University of Pittsburgh | Institutional Review Board
Office of Research Protections

INITIAL APPROVAL (Expedited)
Continuing Review Not Required

Date:	November 6, 2023
IRB:	STUDY23090017
PI:	Martina Anto-Ocrah
Title:	Post Traumatic Growth after Concussion in Women
Funding:	Name: National Institutes of Health, Funding Source ID: K01NS121199

The Institutional Review Board reviewed and approved the above referenced study. The study may begin as outlined in the University of Pittsburgh approved application and documents. Continuing Review is not necessary under 45 CFR 46.109(f)(1)(i).

Approval Documentation

Review type:	Initial Study
Approval Date:	11/6/2023
Expedited Category(ies):	(4) Noninvasive procedures, (7)(a) Behavioral research, (7)(b) Social science methods
Determinations:	• Waiver of consent documentation
Approved Documents:	• Consent form, Category: Waiver Script; • PTG REDCap Survey, Category: Data Collection; • Follow up invitations version 0.02.docx, Category: Recruitment Materials; • Letter of Support from LoveYourBrain, Category: Other; • Letter of Support from PINK Concussion, Category: Other; • PTG after Female Concussion Protocol, Category: IRB Protocol; • Recruitment for PINK , Category: Recruitment Materials; • Submitted grant - no budget details.pdf, Category: Sponsor Attachment; • Summary of the PTG study for survey participants, Category: Waiver Script;

As the Principal Investigator, you are responsible for the conduct of the research and to ensure accurate documentation, protocol compliance, reporting of possibly study-related adverse events and unanticipated problems involving risk to participants or others. The HRPO Reportable Events policy, Chapter 17, is available at http://www.hrpo.pitt.edu/.

Clinical research being conducted in an UPMC facility cannot begin until fiscal approval is received from the UPMC Office of Sponsored Programs and Research Support (OSPARS).

If you have any questions, please contact the University of Pittsburgh IRB Coordinator, Ali Arak.

If you are conducting a federally funded clinical trial, there may be additional requirements. Please refer to information on clinical trials https://www.ecshsr.pitt.edu/ct/documents.

Please take a moment to complete our Satisfaction Survey *as we appreciate your feedback.*

The University of Pittsburgh has a Federal Wide Assurance approved through the Office of Human Research Protections (FWA00006790).

POST-TRAUMATIC GROWTH AFTER CONCUSSION IN WOMEN

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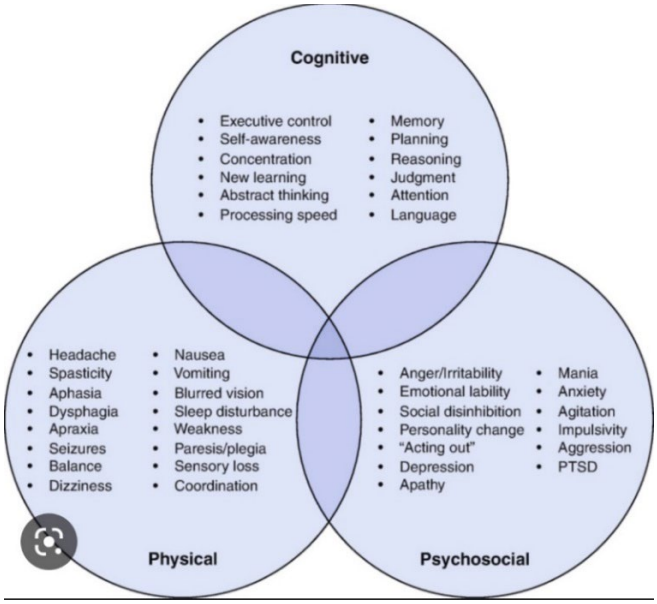
BACKGROUND

According to the Centers for Disease Control and Prevention, between 3.2 million and 5.3 million Traumatic Brain Injuries (TBI) occur in the United States annually, and 176 Americans die from TBI-related deaths every day [1, 2] . In 2019 alone, there were 223,050 TBI-related hospitalizations and 60,611 TBI-related deaths in the United States [1, 2].

