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CONCUSS randomised clinical trial of vergence/accommodative therapy for concussion-related symptomatic convergence insufficiency

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ABSTRACT

Objective The CONCUSS randomised clinical trial compared the effectiveness of immediate office-based vergence/accommodative therapy with movement (OBVAM) to delayed therapy for the treatment of concussion-related convergence insufficiency (CONC-CI) in participants 11–25 years old with persisting postconcussive symptoms 4–24 weeks post injury.

Methods Symptomatic CONC-CI was diagnosed using clinical signs via near point of convergence (NPC) and positive fusional vergence (PFV) and symptoms via the Convergence Insufficiency Symptom Survey (CISS). Participants were randomised to immediate OBVAM (twice weekly for 6 weeks) or delayed OBVAM (starting 6 weeks after baseline enrolment). After 6 weeks (outcome time 1 assessment), the therapeutic outcomes of NPC, PFV and CISS were assessed and compared between the two groups. After the outcome time 1 assessment, the delayed group received twice-weekly OBVAM sessions for 8 weeks, while the immediate group received an additional 2 weeks of twice-weekly OBVAM sessions. The outcome time 2 assessment compared groups after each group received all 16 OBVAM sessions.

Results In the immediate group, 46/52 (88%) were classified as successful or improved at the outcome time one assessment based on the primary outcome measure, a composite of NPC and PFV, compared with 4/52 (8%) in the delayed group ($p < 0.001$). The mean NPC decreased (improved) by 7.9 cm in the immediate group and 1.8 cm in the delayed group (mean difference at outcome time 1 assessment: 5.1 cm (95% CI: 3.9 to 6.3; $p < 0.001$)). The mean PFV increased (improved) by 17.5Δ in the immediate group and 2.5Δ in the delayed group (mean difference at outcome time 1 assessment: 15.0Δ (95% CI: 11.7 to 18.3); $p < 0.001$). At the outcome time 1 assessment, 41/52 (79%) of the participants in the immediate group had improved symptoms based on CISS scores \leq preinjury scores or decreased by 10 points or more, compared with only 7/52 (13%) of participants from the delayed group ($p < 0.001$). When comparing dosing in the immediate group, for 12 OBVAM sessions, 88% were classified as successful or improved using the composite measurement of NPC and PFV, which increased to 94% after 16 OBVAM sessions. For the outcome time 2 assessment, when both groups had received 16 OBVAM sessions, no significant difference was observed for NPC, PFV or CISS ($p = 1.0$).

Conclusion OBVAM therapy is effective in improving the NPC, PFV and symptoms in CONC-CI. Immediate initiation of OBVAM compared with delayed initiation

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Concussion-related convergence insufficiency (CONC-CI) is common in patients with persisting postconcussive symptoms. High-quality evidence has demonstrated that convergence insufficiency without head injury can effectively be treated with office-based vergence/accommodative therapy. A similar investigation of the impact of office-based vergence/accommodative therapy with movement (OBVAM) on CONC-CI has not been previously performed.

WHAT THIS STUDY ADDS

⇒ OBVAM therapy is an effective treatment for CONC-CI, improving near point of convergence, positive fusional vergence and symptom resolution in patients with persisting postconcussive symptoms. Recovery from CONC-CI is rare with watchful waiting only.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ For adolescents and young adults who have not recovered from a concussion after 4 weeks, healthcare providers should consider referral for a comprehensive sensorimotor vision examination. If a convergence problem is found, OBVAM therapy should be considered as a treatment option to expedite recovery.

shortens the period of symptoms experienced and fosters an earlier return to activities.

Trial registration number clinicaltrials.gov identifier: [NCT05262361](https://clinicaltrials.gov/ct2/show/study/NCT05262361).

INTRODUCTION

Multiple studies demonstrate that vision disorders are common after a concussion^{1–9} and may interfere with return to school, work and sports.^{10–12} The most common vision problems are convergence insufficiency (45–49%) and accommodative dysfunction (35–51%).^{4–6} Vision-related symptoms include reading difficulties, eye strain, blurred or double vision, difficulty switching visual focus between near and far objects, light sensitivity and discomfort in busy and dynamic environments.^{13–15}

Box 1 Study eligibility and exclusion criteria

Eligibility criteria

1. Age 11–25 years
2. Clinically diagnosed concussion 4–24 weeks prior
3. Convergence Insufficiency Symptom Survey score ≥ 16 for children 11–17 years, ≥ 21 for adults 18–25 years
4. Receded near point of convergence of ≥ 6 cm break
5. Insufficient positive fusional vergence at near (ie, failing Sheard's criterion or positive fusional vergence $\leq 15\Delta$ base-out break)
6. Best-corrected distance and near visual acuity of 20/25 or better in each eye
7. Random dot stereopsis appreciation of 500 s of arc or better
8. Wearing appropriate refractive correction (spectacles or contact lenses) for at least 2 weeks prior to final determination of eligibility for any spherical equivalent refractive error of ≥ 2.00 D of hyperopia, ≥ 1.00 D of myopia, ≥ 1.00 D of anisometropia or ≥ 1.25 D of astigmatism based on cycloplegic refraction within 1 year.
 - a. Refractive error corrections adhered to the following guidelines: full hyperopic sphere power or symmetrically reduced by no more than 1.50 D, spherical equivalent myopia and spherical equivalent anisometropia within 0.75 D of full correction and astigmatism within 0.75 D of full correction and axis within 6 degrees for magnitudes of ≥ 1.00 D.
9. Not wearing BI prism at near for 2 weeks prior to study enrolment and for the duration of the study
10. Understands protocol and is willing to accept randomisation

Exclusion criteria

1. Diagnosed concussion with symptoms more than 24 weeks or less than 4 weeks prior
2. Constant strabismus at distance or near
3. Vertical heterophoria $\geq 2\Delta$ at distance or near
4. ≥ 2 line interocular difference in best-corrected distance visual acuity
5. Manifest or latent nystagmus
6. History of prior strabismus, intraocular or refractive surgery
7. Convergence insufficiency previously treated with any form of office-based vergence/accommodative therapy or home-based vergence therapy (eg, computerised vergence therapy)
8. Diseases known to affect accommodation, vergence or ocular motility such as multiple sclerosis, Graves' orbitopathy, myasthenia gravis, diabetes mellitus or Parkinson's disease
9. Inability to comprehend and/or perform any study-related test or therapy procedure

There is evidence from rigorous randomised clinical trials (RCTs)^{16–21} and a recent Cochrane network meta-analysis²² that office-based vergence/accommodative therapy (OBVAT) is an effective treatment for persons with typically occurring convergence insufficiency (TYP-CI) that is not related to a concussion. Other studies using objective eye movement recording and functional MRI (fMRI) have investigated the underlying neural mechanistic changes after vergence/accommodative therapy for TYP-CI.^{20 23–27} Another study reports objective eye movement differences between concussion-related convergence insufficiency (CONC-CI), TYP-CI and those with normal binocular vision.²⁸ Due to the acute, post injury onset of CONC-CI and other differences in clinical characteristics, including symptoms

of dizziness, nausea and fogginess,^{5 6} it is reasonable to hypothesise that OBVAT, while effective for TYP-CI, may not work as well for CONC-CI. Potentially, this is due to the additional common symptoms of light sensitivity and movement-provoked symptoms (patient or objects within an environment) sometimes observed in those with CONC-CI. The current literature associated with CONC-CI includes the following: one small-sample RCT,²⁹ one prospective study without a control group,³⁰ one retrospective study¹⁴ and a case series,³¹ all of which lack the same high-level evidence available for TYP-CI. As recently noted by several authors^{32 33} and organisations,³⁴ 'there is a lack of quality evidence regarding the effectiveness of vergence/accommodative therapy for concussion-related vision disorders'. Further research is needed to evaluate whether the therapy regimen that is effective for TYP-CI patients is appropriate for those experiencing CONC-CI.

