Analysis

Our main dependent variable will be PTSD symptoms (as measured using the PCL-5). The results from our developmental phase showed a significant group x time interaction for PCL-5 scores, with significant improvements at 2-weeks and 4-weeks post-intervention for the angling but not the control group. Given that the purpose of the NIHR call is to build robust evidence for the clinical impact of NBIs, it is imperative that study power should be based on the main DV of interest with the lowest difference score (i.e. a difference score that will allow the power calculation of a sample large enough to detect a significant effect (should there be one). This is the effect size observed between groups at 4-weeks post-intervention in the developmental phase (Cohen's d = -0.52). For a 2-tailed test with 95% power, an alpha of .05 and d = -0.52 effect size, the power analysis provides a sample size of n = 196 (98 participants in each group).

2.4.2 Recruitment sample size

The attrition rate after randomisation in the development phase was approximately 25%. We aim to randomise our power analysis sample size + 30% for the main phase. Thus, we aim to randomise 196 + 30% = 254.8 participants (rounded to 264: 132 intervention, 132 controls to facilitate 12 participants per intervention).
We have designed an RCT with 11 intervention groups and 11 waitlist control interventions to be delivered after RCT data are collected. We will run eight angling interventions (4 active:4 controls) sequentially (a maximum of n = 12 participants in each session) in years 1 & 2 and six interventions (3 active:3 controls) in year 3.

2.5 Participant Recruitment

Recruitment into the study will be via on online Qualtrics link embedded in the project website and on all recruitment materials. Potential participants can either engage via the project's webpage or contact the study team via email or telephone. The registration form delivered via a Qualtrics platform provides further information and a mechanism for providing informed consent, following which demographic and PTSD severity (via PCL-5 items) information are requested via questionnaire items for purposes of randomization. Alternative arrangements, such as paper copies of questionnaires, will be provided where requested by participants to ensure inclusivity; participants will be made aware of such options within recruitment materials and communications. Anonymity will be ensured whatever the media used. The website link permits self-referral, enabling us to reach those suffering from PTSD who are not receiving support from either NHS or charitable organisations.

<u>Routes to promote Direct Self -Registration:</u> The development phase showed that the majority of participants were recruited via social media platforms including Facebook. We will advertise the study via the social media platforms (Facebook, Twitter and Instagram) of organisations currently sponsoring iCARP work (angling companies Korda and Nash, who combined have over 527,000 followers on Facebook and 504,000 on Instagram). We will employ three Facebook "pushes" as we did in the development phase in to specifically

target military veterans and ESPs with particular attention to targeting minorities and women.

Routes to promote Self-Registration via Referring Agencies: We will provide stakeholders with capacity to refer/inform potential participants to access the online registration with a flier and information pamphlet that describes what the intervention has to offer as an extension to their existing provision. Feedback will be sought on draughts of the pamphlet from stakeholders, service providers and our PPI. All recruitment materials are designed to convey inclusivity across gender, ethnicity and religion via considered inclusion of diversity in imagery and messaging.

Stakeholders have been identified broadly as charities representing veterans and ESPs, Occupational Health departments of ESPs, ESP outreach events and organisations and Social Prescribers.

2.6 Randomisation Procedure

Participants will be allocated to the control or waitlist condition by covariate adaptive randomisation; a valid technique for clinical trials (Kang et al., 2008; Scott et al., 2022) where specific participant characteristics (covariates) can be controlled for on a sequential basis based on recruitment and allocation to-date (Taves, 1974; Treasure & MacRae, 1998). Participants will be stratified by the following covariates: gender, PTSD severity indicated by the PCL-5 score (Weathers et al., 2014) and service group (i.e. military veterans versus non-military service personnel) to ensure equal allocation to the intervention and waitlist control groups. A randomisation schedule will be devised prior to recruitment using an online tool and applied to eligible participants recruited online after participant identification numbers have been assigned.