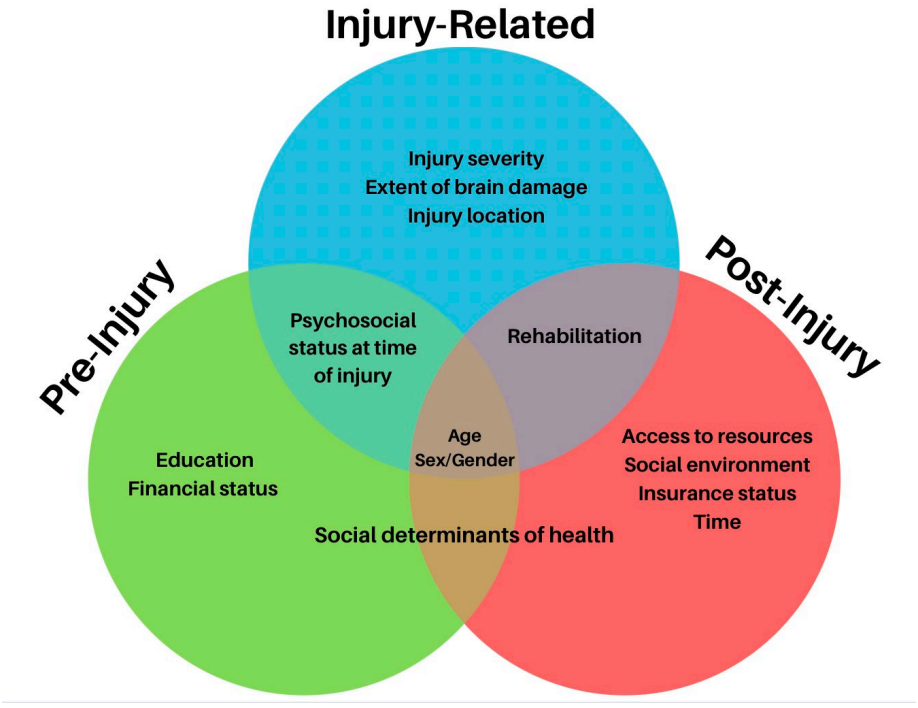
The majority of these injuries (80-90%), are classified as mild traumatic brain injuries (mTBIs) or concussions [3]; “mild” referring to the severity of the trauma, not its consequences, as mTBIs have been shown to result in significant physical, cognitive, and psychosocial sequelae that can span months, if not years, after the initial injury[4] [5] (Figure 1).

Figure 1: The domains of mTBI sequelae [36]



Most research on the impact of mTBI have been deficit-based and focused on the impairments induced by the injury, such as headache and fatigue (physical), low memory recall, impaired learning (cognitive) and psychosocial factors such as depression, Post Traumatic Stress Disorder (PTSD) and social integration (Figure 1); and researchers have often attributing these deficits to individual-level factors (Figure 2)

Figure 2: Social and Individual level determinants of mTBI sequelae [37]



Research shows however, that the effects of trauma are not universally negative, and while some people may experience the deleterious effects of the traumatic event, others may realize psychological benefits. This phenomenon, termed posttraumatic growth (PTG) [6-9], is the positive, psychological change that results from a struggle through a life-altering experience, and in adults is found to include five domains[6] (Figure 3):

(1) Improved interpersonal relationships,

(2) Recognition of new possibilities in one's life course,

(3) Greater personal strength,

(4) Spiritual or religious growth,

(5) Greater appreciation of life

Studies show that one is significantly more likely to experience post-traumatic growth (PTG) (65%) after a traumatic event like TBI, than they are to develop PTSD (25%). https://www.phoenixtraumacenter.com/post-traumatic-growth-3/. Yet, research on TBI survivors' experiences of PTG is sparse. (Figure 4)

As strengths-based approaches take the forefront of research [10, 11] (particularly in this post-COVID era), understanding the protective factors that promote survivors' recovery and wellbeing after TBI, is critical.

Figure 3: The 5 domains of Post Traumatic Growth [38]