Another gap in the current literature is the persistence, stability and natural recovery of concussion-related vision disorders, such as convergence insufficiency and accommodative dysfunction. There are insufficient prospective data regarding the duration and time to resolution for concussion-related vision disorders, which subsequently affect treatment and management decisions.³⁴ Furthermore, it is unclear how many sessions are needed to remediate symptoms. To address these gaps, the CONC-CI CONCUSS RCT will address three clinical aims. The primary clinical aim and purpose of the CONCUSS RCT is to determine the effectiveness of office-based vergence/accommodative with movement (OBVAM) therapy for the treatment of symptomatic CONC-CI (4–24 weeks post injury) and to collect information about persistence or natural recovery without direct intervention in participants 11–25 years of age. A secondary clinical aim is to compare 12 versus 16 sessions of OBVAM to determine the impact of the dose on its effectiveness. The third clinical aim is to assess whether a further 6-week delay from study enrolment (10–30 weeks post injury) in treatment impacts the overall effectiveness of OBVAM. The CONCUSS RCT's outcome measures included clinical signs and symptoms, objective eye movement recording and brain-imaging techniques (fMRI) results. Here, we report on the clinical outcome signs and symptoms related to the diagnostic criteria of CONC-CI. This information will enable clinicians and researchers to make data-driven decisions about the timing, dosing and need for active treatment for CONC-CI.

PARTICIPANTS AND METHODS

The study was supported by the National Eye Institute of the National Institutes of Health and conducted according to the tenets of the Declaration of Helsinki. Participating sites, Children's Hospital of Philadelphia (CHOP), Rutgers University and Salus University signed reliance agreements with the New Jersey Institute of Technology Institutional Review Board, which approved the protocol and Health Insurance Portability and Accountability Act authorisation-informed consent forms. For children and adolescents, the parent or legal guardian gave written informed consent, and each child or adolescent participant gave written assent to participate. Adult participants gave written consent. The study is registered at www.clinicaltrials.gov (NCT05262361).

In this publication, 'baseline examination' refers to the initial study-related assessment after sustaining a concussion. Outcome time 1 and 2 assessments refer to the time points when the sensorimotor vision examinations and other objective measurements were obtained. The primary outcome measurement is a composite of the clinical signs of the near point of convergence (NPC) and

positive fusional vergence (PFV). Secondary outcomes of interest included measurements of NPC, PFV and the Convergence Insufficiency Symptom Survey (CISS) as independent variables. Future studies will investigate the other clinical signs, such as accommodative facility and monocular amplitude of accommodation, obtained during the sensorimotor vision examinations.

Participant selection

All participants were recruited from the private practice of a sports concussion specialist (coauthor AG) in New Jersey or from the Minds Matter Concussion Program at the CHOP King of Prussia location (coauthor CLM). The study included participants who were 11 to 25 years of age with a medical diagnosis of concussion with persisting postconcussive symptoms, 4–24 weeks after the last concussion. Participants were enrolled between 16 November 2021 and 08 July 2024. Participants could have one or more concussions to be eligible for this study. To be enrolled, participants had to have symptomatic convergence insufficiency defined as: (1) a receded (≥ 6 cm) NPC, (2) insufficient PFV (ie, convergence amplitudes) at near defined as failing Sheard's criterion (base-out blur (break, if no blur) less than twice the near phoria³⁵) or minimum PFV at near of $\leq 15\Delta$ base-out break and (3) a score ≥ 16 on the CISS for children who are 11–17 years of age or a score ≥ 21 for adults (18 years of age or older).^{36 37} The full eligibility and exclusion criteria are listed in [box 1](#). These eligibility and exclusion criteria have been used in numerous prior RCTs investigating CI in a population without head injury.^{16 38 39} While some studies support that NPC changes with age, the measurement technique used within the CONCUSS RCT is not the same as that used in other studies of NPC.^{40 41} Other population studies of NPC show that for children and young adults up to 37 years old, the NPC is stable, and this led to the criteria of NPC ≥ 6 cm being abnormal using the same method used here.^{42 43}

Enrolment and sensorimotor vision examinations

Using a standardised protocol, a study-certified optometrist (coauthor MS) administered the CISS to quantify symptoms^{37 44 45} and assess best-corrected visual acuity at distance, subjective refraction, cover testing at distance and near, NPC, PFV (convergence amplitudes) at near (prism bar), negative fusional vergence (divergence amplitudes), near and distance vergence facility (12 Δ base-out and 3 Δ base-in),⁴⁶ near random dot stereoacuity, monocular accommodative amplitude (push-up method) for the right and left eye and monocular (right eye) accommodative facility (± 2.0 D lenses).⁴⁷ We also administered the CISS twice: at the baseline examination to quantify symptoms during enrolment and preinjury.^{37 44 45} For the retrospective preinjury CISS, we instructed the participants to complete the CISS by recalling their symptoms before the concussion occurred. Once completed, the participant was asked to complete the survey again based on how they felt during the past few days after their concussion. These data served as the baseline measures for the eligible participants enrolled in the study. Full details of the assessment are available in the CONCUSS study design publication.⁴⁸

To elaborate on the specific details of how the main diagnostic signs and symptoms were assessed, the NPC was measured with an Astron Accommodative Rule (Bernell, Mishawaka, Indiana, USA, item GR50), which was used with a single column of letters of 20/30 equivalent at 40 cm that was movable. The instrument was placed on midline in the vicinity of the nasion, glabella and the bridge of the nose, and the target was slowly

brought closer (1–2 cm/s) until the participant's image doubled or the optometrist observed loss of fusion. When a participant reported diplopia, the optometrist would ask, 'Does the letter stay two or does it come back into one? It is ok if the target is blurry'. If the patient recovered single vision within 1–2 s, the target was brought closer to the participant until they could not regain fusion. To measure the PFV, the Gulden Ophthalmics (Elkins Park, Pennsylvania, USA) horizontal prism bar with the following prisms, 1 Δ , 2–20 Δ in 2 Δ increments and 20–45 Δ in 5 Δ increments, and a fixation target (Gulden fixation Stick Number 15302) was used. The fixation target contained a single column of letters of 20/30 equivalent and was held at a measured distance of 40 cm from the midsagittal plane. The participant was allowed about 2–3 s to fuse between the change in prismatic demands. The participant was asked to report when the letters became blurred and doubled and when they could recover their single vision, which was recorded as blurred, break (double vision) and recovery (regaining single vision) values. PFV was recorded as the blur perception or break point if blur was not perceived. The CISS recorded clinical symptoms comprising 15 questions assessing visual comfort while reading. CISS used a Likert scale of 0–4 where a participant stated whether the visual symptoms never (point value of 0), not very often (1), sometimes (2), fairly often (3) or always (4) occurred. Hence, the range was from 0 to 60 points, where participants were asked to evaluate their average symptoms over the last 2–3 days. The responses were summed and symptomatic thresholds of ≥ 21 for adults or ≥ 16 for children were used to define symptomatology.³⁶

Trial design and randomisation

The CONCUSS RCT study design is a parallel group with a 1:1 allocation ratio. Participants were randomly assigned to either immediate OBVAM and home reinforcement, hereafter referred to as the immediate group, or delayed (by 6 weeks) OBVAM therapy, hereafter referred to as the delayed group. Allocation was done using a randomised vector created by a random number generator within a custom MATLAB script (Natick, Massachusetts, USA) in accordance with the CONSORT 2010 agreement.⁴⁹ The randomised vector was programmed into Research Electronic Data Capture (REDCap)⁵⁰ and was only accessible to the research coordinators; hence, the investigator completing the outcome examinations was concealed from treatment assignments.