2.7 Intervention Content

Following our preliminary work and the developmental phase of the current project, we have a well-established and manualised protocol for the intervention:

- Day 1 am – arrival at fishing lake, introduced to personal angling coach, shown to designated lakeside 'swim' with tent and seat, health and safety briefing, set-up equipment, recording of 'arrival' process measures.
- Day 1 pm – fishing instruction, fishing and social interaction, evening meal, participants fish through the night or sleep as they choose.
- Day 2 am – breakfast, fishing and social interaction.
- Day 2 pm – fishing and pack-up equipment, recording of 'departure' process measures, instructions on how to keep in contact via social media etc.

Prior to their intervention, participants will be sent a letter and an infographic developed for the study visualising what to expect at the intervention. The venue will be available exclusively to participants. Professional angling coaches with Angling Trust certification will be provided at a ratio of 1:2 participants. As recommended by Husk et al., (2020) participants will be supported to travel to the venue. iCARP's 'Lifted Lakes' venue has a covered socialising area with a fire-pit and participants are encouraged to bring warm

clothing, since socialising with peers is a key component of the intervention. Participants are free to move around the lake and talk to other participants and use the communal area for socialising and taking warm drink breaks. Food will be cooked and shared by iCARP volunteers. At the end of the experience, participants will be encouraged to join a 'Facebook' group in order to keep in contact via social media and will be offered a selection of exit routes.

2.8 Measures

All primary and secondary and follow-up questionnaire measures will be delivered via Qualtrics (University of Essex site license).

2.8.1 Sample Descriptive Measures

At recruitment, participant characteristics will be collected and recorded: socio-demographics (age, gender, heritage), nature of trauma experienced, duration of PTSD, previous or current treatment/psychotropic medication prescription and use, living circumstances (alone, with a partner/friend/housemate), romantic relationship status, children, current and past employment status, income, health service use. Postcodes will be collected for transformation into an established small area deprivation index such as the Carstairs (Carstairs & Morris, 1989).

2.8.2 Primary Dependent Outcome Measures

The following measures will be employed to evaluate the effectiveness of the intervention and will be assessed 2-weeks before the intervention and 2-weeks and 4-weeks post-intervention. NICE (2018) recommends the use of self-report measures for evaluation of outcome in PTSD interventions. These measures of PTSD, anxiety, depression, and wellbeing were used in the development phase, establishing their acceptability and sensitivity to change over the short to medium term: PTSD symptoms are assessed by the PCL-5 (Weathers et al., 2014); Depression by the PHQ-9 (Kroenke et al., 2001); Anxiety by the GAD-7 (Spitzer et al., 2006). Participants will also complete the 7-item Short Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS; Tennant et al., 2007) to evaluate positive feelings of wellbeing.

2.8.3 Secondary Dependent Outcome Measures

The following measures of loneliness and expressed anger were included in the developmental phase and will be assessed as follows: Loneliness will be assessed by the Short Version of the Social and Emotional Loneliness Scale for Adults (SELSA-S; DiTommaso et al., 2004) 2-weeks prior and 2- and 4-weeks post intervention. Expressed anger will be assessed by the State–Trait Anger Expression Inventory (STAXI: Spielberger, 1999) measuring how frequently participants have expressed anger verbally or physically in the last month. This will be taken 2-weeks pre-intervention and 4-weeks post-intervention. The Work and Social Adjustment scale (WSAS; Mundt et al., 2002) is a 5-item measure of impairment in general social functioning. This will be measured 2-weeks pre-intervention and at a 6-month and 12-month follow-up since it will not be sensitive to short-term change.

2.8.4 Follow Up Measures at 6 and 12 months (MP2)

It is not possible to include long-term follow-up measures in the RCT because the waitlist group will receive the intervention after the RCT 4-week data collection is completed. Instead, we will take measures of PTSD symptoms, anxiety, depression, wellbeing, loneliness, expressed anger, social functioning, to provide pre-post data from the active fishing group only at 6-months and 12-months after their intervention. We will also measure changes in NHS service use and employment at these times. In addition, to gauge the impact of the NBI on long-term behaviour and engagement with nature-based activities, we will follow-up on the participant exit strategy to assess how participants have engaged with angling or other nature-based activities since the intervention.