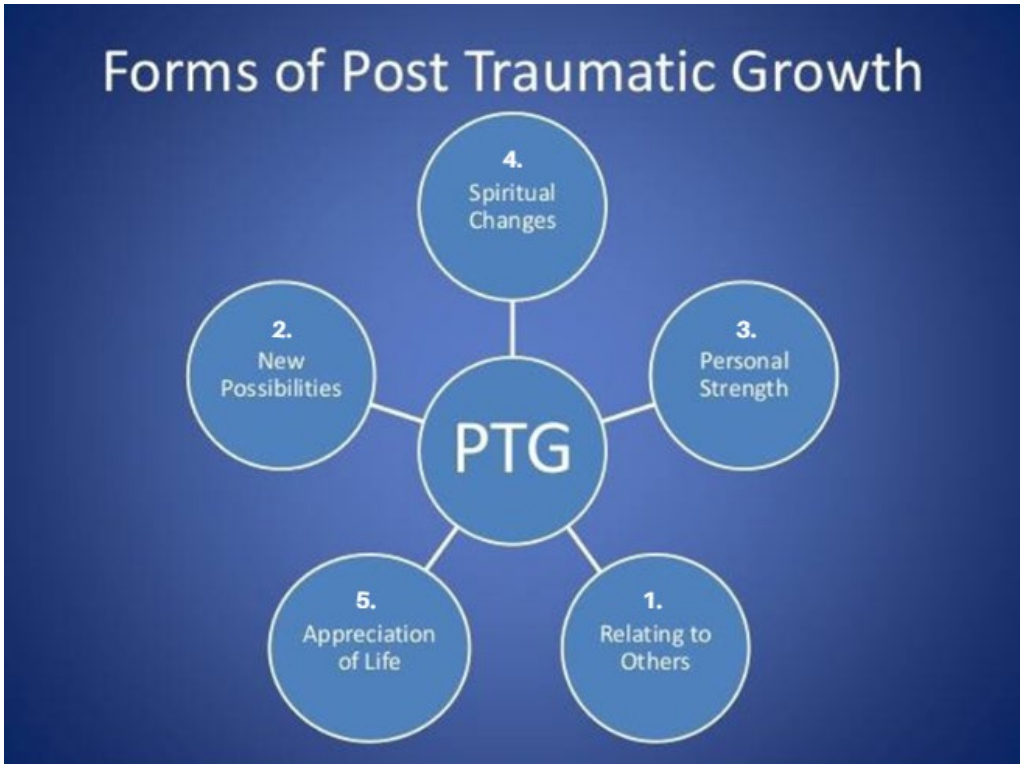
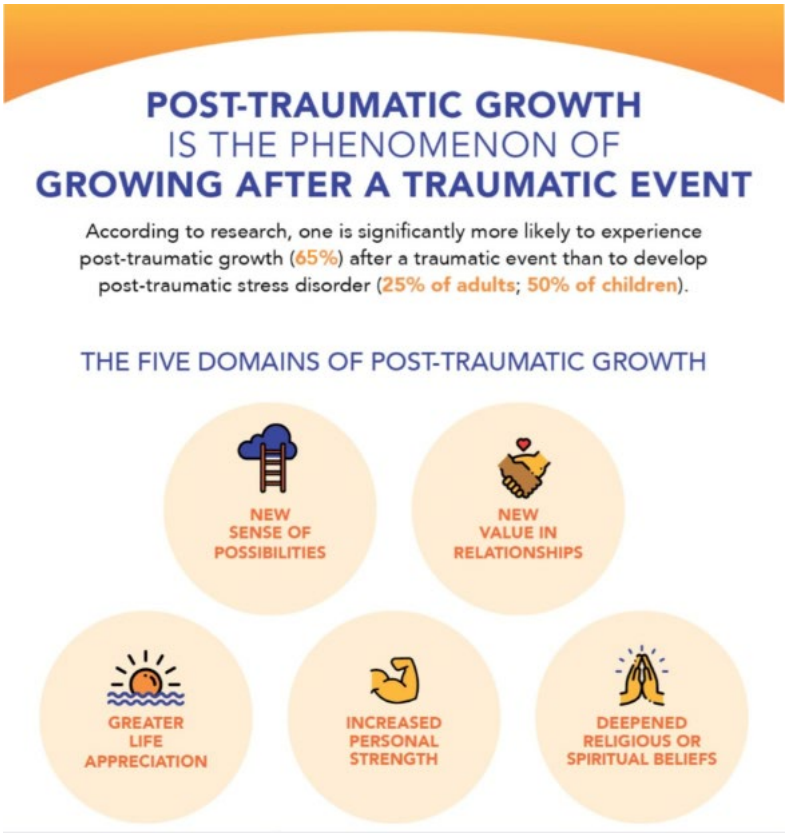


Figure 4: https://www.phoenixtraumacenter.com/post-traumatic-growth-3/



Definition of Domains: [39]

1. **New value in relationships (relating to others):** The process of coping with trauma requires relationships - friends, family, therapists, support groups, etc. As humans, we are neurobiologically wired to regulate our emotions through relationships. The experience of utilizing support after trauma increases these connections and helps us remember how important they are.

2. **New possibilities (in health, work/life):** Trauma and loss shake us to our core and challenge us in ways that we might not have imagined as possible. As a result, many survivors begin to see new possibilities in life and the opening of new doors of opportunity.

3. **New sense of personal strength:** Surviving trauma and asking for help to cope with its aftermath requires incredible strength. Trauma survivors demonstrate extraordinary courage, resilience, vulnerability, trust, hope, and compassion, among other strengths. When an overwhelming event forces us to utilize all the strengths we have (and often develop new ones), we are much more aware of them going forward. “If I survived that trauma, I can survive anything”.

4. **Deepening of spiritual/religious views**: Because trauma is so often experienced through relationships and involving other human beings, many trauma survivors turn to spirituality or religion for strength, hope, and inspiration. Trauma is an existential crisis that challenges us to make sense of it, often through spiritual, religious, or existential belief systems.

5. **Greater appreciation for life**: Trauma, by its nature, threatens our safety, security, and often our lives. Trauma and loss remind us how precious life is and how fragile it can be. It has the ability to help us see the big picture and reconsider our priorities in life.