Selection of a 6-week time delay

Observing the participants in the delayed group who did not receive OBVAM therapy for 6 weeks enabled insights into the persistence, stability, natural recovery time course and frequency of resolution of CONC-CI. While a more extended observation of the untreated group may have offered deeper insights, the study physicians felt it was ethically untenable. After consultation with the study concussion specialists and referring community physicians, they were unwilling to postpone vision treatment for CONC-CI patients beyond 6 weeks because the initial concussion occurred 4–24 weeks earlier.

Treatment protocols for both treatment groups

Participants in both treatment groups had received standard concussion care (SCC). For the immediate group, a 16-session programme (60 min for each session) of office-based therapy (face-to-face), twice per week (never on consecutive days), was administered by study-certified therapists. This same therapy was also provided to the delayed group after 6 weeks from study

enrolment. Online supplemental table 1 provides an overview of the OBVAM therapy programme.^{39–51} Full details of the SCC and OBVAM (see OBVAM manual of procedure in online supplemental file 1) therapeutic interventions are available in the online supplemental appendix.

Immediate group study flow

After baseline assessment, participants in the immediate group received SCC from their physician and OBVAM therapy sessions twice-weekly for 6 weeks, totalling 12 sessions, by a study-certified vision therapist. This was followed by an outcome time 1 assessment. After this assessment, therapy continued for two more weeks (twice weekly), adding four sessions to complete 16 OBVAM sessions in total. The outcome time 2 assessment took place after 16 OBVAM sessions.

Delayed group study flow

Participants in the delayed group received SCC only and did not receive OBVAM therapy for the initial 6 weeks. They had their outcome time 1 assessment after a 6-week delay. After the outcome time 1 assessment, they started OBVAM therapy sessions twice weekly for 8 weeks, totalling 16 sessions. Their outcome time 2 assessment took place after 16 OBVAM sessions.

Outcome assessments

All follow-up assessments were conducted by a study-certified optometrist (coauthor MS) masked to the participants' treatment group. There were two outcome sensorimotor vision examinations. Participants in the immediate group completed 12 sessions of OBVAM, and those in the delayed group only received SCC for 6 weeks. Outcome time 1 assessment between the immediate and delayed groups allowed an evaluation of the effectiveness of OBVAM compared with watchful waiting. The difference between outcome time 1 and 2 assessments for the immediate group allowed the assessment of 12 versus 16 OBVAM sessions. The outcome time 2 assessment was conducted after completing all 16 OBVAM therapy sessions in both groups. For the immediate group, this was at 10 weeks post enrolment, and for the delayed group, it was at 16 weeks post enrolment. The difference in outcome time 2 assessments between the immediate and delayed groups allowed for the evaluation of the impact of watchful waiting for natural recovery of CONC-CI with a 6-week delay of OBVAM on the effectiveness of OBVAM. The examiner administered the same sensorimotor vision examination at baseline and during outcome time 1 and 2 assessments. At the outcome time 1 and 2 assessments, participants completed the CISS based on their symptoms within the last few days.

Study visits/flow of CONCUSS RCT

After enrolment, participants were randomised to one of two groups: immediate or delayed OBVAM therapy. Figure 1 illustrates the treatment, retention and assessment schedule from randomisation.

Masking/blinding

While therapists and participants could not be masked/blinded to treatment assignment, the investigator who performed the outcome examination (coauthor MS) was masked to the participants' treatment group. Before the outcome examination, the study coordinator reminded participants not to discuss their group assignment or any treatment they may be receiving with the masked examiner.

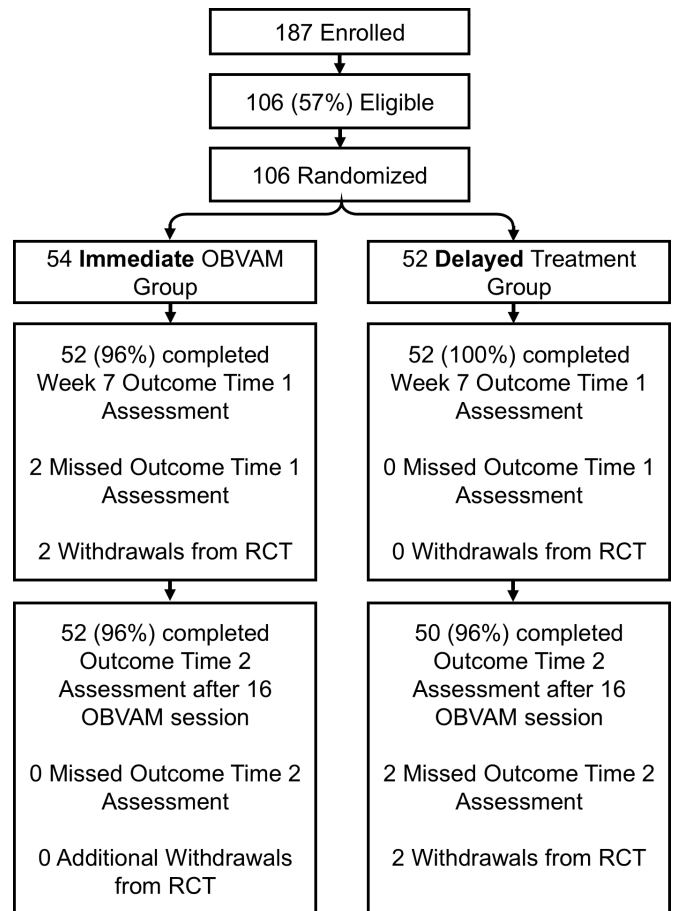


Figure 1 Flow Chart of CONCUSS Randomised Clinical Trial. OBVAM, office-based vergence/accommodative therapy with movement; RCT, randomised clinical trial.

Home treatment adherence

Home treatment adherence was quantitatively assessed using the electronic data from the home computer programme.

Primary outcome measure

The primary outcome measure was the between-group difference of the composite change in the NPC and PFV calculated using an intention-to-treat analysis. Based on the changes in both the NPC and PFV data, the participant's primary outcome measure was categorised as 'successful', 'improved' or 'non-responder'. The primary outcome measure was calculated at the outcome time 1 assessment (after 6 weeks of treatment (12 OBVAM sessions) in the immediate group and 6 weeks of SCC only in the delayed group) and at the outcome time 2 assessment (after an additional 4 OBVAM sessions in the immediate group and 16 OBVAM sessions in the delayed group).