2.8.5 Process Measures

During the developmental phase of this project, we developed measures to assess how the active elements of the intervention were experienced by participants: 1. Restorative benefits of a tranquil natural setting. 2. Connection with similar peers with PTSD. 3. Skill learning through fishing activity and self-confidence building. The developmental phase confirmed the fidelity of the intervention in delivering these experiences and provided important preliminary evidence that intervention experience was related to mood change. The following measures will be collected at arrival and before departing the intervention.

2.8.5.1 Questionnaire and Physiological Measures of Mood State

We will evaluate mood using the brief Profile of Mood States (POMS; Shacham, 1983). Our developmental phase has shown that these measures are sensitive to detect change between arrival and departure at the intervention. Following consultation in the development phase, we will include objective physiological measures of psychological states: pulse heart rate, heart rate variability, blood pressure and will assess hypervigilance using a mobile eye-tracking device to quantify saccadic behaviour.

2.8.5.2 Active elements of the intervention

We developed an item pool during the developmental phase. These measures will be taken prior to departure. Eight items from The Perceived Restorativeness Scale (PRS; Hartig et al., 1997) measure perceived experience of restoration from the environmental surroundings. Bespoke questions have been developed to evaluate self-efficacy, experience of fishing and being in a group of veterans. Fourteen questions explore participants' experience of fishing (e.g." I found I could focus on the fishing"). Eleven questions explored participants' experience of peer support over the weekend (e.g. "I felt the people around me understood").

2.9 Outcome Analyses

2.9.1 Primary Outcome Analyses

1. The key analysis relates to the comparison of pre- (2-weeks before the intervention) and post-intervention measures for the intervention and control groups taken at 2- and 4-weeks after the intervention). A mixed MANOVA with one between groups factor (intervention vs. waitlist control) and repeated measures on all outcomes (baseline vs. 4-weeks post intervention) will be conducted.
2. We will also assess if the changes in PTSD symptoms observed might be considered clinically significant or reliable. We will assess Clinically Significant Change (a decrease of >= 10 points on the PCL-5) and Reliable Change (as decrease of >= 5 points on the PCL-5) between the baseline and 2-weeks and 4-weeks post-intervention. All analyses will be carried out on veterans & emergency service personnel combined.

2.9.2 Secondary Analyses

A psychometric analysis of process measures will be conducted via factor analysis and reliability analysis. Path analyses will explore the relationship of process measures regarding the intervention experience to mood change assessed via the POMS questionnaire and psychophysiological data during the intervention and change in outcomes.

2.10 Harms

Serious Adverse Events (SAE; untoward occurrences that result in harm) are reported by the PI to the sponsor within 24 hours of becoming aware of the event. The sponsor reviews all reports within 2 days of receiving the report and the outcome is recorded in the site management file and the sponsors' research governance committee. SAEs that are determined to be related and unexpected are reported to the ethics committee.

2.11 Study withdrawal

Participants may drop out of the study without giving a reason. However, any data collected up to the point of withdrawal will be retained unless requested otherwise.

2.12 Dissemination

The primary outcome will be the analysis of change in PTSD symptoms pre-post intervention for intervention groups versus waitlist control groups. This will be disseminated in the following ways:

- Liaise with DHSC to hold a workshop on NBIs for policy makers.
- Finalise intervention manual to ensure consistent intervention delivery going forwards.
- Create plain English information pamphlet to provide clear information about the intervention.
- A written report to the funder.
- Papers submitted for publication in leading academic journals.
- Presentations at academic/health/environmental conferences and forums.

- Dissemination events at the University of Essex and elsewhere to publicise the study findings, distribute our plain English summary and to develop further ties with service providers.

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