In this study, we will explore the levels of PTG in a population of TBI survivors, using the Pink Concussion network. PINK Concussions is the FIRST non-profit organization focusing on women and girls with concussions/mTBIs. PINK Concussions’ mission is to drive change and innovation to develop sex/gender-appropriate, evidence-based research approaches on identification, management and support of women and girls with brain injuries from various mechanisms across civilian and military populations. The organization also facilitates online support groups and information for over 8,000 women, teen girls, and their parents/spouses/caregivers. [40]

Our study will focus on female concussions because concussions tend to be more prevalent in females, and regardless of study sample or injury mechanism (sports[12], civilian, military), women (compared to men), report greater concussion morbidity (prolonged recovery, worse physical, cognitive and psychosocial symptom reporting[13, 14], [40]), and experience poorer treatment pathways[14]. **Interestingly, women also report greater PTG after trauma, but no research has evaluated the intersection of PTG and mTBI in female concussion survivors. Not only will we be filling this gap in the field, but we will take the work further and conduct a pilot assessment of whether mindfulness based interventions such as yoga, which have been shown to improve mTBI sequelae[2], also improve PTG for individuals with low PTG in the study sample. This pilot intervention is not only important for exploring protective recovery pathways, but also aligns with emerging research advocating for exercise as medicine for concussion [2, 15, 16].**

Thus, the aims of this research are to:

Aim 1: a) Determine the prevalence of low PTG in a population of female concussion survivors.

We hypothesize that at least 35% of the study sample will have low PTG (score <75 on PTG scale)[17]

Aim 1b) Determine what (concussion-related factors) predict low PTG.[18]

We hypothesize that predictors of low PTG will include: older current age[19], older age at time of injury[19], non-White race[20], history of multiple concussions, high burden of post-concussion symptoms, and high burden of mood disorders (Anxiety, depression) and PTSD

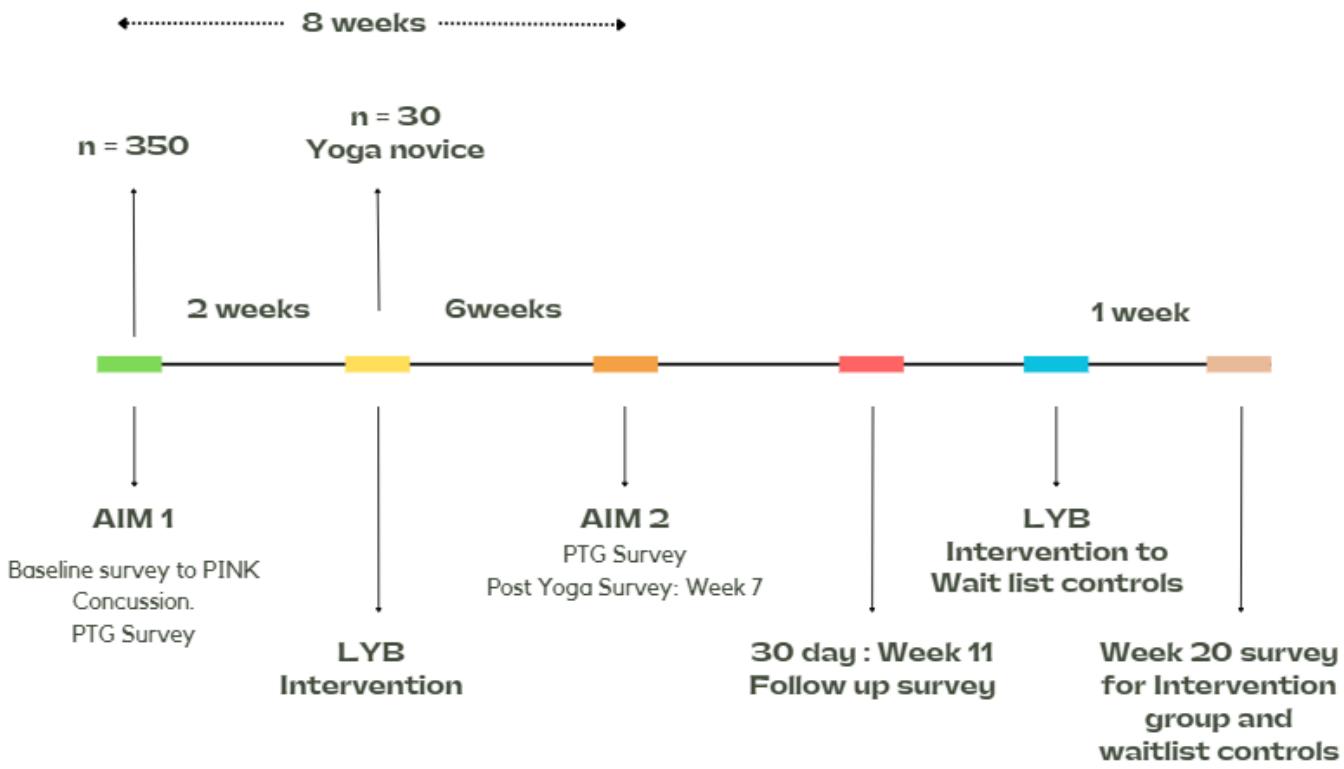
Aim 1c) Identify which of the 5 PTG domains are least prevalent and could be targeted for future interventions.