There were three a priori classifications for the primary outcome, described as follows:

- ▶ **Successful:** participants were classified as achieving a successful primary outcome if they met the following criteria. (1) Normal NPC (<6 cm) and decrease (better function) of ≥ 4 cm; (2) normal PFV (met Sheard's criterion and break value $> 15\Delta$) and a increase (better function) of $\geq 10\Delta$.
- ▶ **Improved:** the outcome was classified as improved if the NPC and PFV were either normal or decreased (better function) of ≥ 4 cm for NPC or increase (better function) of $\geq 10\Delta$ for PFV.

- ▶ Non-responder: the outcome was classified as a non-responder when at least one of the two clinical measures (NPC, PFV) was neither normal nor decreased by ≥ 4 cm for NPC or increased by $\geq 10\Delta$ for PFV. In other words, a non-responder did not improve.

Secondary outcome measures

Individual categories of 'successful', 'improved' or 'non-responder' for NPC, PFV and CISS

The effectiveness of treatment was also calculated individually for NPC, PFV and CISS and labelled 'successful', 'improved' or 'non-responder'. These individual categories for each of the measurements were as follows:

NPC: successful was defined as normal NPC and decreased (better function) ≥ 4 cm. Improved was defined as normal NPC or decrease ≥ 4 cm. Participants without a normal NPC or decrease ≥ 4 cm in NPC were categorised as non-responder in NPC.

PFV: successful was defined as normal PFV and increased (better function) $\geq 10\Delta$. Improved was defined as normal PFV or increased $\geq 10\Delta$. Participants without a normal PFV or an increase of $\geq 10\Delta$ were categorised as non-responder in PFV.

CISS: successful was defined as a CISS < 16 (adolescent)/CISS < 21 (adult) and decrease (less symptoms) ≥ 10 points. Improved was defined as CISS < 16 (adolescent)/CISS < 21 (adult) or decrease ≥ 10 points. Participants with age-dependent symptomatic CISS or without a decrease of ≥ 10 points were categorised as non-responders in CISS.

Individual clinical measures

The changes in NPC and PFV between the two groups from baseline to the outcome time 1 assessment and outcome time 2 assessment were compared. For the CISS, the change in the preinjury CISS score to the outcome time 1 and 2 assessments, and the baseline CISS score to the outcome time 1 assessment and outcome time 2 assessment were compared.

Change in composite outcomes and individual measures after 16 OBVAM sessions in the immediate group

A within-group analysis was conducted to determine whether the four additional OBVAM therapy sessions administered to the immediate group participants after the outcome time 1 assessment were beneficial.

Comparison of CISS score between preinjury or baseline to outcome time 1 and outcome time 2 assessments

This study recorded both the baseline (time of study enrolment) CISS score and the 'preinjury' CISS score. The change in the CISS score from preinjury to outcome time 1 assessment and preinjury to outcome time 2 was assessed. The change in the CISS score from baseline to outcome time 1 assessment and from baseline to outcome time 2 was also assessed.

Normalisation measures

Normal is defined as NPC (< 6 cm) and PFV (meets Sheard's criterion and break value $> 15\Delta$). The percentage of participants who attained a normal NPC and PFV was calculated at outcome time 1 and 2 assessments.

Statistical methods

Data entry and management were completed using the REDCap system hosted at the Children's Hospital of Philadelphia (CHOP).⁵⁰ All statistical analyses were conducted using Jamovi

software, which is written in the R package,⁵² and the R package alone. Demographic descriptive statistics were calculated for each group at baseline for PFV, NPC and CISS, using means and standard deviation (SD) for continuous variables and frequencies for categorical variables. For CISS, preinjury values were also included. Unadjusted mean values 95% confidence intervals (95% CIs) were calculated for the primary and secondary outcome variables assessed at the following time points: preinjury (for CISS only), baseline, outcome time 1 assessment and outcome time 2 assessment.

For the primary outcome measure comparing outcome time 1 assessment and outcome time 2 assessment for the immediate versus delayed groups, a χ^2 test was conducted to compare the participants' primary outcomes categorised as 'successful', 'improved' or 'non-responder' between groups. Individuals were categorised as 'successful', 'improved' or 'non-responder' based on NPC, PFV and CISS, as secondary outcome measures for both groups at outcome time 1 and time 2 assessments.

For all other secondary outcome measures, a mixed-effects model⁵³ was employed to analyse the longitudinal repeated measures, assessing the effects of time of intervention, group and their interaction on clinical measures as described in the study protocol.⁴⁸ The model included fixed effects for time (baseline, outcome time 1 assessment, outcome time 2 assessment), group (immediate group, delayed group), and their interaction (time \times group). Fixed effects for time for the CISS also included the preinjury factor. Random intercepts were included for participants to account for within-participant correlation. Additionally, age, sex, race, time since the last concussion injury and number of prior concussions were included as covariates in the model. For all outcome variables, intention-to-treat analyses included all available data at preinjury (for CISS only), baseline, outcome time 1 assessment and outcome time 2 assessment. Mean differences between preinjury and baseline (for CISS only), baseline and outcome time 1 assessment and baseline and outcome time 2 assessment were calculated as the interaction term between the treatment group and time. The 95% CI were calculated.

The formula for the mixed-effects model is as follows:

$$\text{Dep} \sim 1 + \text{time} + \text{group} + \text{age} + \text{sex} + \text{race} + \text{time since last concussion injury} + \text{number of prior concussions} + \text{time:group} + (1 | \text{participants}),$$

where:

- ▶ Dep is the dependent variable for NPC, PFV or CISS.
- ▶ Time is an independent variable for baseline, outcome time 1 assessment and outcome time 2 assessments (for CISS, preinjury values were also included).
- ▶ Group is an independent variable for immediate group and delayed group.
- ▶ Age, sex, race, time since the last concussion injury and the number of prior concussions are covariates.
- ▶ Time:group is the interaction between time measurements and group measurements.
- ▶ (1 | participants) is the random intercept accounting for within-participant variability.

Post-hoc Bonferroni correction for multiple comparisons was conducted to explore the within-group and between-group differences over time. Post-hoc tests were based on the estimated marginal means rather than simple pairwise comparisons of the raw value data. The alpha level used for determining statistical significance was 0.05. Cohen's d effect sizes were calculated as the mean difference divided by the pooled standard deviations of the baseline scores. Cohen's d effect sizes were computed using the psych package in R. Effect sizes of 0.2 were considered small, 0.5 as moderate and 0.8 as large.⁵⁴

Sample size

A priori sample size calculation was performed. The Convergence Insufficiency Treatment Trial (CITT) RCT defined the clinically relevant true mean difference for NPC, PFV and CISS as 4 cm, 10 Δ and 10 points, with an SD of 4.5 cm, 11.3 Δ and 12 points, respectively.¹⁸ To achieve clinically relevant true mean difference for NPC, PFV and CISS and assuming 80% power, alpha equal to 0.05, adjusting for an 80% retention rate and 15% data loss, the maximum sample size for all conditions to be satisfied (NPC, PFV and CISS) resulted in a group size of 46 per group.⁴⁸ The final sample size to be included in each group was rounded up to 50 participants per group.

Patient and public involvement in research

A feasibility study was conducted using the sensorimotor examination and objective measures^{28 31} to learn whether the severity of symptoms for CONC-CI participants could be tolerated during the test assessments. Adjustments were made so that most CONC-CI could tolerate the assessments. Objective measures to understand the underlying neural mechanism of OBVAM will be the basis of future papers.

Equity, diversity and inclusion statement

The authors included six women and three men with a mix of early-stage, middle-stage and late-stage career researchers. Participants could participate regardless of sex, gender, race/ethnicity or socioeconomic level. The research participants were predominantly female (70%) and white (83%), primarily due to the typical demographics of each clinical site.

RESULTS

Enrolment and baseline characteristics

The CONCUSS RCT used an intention-to-treat method. Of the 106 participants enrolled in the study, all were randomly assigned to either immediate or delayed intervention groups. None of the participants changed the treatment arms assigned to them in the study. Of the 106 participants, four did not finish the study. These withdrawals occurred within the first 6 months of study enrolment when evening hours for OBVAM were not offered at one clinical site. Once OBVAM was offered during evening hours, no other study drop-outs occurred. Hence, the study participant withdrawals are speculated to have occurred due to a lack of therapy sessions after workday hours. Of the 106 enrolled participants, two participants withdrew after the outcome time 1 assessment, where there were equal numbers of participants (n=52) in each group or a dropout of about 2%. Two additional participants withdrew before outcome time 2, for a total of four participant withdrawals (two from each arm). Hence, 52 participants completed the immediate group treatment, and 50 participants completed the delayed group treatment, resulting in a total dropout rate of approximately 4%. A multiple imputation analysis is not warranted since the dropout rate was less than 5% for each outcome time assessment.⁵⁵ For the two participants who had outcome time 1 assessment data but withdrew before outcome time 2 assessment data, both were in the delayed group, where the outcome time 1 assessment data showed that one participant successfully remediated after 6 weeks of watchful waiting. The other participant was classified as a non-responder. Since one participant supports and the other refutes the hypothesis that OBVAM would significantly improve convergence while watchful waiting would have minimal improvement, a sensitivity analysis is unnecessary. A sensitivity analysis is warranted when there are substantial missing data.

Between 16 November 2021 and 08 July 2024, 187 participants were evaluated and 106 were eligible; 106 participants were enrolled at two clinical sites. The CHOP clinical site enrolled 46 participants, and the NJIT clinical site enrolled 60 participants. At the CHOP clinical site, four dropped out of the protocol (two from the immediate group and two from the delayed group). At the NJIT clinical site, no dropouts occurred. Hence, a total of 102 participants completed the protocol, comprising 52 in the immediate group and 50 in the delayed group. Age, sex, race and ethnicity of the 106 participants are reported in [table 1](#). Baseline demographic and clinical characteristics were similar in both treatment groups ([table 1](#)).

Adverse events

Two participants were diagnosed with another concussion during the study, not caused by OBVAM treatment, one from each group. For the participant in the delayed group, the concussion (from an after-school activity) occurred after the fourth OBVAM session, and the participant took a 1 week break from the protocol and was classified as successful at outcome time 2. The other participant was in the immediate group and had a concussion (from a motor vehicle accident) after the 11th OBVAM session, took a 2-week break in the protocol, received the 12th OBVAM session and then had outcome time 1 assessment, where the participant was classified as improved. After 16 OBVAM sessions, for outcome time 2 assessment, this participant was classified as successful. Only 2% (2/102) of participants for outcome time 2 incurred a concussion during the protocol, and both were classified as successful; hence, these adverse effects did not impact the overall study results. Otherwise, there were no harmful or unintended adverse effects in either group.

Session completion

Of the 1632 scheduled OBVAM therapy sessions, 1608 (99%) were completed, with no clinically meaningful difference between the immediate group (99%) and the delayed group (98%). If a participant missed a therapy session, it was rescheduled with the goal of having two sessions per week.

The outcome time 1 assessment was completed by 96% (52 of 54) of the participants in the immediate group and 100% (52 of 52) in the delayed group ([figure 1](#)). The outcome time 2 assessment was completed by 96% (52 of 54) of the participants in the immediate group and 96% (50 of 52) in the delayed group.

Standard concussion care

SCC was provided to both groups and was diagnosis-dependent. Online supplemental table 2 displays the percentages of participants who received home-based exercises prescribed by the physician during the clinical trial. The percentages of participants receiving the various exercises were balanced between the two groups. In addition, all physicians prescribed a short period of physical and cognitive rest immediately following the injury to allow acute concussion symptoms to improve, followed by aerobic exercise and a gradual reintroduction of activities.⁵⁶ All SCC activities were designed not to stimulate convergence. Since the prescribed activities are balanced between the immediate and delayed groups, SCC should not impact the overall results of this study.

Primary outcome measure (clinical composite of NPC and PFV)

Using the definitions described above, within the immediate group, 32/52 (62%) were classified as successful, 46/52 (88%)

Table 1 Baseline demographic and clinical characteristics by treatment group

	Immediate OBVAM n=54	Delayed OBVAM n=52
Sex: female n (%)	33 (61)	41 (79)
Age at baseline exam: mean years (SD)	16.8 (3.2)	16.5 (2.7)
Race n (%)		
American Indian or Alaskan Native	0 (0)	0 (0)
Asian	4 (7)	4 (8)
Black or African American	1 (2)	2 (4)
White	46 (85)	42 (81)
More than one race	3 (6)	4 (8)
Ethnicity		
Hispanic or Latino	3 (6)	5 (10)
Number of concussions n (%)	Immediate OBVAM	Delayed OBVAM
1	31 (57)	25 (48)
2	12 (22)	13 (25)
3 or more	11 (20)	14 (27)
Type of injury n (%)		
Sports-related	32 (59)	29 (56)
Fall	9 (17)	14 (27)
Motor vehicle	5 (9)	4 (8)
Pedestrian struck	1 (2)	0 (0)
Struck by or against an object	25 (46)	24 (46)
Struck by a person	11 (20)	9 (17)
Other	3 (6)	1 (2)
Self-reported symptoms, mean (SD)		
CISS Preinjury	15.4 (12.5)	12.8 (9.1)
CISS Baseline (post injury)	34.7 (10.7)	34.6 (10.7)
Clinical Findings, mean (SD)		
Spherical refractive error OD right eye (D)	-0.83 (1.89)	-0.41 (1.5)
Spherical refractive error OS left eye (D)	-0.76 (1.6)	-0.29 (1.8)
Exodeviation at distance (Δ)	-1.2 (1.7)	-0.8 (0.9)
Exodeviation at near (Δ)	-6.6 (4.6)	-6.4 (3.7)
Near point of convergence break (cm)	11.4 (4.7)	10.7 (3.2)
Near point of convergence recovery (cm)	13 (5.2)	13.1 (3.6)
Positive fusional vergence (blur/break)(Δ)	10.3 (3.1)	10.4 (3.3)
Negative fusional vergence (blur/break)(Δ)	10.2 (3.7)	11.2 (4.3)
Near vergence facility cpm (12 Δ BO/ 3 Δ BI)	9.1 (6.8)	9.7 (6.6)
Distance vergence facility using 12 Δ BO/ 3 Δ BI (cpm)	2.0 (3.7)	3.3 (4.8)
Monocular accommodative amplitude OD right eye (D)	7.4 (2.3)	7.8 (2.3)
Monocular accommodative amplitude OS left eye (D)	7.3 (2.4)	8.0 (2.5)
Monocular accommodative facility using \pm 2.00 D (cpm)	6.7 (6.2)	6.2 (6.1)
Co-occurring diagnoses n (%)		
Accommodative insufficiency*	38 (70%)	36 (69%)
Accommodative excess†	16 (30%)	14 (27%)
Accommodative infacility‡	4 (7%)	2 (4%)

*Accommodative insufficiency defined as monocular accommodative amplitude < Hoffstetter's minimum accommodative amplitude criteria⁶⁷ minus 2.0 D and accommodative facility test \leq 6 cpm with difficulty clearing the minus lens only.