Aim 2: a) Determine if a pilot yoga intervention improves PTG scores for individuals with low PTG.

We hypothesize that PTG scores will increase after the yoga intervention for those with low PTG who partake in the intervention.

Aim 2b) Identify which of the 5 PTG domains (in Aim 1c) are improved by the intervention

Figure 5: Schematic Diagram of the Project

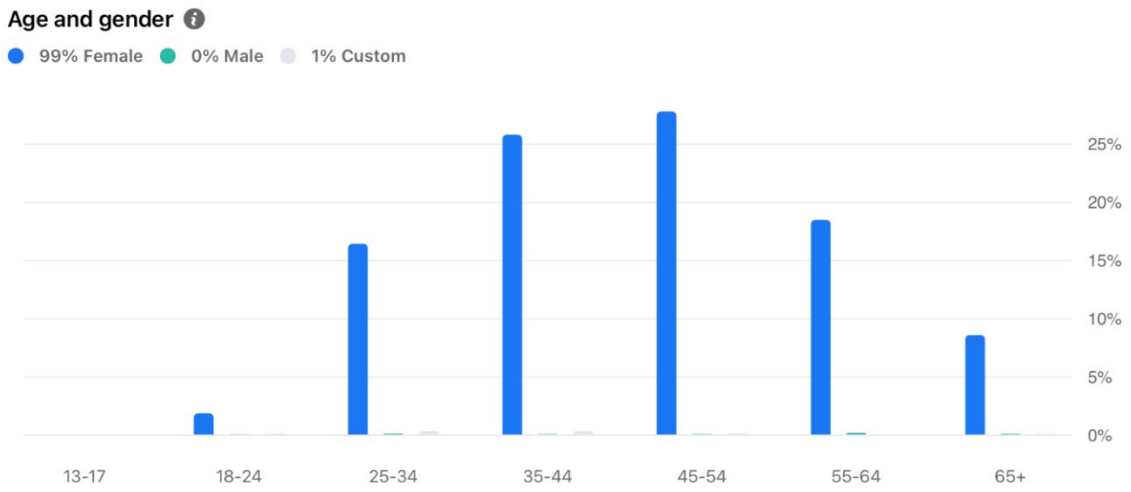


METHODS

Population and Recruitment

As previously stated, we will be collaborating with the Pink Concussion network on this endeavor to recruit study participants who are residents of United States (see letter of support and Appendix on Pink groups).

There are over 4500 women in PINK's #1 Women's Group, with the following age, gender, and country breakdowns (Figure 6: PINK age and gender breakdown):

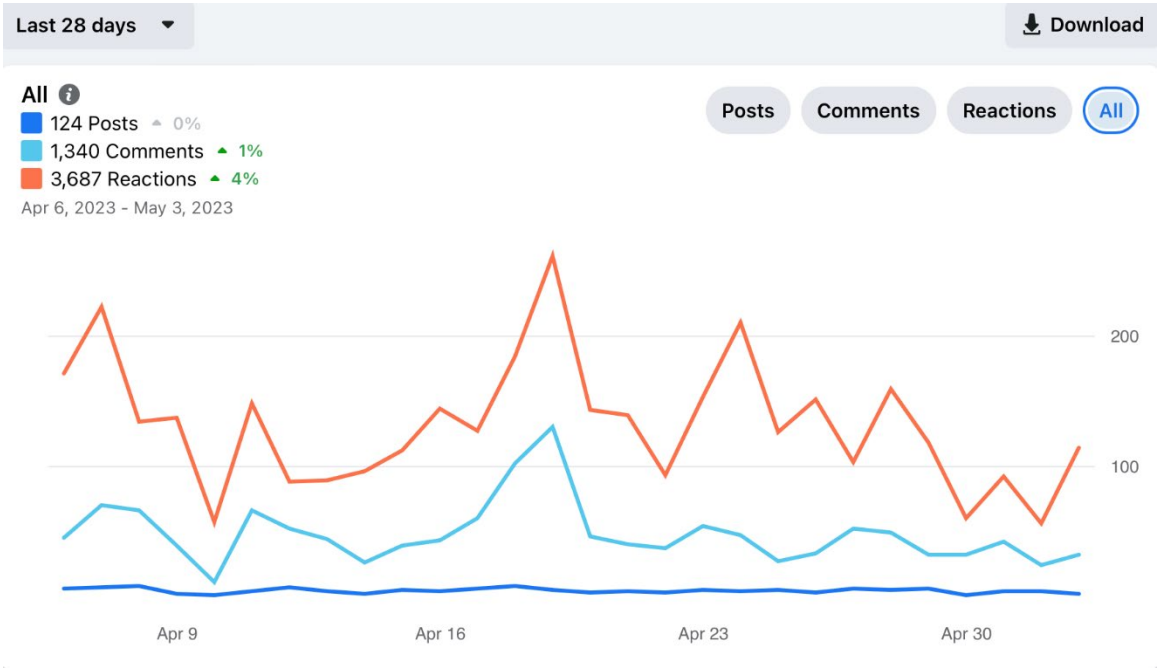


Country distribution of members of PINK Concussion group (Figure 7: PINK countries of origin):

Top countries	
United States	3,314
Canada	842
United Kingdom	119
Australia	78
New Zealand	62
Netherlands	11
Ireland	10
Germany	9
Sweden	8
Denmark	8

The group has an active membership, with a high level of member engagement. As shown in the Figure 8 below, between April 6 and May 3 2023, there were 124 posts, 1,349 comments, and over 3000 reactions to the various posts.

Figure 8: PINK Group leaves of engagement; April 6-May 3 2023



To ensure that we have a representative sample of minority women, we will target participants from PINK's BIPOC - Women of Color Group. Studies show that women[14] and minorities[21, 22] are less likely to get the care they need after TBI, therefore getting the views of this unique population of women about their PTG and the Yoga intervention, will be critical in identifying the needs of vulnerable subgroups of head injured women.

This is a minimal-risk survey study. The data source will be a survey that is distributed as a link through the PINK Concussion Facebook and other social media pages. Survey data will be collected and stored through REDCap.

We are requesting a waiver of documentation of consent as participants will be recruited online using an IRB approved consent form that will be on the study's landing page. Upon clicking the survey invitation link, potential survey takers will be brought to the very first page of the survey which will be the IRB-approved consent page. This will list the risks, benefits, incentives, and overall research processes. The consent will also state that the research is no greater than minimal risk and involves procedures for which written consent is normally ***not*** required outside of the research context. After reviewing the approved information sheet, participants will be prompted to consent yes in order to move on to the survey body. Those who do not consent will be sent to a "Thank you page" and not continue. Those who do so, will begin the survey. All survey questions will be voluntary and responses will be de-identified and analyzed in aggregate to ensure anonymity.

We are also requesting a waiver of Vincent cards for incentives, as we will be using e-gift cards for providing incentives to the study participants. We will collect PHI (full name, email, address, etc.) to incentivize participants. Collected PHI will be removed in the final data set, after all incentives are provided to those who complete the study, including the Yoga intervention (if they are selected). PHI will not be reused or disclosed to any other person or entity outside of the scope of this research except (i) as required by law, (ii) for authorized oversight of the research study, or (iii) for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule.

a) **Number of Subjects:** We seek to have at least 350 participants using an alpha of 0.05, 95% confidence interval and a low PTG prevalence of 35%.
b) **Gender and Age of Subjects:** To be eligible for this study, participants must be at least 18 years of age. There is no gender or gender identity restriction.
c) **Racial and Ethnic Origin:** Enrollment will not be based upon racial or ethnic origin.

Inclusion and Exclusion Criteria

a) Inclusion Criteria:

- 18 years of age or older
- Assigned female at birth
- Belongs to PINK Concussion Facebook group from as a concussion survivor
- Should be a resident of United States

b) Exclusion Criteria:

- Does not consent to study

Study Procedures and Assessments

Self-reported Measures of PTG outcomes and Domains

PTG assessment (primary): We will use the 25-item scale of the PTG Inventory (PTGI-X), which has more spirituality questions [49]. Score range of 0-125, with greater scores indicating greater growth. The PTGI-X score range is from 0-5, and the cutoff point of ≥3 across items is defined as moderate-to-high PTG levels. Thus scores ≥75 (3*25 item scale) is moderate to high on a scale of 0-125 and scores <75 are deemed low PTG [17]. The PTGI-X can be completed in 7-9 minutes.[23]

PTG assessment (secondary): We will additionally assess the 5 domains of PTG using the following secondary measures:

1. **Domain 1: Relationships with others**

   We will measure social support in this domain using the **Interpersonal Support Evaluation List (ISEL-12).** This is a short-form measure of the ISEL of perceived social support, containing 12 items which assess the perceived availability of social support.[24] Item responses range from 0-3, which are summed to yield a total score (range 0-36), with higher scores indicating greater perceived social support. The measure can be separated into three subscales: appraisal, belonging, and tangible support (subscale range 0-12). It can be completed in 4-5 minutes.