†Accommodative excess defined as monocular amplitude \geq Hoffstetter's minimum accommodative criteria and accommodative facility test \leq 6 cpm with difficulty clearing the plus lens only.

‡Accommodative infacility defined as accommodative facility \leq 6 cpm (difficulty clearing both plus and minus lenses).

BI, base in; BO, base out; CISS, Convergence Insufficiency Symptom Survey; cpm, cycles per minute; D, diopters; Eso, positive values; Exo, negative; OBVAM, office-based vergence/accommodative therapy with movement; OD, right eye; OS, oculus sinister or left eye; SD, standard deviation; Δ , prism diopters.

only 3/52 (6%) successful, 4/52 (8%) improved and 48/52 (92%) non-responder (χ^2 (2)=67.96; $p < 0.001$), see [table 2](#). Using the same definitions, within the immediate group, 42/52 (81%) were classified as successful, 49/52 (94%) improved and 3/52 (6%) non-responders at the outcome time 2 assessment. Within the delayed group, 41/50 (82%) were classified as successful, 48/50 (96%) improved and 2/50 (4%) were non-responders, see [table 2](#). No statistically significant difference was found between the two groups at the outcome time 2 assessment (χ^2 (2)=0.17; $p=0.91$).

Secondary clinical outcome measures

[Table 2](#) provides individual categories of 'successful', 'improved' or 'non-responder' for NPC, PFV and CISS. [Table 3](#) presents the results of the mixed model, intention-to-treat analyses, including changes at baseline (preinjury data for CISS only), outcome time 1 assessment and outcome time 2 assessments, along with the corresponding 95% confidence intervals (95% CI) for within-group comparisons. [Table 3](#) also presents the between-group comparisons for differences in clinical outcome measures at outcome time 1 and 2 assessments, along with associated p values and Cohen's d effect sizes. Unadjusted mean values with 95% CIs at preinjury (for CISS only), baseline, outcome time 1 assessment and outcome time 2 assessment are provided in online supplemental table 3. Additionally, these data are presented in [figure 2](#). Figure subplots 2A, 2C and 2E show the mean for NPC, PFV and CISS with 95% CI for each time point (preinjury for CISS only, baseline, outcome time 1 assessment and outcome time 2 assessment) for both groups. The box and violin plots in Figure subplots 2B, 2D and 2F display the median, interquartile range (IQR), density (wider indicating a greater frequency) and variability of the data at each assessment.

Another secondary outcome measure was the evaluation of whether NPC and PFV reached normal clinical values, as described in the Participants and Methods section. At outcome time assessment 1, 44/52 (85%) in the immediate group reached normal NPC and PFV, compared with 6/52 (12%) in the delayed group. Once both groups completed 16 OBVAM sessions for outcome time 2 assessment, the groups were similar, with 49/52 (94%) for the immediate group and 48/50 (96%) for the delayed group reaching normal NPC and PFV values.

Near point of convergence

The mean change (better function) in NPC was 7.9 cm ($p < 0.001$) for the immediate group versus 1.8 cm ($p=0.01$) for the delayed group at outcome time 1 assessment and was significantly different ($p < 0.001$) between participants assigned to the immediate and delayed groups (95% CI: 6.7 to 9.1 (immediate group) versus 0.8 to 2.9 (delayed group)), see [table 3](#). There was a statistically significant difference between the mean NPC in the immediate and the delayed groups at the outcome time 1 assessment (mean difference=5.1 cm; 95% CI: 3.9 to 6.3; $p < 0.001$, Cohen's d effect size=1.3), as summarised in [table 3](#). The two groups did not show a significant difference in the mean NPC at outcome time 2 (mean difference=0.6 cm; 95% CI -0.7 to 1.8; $p=1.00$, Cohen's d effect size=0.06), see [table 3](#). [Figure 2A](#) is a visual display comparing the NPC results of the OBVAM immediate group (mean=11.4 cm) compared with the delayed group (mean=10.6 cm) at baseline with the following: outcome time 1 assessment (immediate group mean=4.1 cm, delayed group mean=9.2 cm) and outcome time 2 assessment (immediate group mean=3.4 cm, delayed group mean=3.2 cm). [Figure 2](#) illustrates the balance between the two groups at baseline, the significant

improved and 6/52 (12%) non-responders at the outcome time 1 assessment. Statistically significant lower percentages were found in the delayed group at the outcome time 1 assessment, with

Table 2 Effectiveness of OBVAM for primary outcome measure using a composite score of NPC (cm) and PFV (Δ)

Primary outcome measure condition N (%)					
Outcome measure	Therapy group	N	Successful (normal NPC AND decreased (better function) ≥ 4 cm) AND (normal PFV AND increased (better function) $\geq 10\Delta$)	Improved (normal NPC OR decreased (better function) ≥ 4 cm) AND (normal PFV OR increased (better function) $\geq 10\Delta$)	Non-responder not improved
Composite score NPC and PFV	Immediate OBVAM (outcome time 1 assessment=12 sessions)	52	32 (62%)	46 (88%)	6 (12%)
	Delayed OBVAM (outcome time 1 assessment=no OBVAM)	52	3 (6%)	4 (8%)	48 (92%)
	Immediate OBVAM (outcome time 2 assessment=16 sessions)	52	42 (81%)	49 (94%)	3 (6%)
	Delayed OBVAM (outcome time 2 assessment=16 sessions)	50	41 (82%)	48 (96%)	2 (4%)
Secondary Outcome Measures Condition N (%)					
NPC (cm)			Successful Normal NPC AND decreased (better function) ≥ 4 cm	Improved Normal NPC OR decreased (better function) ≥ 4 cm	Non-responder not improved
	Immediate OBVAM (outcome time 1 assessment=12 sessions)	52	41 (79%)	50 (96%)	2 (4%)
	Delayed OBVAM (outcome time 1 assessment=no OBVAM)	52	5 (10%)	15 (29%)	37 (71%)
	Immediate OBVAM (outcome time 2 assessment=16 sessions)	52	45 (87%)	51 (98%)	1 (2%)
	Delayed OBVAM (outcome time 2 assessment=16 sessions)	50	46 (92%)	49 (98%)	1 (2%)
PFV (Δ)			Successful Normal PFV AND increased (better function) $\geq 10\Delta$	Improved Normal PFV OR increased (better function) $\geq 10\Delta$	Non-responder not improved
	Immediate OBVAM (outcome time 1 assessment=12 sessions)	52	38 (73%)	45 (87%)	7 (13%)
	Delayed OBVAM (outcome time 1 assessment=no OBVAM)	52	5 (10%)	14 (27%)	38 (73%)
	Immediate OBVAM (outcome time 2 assessment=16 sessions)	52	44 (85%)	49 (94%)	3 (6%)
	Delayed OBVAM (outcome time 2 assessment=16 sessions)	50	42 (84%)	49 (98%)	1 (2%)
CISS (points)			Successful CISS <16 (adolescent) CISS <21 (adult) AND decreased (less symptoms) ≥ 10 points	Improved CISS <16 (adolescent) CISS <21 (adult) OR decreased (less symptoms) ≥ 10 points	Non-responder not improved
	Immediate OBVAM (outcome time 1 assessment=12 sessions)	52	26 (50%)	41 (79%)	11 (21%)
	Delayed OBVAM (outcome time 1 assessment=no OBVAM)	52	5 (10%)	14 (27%)	38 (73%)
	Immediate OBVAM (outcome time 2 assessment=16 sessions)	52	27 (52%)	42 (81%)	10 (19%)
	Delayed OBVAM (outcome time 2 assessment=16 sessions)	50	31 (62%)	41 (82%)	9 (18%)