   We will also assess intimacy/relationships after brain injury with the Female sexual function index (FSFI) and the Female Sexual Distress Scale (FSFD-R). FSFD-R takes about 5 mins to complete. FSFI-6 takes about 3 mins to complete.

   The **FSFI-6 questionnaire** [57] consists of 6 questions related to sexual activity within the 4 weeks prior to the examination and includes sexual desire, sexual arousal, lubrication, orgasm, satisfaction, and pain. Scoring is based on Likert scoring from 0-5. Total scores range from 2-30 with lower scores corresponding to worse sexual functioning. Cut off is 19 (<=19 is low sexual function, 20-30 is good). For the 13-item FSDS-R, women will rate each item in terms of frequency from 0 (never) to 4 (always). Items will be summed to create a total score ranging from 0 to 52, with higher scores indicating more sexually related distress [59].

2. **Domain 2: New possibilities in health, work/life**

   There is literature to show that TBI is associated with fewer healthcare visits. In this domain, we seek to explore the association between PTG and preventative healthcare visits. Therefore, we will evaluate if low PTG is associated with fewer provider visits, and/or less upkeep with recommended (age-specific)

screening and testing e.g. mammograms, Pap smears, etc. We will also ask about changes in employment, relationships, etc. These questions should take about 5-7mins to complete.

3. **Domain 3: Personal strength: Resilience scale**

   We will measure using the 25-item Resilience Scale, which ranges from 25-175 in total score on a 1-7point Likert scale. Total score ≤130 is suggestive of low resilience [55,56]. These questions should take about 5 mins to complete

4. **Domain 4: Spiritual change**

   We will measure this with the Spirituality scale. [52] Possible scores on the 23-item scale range from 23 to 138 on a 1-6point Likert scale. Scores can be interpreted and grouped into four different levels of spirituality, indicating how important or to what extent spirituality is to or manifested by an individual. According to Delaney (2003), scores can be classified as follows:

   Very low: 23 - 60
   Low: 61 - 91
   Moderate: 92 -117
   High: 118 to 138 [54]

   These questions should take about 5 mins to complete

5. **Domain 5: Appreciation of life**

   We will measure using the flourishing index scale [50]. Total score is obtained by summing the 12 questions in all six domains to obtain a score range of 0 – 120. Often, for purposes of interpretation however, the score is reported as an average of the questions (rather than sum) so that all scores are on a scale of 0-10. Higher scores are indicative of greater flourishing. These questions should take about 5 mins to complete

Other outcomes of interest:

Post-concussion symptoms:

We will use the Rivermead Post-Concussion Questionnaire [45] to evaluate prevalence of persistent Post-concussion Symptoms among study participants.

The RPQ is a 16-item self-report measure of the presence and severity of the 16 most commonly reported post-concussive symptoms observed in the literature. The scale compares any current symptoms to pre-injury symptom levels to account for potential symptom exacerbation subsequent to the head injury. Values for each of the 16 items are ranked on a five-point scale (0 = not experienced at all, 4 = severe problem). Scores on the RPQ range from 0 to 64, with higher scores suggestive of greater PCS burden. This scale has been endorsed for mTBI populations by the National Institutes of Health (NIH) division of National Institutes of Neurological Disorders and Stroke (NINDS), and used previously to assess outcomes in mTBI populations. The RPQ takes 4 to 6 min to complete.

Anxiety:

The General Anxiety Disorder (GAD-7) is a brief instrument to detect generalized anxiety disorder in a clinical setting, with demonstrated utility in TBI.80 Participants respond to how often they have been bothered in the

last two weeks by symptoms, from 0 (not at all) to 3 (nearly every day). The GAD-7 takes 1-3 minutes to complete.[27]

Depression:

The Patient Health Questionnaire (PHQ-9) is a 9-item screener to assess the frequency of depressed mood/anhedonia over the past two weeks.78. Participants respond to how often they have been bothered by symptoms, from 0 (not at all) to 3 (nearly every day). The PHQ-9 has demonstrated reliability and validity in TBI and takes 2-4 minutes to complete[28, 29].

PTSD:

The PTSD Checklist for The Diagnostic and Statistical Manual of Mental Disorders 5th Edition (DSM-V) (PCL-5) is a well-validated 20-item scale that assesses symptoms mirrored from the diagnostic criteria for PTSD in the DSM-V.[30, 31] Participants rate the extent that symptoms have bothered them in the past month on a 5-point scale from 0-4, with total scores ranging from 0-80 and higher scores indicating greater symptom severity. Symptoms can be further organized into symptom clusters of intrusion, avoidance, negative alterations of cognitions and mood, and alterations in arousal and reactivity[32].

The PCL-5 has demonstrated good initial reliability and validity in TBI populations[33]. Participants will complete the measure in response to the event that caused their TBI. The PCL-5 can be completed in 5-10 minutes.

Demographics and other injury-related attributes

We will design a survey to collect basic demographic and injury-related variables such as current age, age at time of injury, parity, marital status, history of previous concussions, number of previous concussions, educational attainment, services they are currently receiving, etc.

Design & Implementation of Yoga Intervention (Aim 2)

The yoga intervention will be administered by LoveYourBrain Yoga, a US-based global non-profit organization that aims to improves the quality of life of people affected by traumatic brain injury through Yoga and meditation, education and other brain-health initiatives.

The LYB Yoga intervention

Thirty participants will be randomly selected to participate in the LYB Yoga intervention (An overview of randomization techniques: An unbiased assessment of outcome in clinical research - PMC (nih.gov)). The Yoga sessions will be virtual and study participants will be able to complete these sessions at home. The session will not be recorded. They will be free of cost for the study participants. Yoga that will be taught is a simple form of exercise that is tailored to people with a history of TBI. The movements are slow and study participants will have the choice to participate up to their comfort level.The role of LoveYourBrain will be to administer the yoga intervention and will not be engaged in the research study.

To be included, they should:

1. Have low PTG (PGI-X score <75)
2. Be inexperienced/novice yoga users
3. Not be receiving rehab services (per Erin on 6/12/2023: exclude anyone who is receiving counseling, psychiatry, PM&R, neuro, OT, psychotherapy, social work etc.)

DATA ANALYSIS PLAN

We will initially use univariate analyses and descriptive statistics to examine the frequencies and distributions of the data. Established cut-offs will be used to define the low and high PTG groups, and compare the

distribution of PTG domains, PCS, mood and PTSD between the groups. In bivariate analyses, we will use Chi-square tests (X2) to compare differences between the low PTG and high groups across various demographic and injury-related factors. Variables that meet a p-value cutoff of $p< 0.2$ during the bivariate analyses will be included in adjusted regression models. We are using a $p<0.2$ cutoff instead of $p<0.05$ to be conservative, since this is the first exploration of PTG outcomes in a female concussion sample that we are aware of. Crude and adjusted logistic regression models will be used for effect estimates and prediction models, using a significance level of $p < .05$

For Aim 2, we will use paired t-test to compare the mean difference in PTG scores and domains before and after the yoga intervention to determine its effectiveness. We will administer the PTG surveys again at 7 weeks and 30 days to 15 Yoga and 15 Wait list controls (see Figure 5). The 15 Yoga participants will also do the post-yoga assessments at 7 weeks. The 15 Wait list controls will do the LYB program after the 30-day PTG surveys have been completed. The 15 Wait list controls will receive a follow up survey, 1 week after the completion of the LYB program. The intervention group participants who have attended 3 or more LYB yoga sessions will also receive a week-20 follow up survey and the participants who complete the survey will receive $30 incentive.

To evaluate the feasibility & acceptability of the intervention, we will collect the following metrics:

A) Overall Yoga intervention **interest rate**=# interested in participating in Yoga/total # participants (how many PINK women are interested in the Yoga overall? If high can speak to using Yoga as an effective intervention for this population. If low, explore reasons)

B) PTG-specific interest rate: #interested participants with low PTG (score <75)/total #participants (how many people with low PTG are interested in Yoga? We expect this proportion to be lower than overall metric in A above)

C) Yoga intervention participation rate=# who enroll in LYB program (n=30)/#interested participants with low PTG (We will invite 30 people to participate so we know the numerator)

D) Yoga intervention completion rate =# who enroll in LYB program (n=30)/#who complete the LYB intervention

E) Acceptability of intervention: LYB collects this data at the last session on gratitude so we can get some qualitative data

POWER AND SAMPLE SIZE (based on PTG prevalence)

Using a low PTG prevalence of 35%, an alpha of 0.05 and 95% confidence interval, a sample size of 350 will provide sufficient power of 80% for the intended analyses.

INCENTIVES

Participants will receive $40 and the 30 who participate in the Yoga intervention will receive another $60 for completing all 6 weeks of the intervention.

For the 15 Wait list controls, who participate in the Yoga intervention and complete the follow up survey will receive $30.

The intervention group participants who have completed 3 or more LYB yoga sessions and who have completed the week-20 follow up survey will receive $30 incentive.

LIMITATIONS OF THE STUDY

First and foremost, this study is limited to female concussion survivors only and as such, is not generalizable to men who experience TBI. Secondly, the study is recruiting from the PINK concussion group, so the study cannot be generalizable to anyone not in this group, and/or all females with TBI. As this is a pilot, the Yoga intervention will have only 30 participants therefore there's the potential for Type 2 error (false negatives). We will need a larger, more powered study -ideally a clinical trial-to determine the true effect of the Yoga intervention.

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