Effectiveness of secondary measures for NPC (cm), PFV (Δ) and Convergence Insufficiency Symptom Survey (CISS) (points), independently. The number and percentage of participants in the immediate group and delayed group that were classified as Successful, Improved or Non-responder from Baseline to the Outcome Time 1 Assessment (12 sessions OBVAM for the immediate group versus 6-weeks watchful waiting for the delayed group) and from Baseline to the Outcome Time 2 Assessment (16 sessions OBVAM for both groups) for each outcome measure.

CISS, Convergence Insufficiency Symptom Survey; NPC, near point of convergence; OBVAM, office-based vergence/accommodative therapy with movement; PFV, positive fusional vergence.

improvement in NPC of the immediate group compared with the delayed group after 6 weeks, and the lack of a difference between the two groups once both groups complete 16 OBVAM sessions. [Figure 2B](#) displays the box and violin plots for NPC at each time point.

[Table 2](#) provides additional data showing the number and percentage of participants in the two treatment groups classified

as successful or improved for the NPC at the outcome time 1 assessment and outcome time 2 assessments compared with baseline. For the NPC measurement alone at outcome time 1 assessment, 41/52 (79%) of the participants were classified as successful within the immediate group compared with 5/52 (10%) in the delayed group. After completing the full 16 sessions of the OBVAM protocol measured at outcome time 2 assessment,

Table 3 Intention to treat analysis: differences in outcome measures at outcome time 1 and time 2 assessments mean with (95% CI)

Metric	Comparison	
	Within group differences baseline to outcome time 1 assessment	
NPC (cm) Mean (95% CI)	Immediate group	Delayed group
	7.9 (6.7 to 9.1)	1.8 (0.8 to 2.9)
	Within group differences baseline to outcome time 2 assessment	
	Immediate group	Delayed group
	8.8 (7.4 to 10.2)	8.4 (6.8 to 10.0)
	Within group differences outcome time 1 assessment to outcome time 2 assessment	
	Immediate group	Delayed group
	0.9 (-0.1 to 1.9)	6.6 (5.4 to 7.9)
	Between group differences at outcome time 1 assessment	
	IG versus DG	Significance, p value*
5.1 (3.9 to 6.3)	p<0.001	1.3 (0.8 to 1.7)
Between group differences at outcome time 2 assessment		
IG versus DG	Significance, p value*	Effect size†
0.6 (-0.7 to 1.8)	p=1.0	0.06 (-0.3 to 0.5)
PFV (Δ) ‡ Mean (95% CI)	Within group differences baseline to outcome time 1 assessment	
	Immediate group	Delayed group
	17.5 (14.0 to 20.9)	2.5 (0.6 to 5.5)
	Within group differences baseline to outcome time 2 assessment	
	Immediate group	Delayed group
	19.1 (15.2 to 23.0)	20.6 (16.1 to 25.1)
	Within group differences outcome time 1 assessment to outcome time 2 assessment	
	Immediate group	Delayed group
	1.7 (1.2 to 4.5)	18.2 (14.6 to 21.7)
	Between group differences at outcome time 1 assessment	
IG versus DG	Significance, p value*	Effect size†
15.0 (11.7 to 18.3)	p<0.001	4.7 (4.0 to 5.5)
Between group differences at outcome time 2 assessment		
IG versus DG	Significance, p value*	Effect size†
1.5 (-5.0 to 1.9)	p=1.0	0.5 (0.09 to 0.9)
CISS (points) Mean (95% CI)	Within group differences preinjury to baseline	
	Immediate group	Delayed group
	16.9 (12.5 to 21.2)	18.5 (13.7 to 23.3)
	Within group differences preinjury to outcome time 1 assessment	
	Immediate group	Delayed group
	2.5 (-3.6 to 8.5)	12.0 (6.1 to 17.9)
	Within group differences preinjury to outcome time 2 assessment	
	Immediate group	Delayed group
	6.9 (0.2 to 13.7)	7.8 (-0.3 to 16.0)
	Within group differences baseline to outcome time 1 assessment	
Immediate group	Delayed group	
19.3 (15.1 to 23.5)	6.5 (2.8 to 10.2)	
Within group differences baseline to outcome time 2 assessment		
Immediate group	Delayed group	
23.8 (19.0 to 28.6)	26.3 (20.8 to 31.9)	
Within group differences outcome time 1 assessment to outcome time 2 assessment		
Immediate group	Delayed group	
4.5 (1.0 to 7.9)	19.8 (15.5 to 24.2)	
Between group differences at outcome time 1 assessment		
IG versus DG	Significance, p value*	Effect size†
12.2 (7.5 to 16.8)	p<0.001	1.1 (0.7 to 1.5)
Between group differences at outcome time 2 assessment		
IG versus DG	Significance, p value*	Effect size†
3.2 (-1.7 to 8.0)	p=1.0	0.1 (-0.3 to 0.5)

Continued

Table 3 Continued

Metric	Comparison	
	Within group differences baseline to outcome time 1 assessment	
*P value Bonferroni corrected for multiple comparison bold font means statistically significant.		
†Cohen's D computed as the mean difference relative to the pooled standard deviation (SD) of baseline scores.		
‡The blur measurement was used, but if the participant did not report blur, then the break measurement was used.		
CISS, Convergence Insufficiency Symptom Survey; DG, delayed group; IG, immediate group; NPC, near point of convergence; PFV, positive fusional vergence.		

the immediate group had 45/52 (87%) successful participants and the number in the delayed group was 46/50 (92%).

Positive fusional vergence

The mean change (better function) in PFV was 17.5Δ (p<0.001) versus 2.5Δ (p=1.00) at the outcome time 1 assessment for participants assigned to the immediate and the delayed groups, respectively (95% CI: 14.0 to 20.9Δ immediate group versus 0.6 to 5.5Δ delayed group, table 3). The between-group analysis demonstrates that the immediate group experienced statistically significant improvement in PFV compared with the delayed group at the outcome time 1 assessment (mean difference=15.0Δ; 95% CI: 11.7 to 18.3Δ; p<0.001, table 3). At outcome time 1, the difference in PFV demonstrated a large Cohen's d effect size of 4.7, see table 3. The two groups did not show a significant difference at the outcome time 2 assessment regarding mean PFV (mean difference=1.5Δ; 95% CI: -5.0 to 1.9Δ; p=1.00, Cohen's d effect size=0.5, see table 3). Figure 2C is a visual display comparing the PFV results of the immediate group (mean=10.3Δ) compared with the delayed group (mean=10.4Δ) at baseline, as well as outcome time 1 assessments (immediate group mean=27.8Δ, delayed group mean=12.9Δ) and outcome time 2 assessments (immediate group mean=29.5Δ, delayed group mean=31Δ). This figure illustrates the balance between the two groups at baseline, the significant improvement of the immediate group compared with the delayed group after 6 weeks, and the lack of a difference between the two groups once both groups complete the 16 sessions of OBVAM. Figure 2D displays the box and violin plots for PFV at each time point.

Table 2 provides additional data showing the number and percentage of participants in the two treatment groups classified as successful or improved PFV at the outcome time 1 and 2 assessments. For the PFV measurement alone at outcome time 1 assessment, 38/52 (73%) participants were classified as successful within the immediate group compared with 5/52 (10%) in the delayed group. After completing the full 16 sessions of the OBVAM protocol measured at outcome time 2 assessment, the immediate group had 44/50 (85%) successful participants and the number in the delayed group was 42/50 (84%).

Symptom outcome measure: convergence insufficiency symptom score (CISS)

The mean change (less symptoms) in CISS from baseline to the outcome time 1 assessment was 19.3 points (p<0.001) versus 6.5 points (p=0.017) for participants assigned to the immediate and the delayed groups, respectively (95% CI: 15.1 to 23.5 points for the immediate group versus 2.8 to 10.2 points for the delayed group, table 2). There was a statistically significant difference between the mean CISS in the immediate and delayed groups for the outcome time 1 assessment (mean difference=12.2 points; 95% CI: 7.5 to 16.8 points; p<0.001, Cohen's d effect size=1.1,

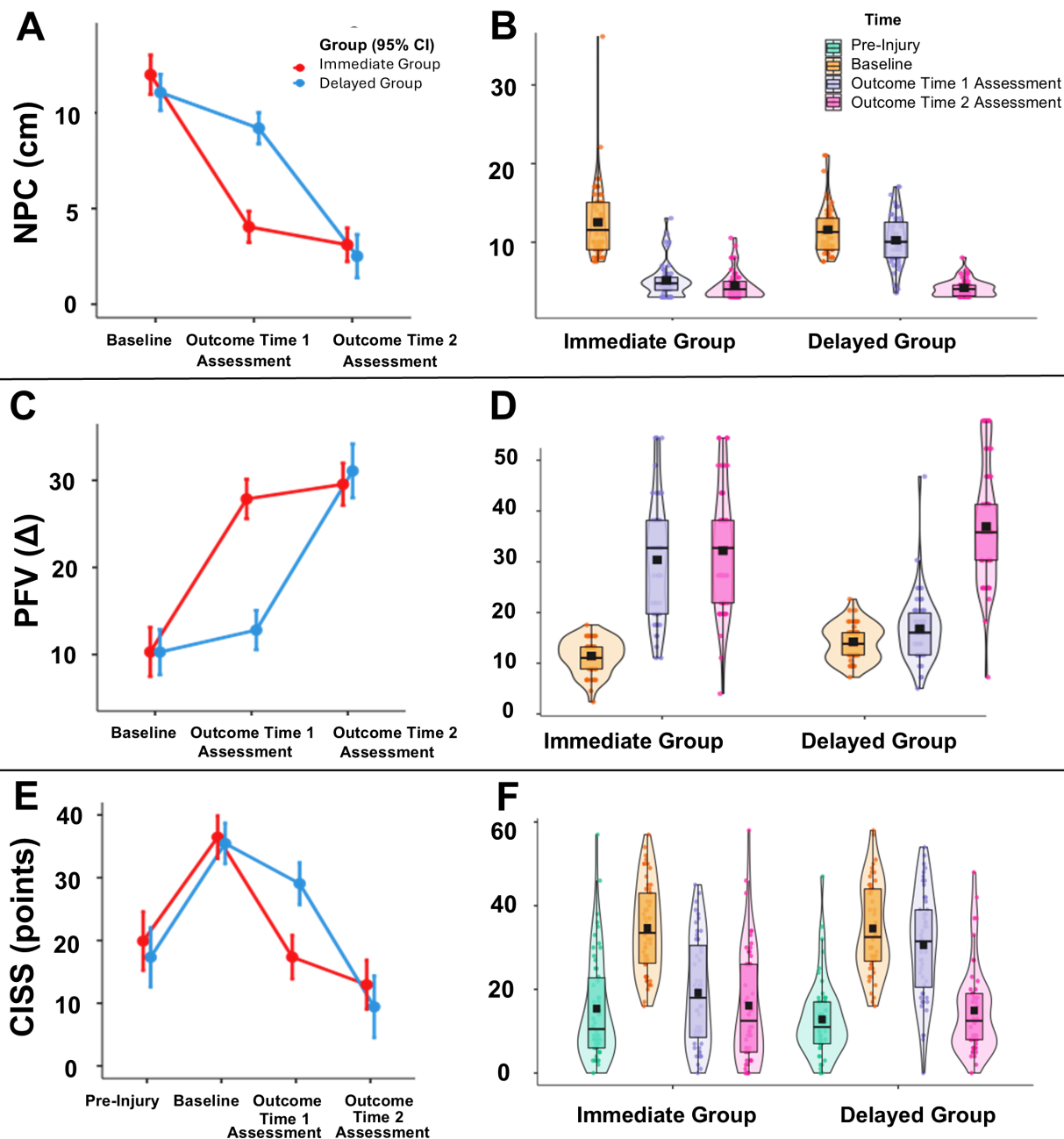


Figure 2 Plots of mean with 95% CI for each time point (preinjury for CISS only, baseline, outcome time 1 assessment and outcome time 2 assessment) for the immediate group (red line) and the delayed group (blue line) for NPC (A), PFV (C) and CISS (E). Violin plots for medium (solid line) mean (square) and the range of data and the box is the first and third quartile of data for preinjury (CISS only) in green, baseline in yellow, outcome time 1 assessment in purple and outcome time 2 assessment in pink for NPC (B), PFV (D) and CISS (F). CISS, Convergence Insufficiency Symptom Survey (points); NPC, near point of convergence (cm); PFV, positive fusional vergence (Δ).

table 3). The two groups did not show significant differences in the mean CISS at outcome time 2 assessment (mean difference=3.2 points; 95% CI: -1.7 to 8.0; $p=1.00$, Cohen's d effect size=0.1, table 3). Figure 2E is a visual display comparing the CISS scores of the immediate compared with the delayed group preinjury (immediate group mean=15.4 points, delayed group mean=12.8 points), at baseline (immediate group mean=34.7 points, delayed group mean=34.6 points), outcome time 1 assessment (immediate group mean=19.2 points, delayed group mean=30.6 points) and outcome time 2 assessment (immediate group mean=16.1 points, delayed group mean=14.9 points). This figure illustrates the balance between the two groups at the preinjury and baseline assessments, the significant improvement

of the immediate group compared with the delayed group at the outcome time 1 assessment (after 6 weeks), and the lack of a difference between the two groups once both groups complete the 16 OBVAM sessions at outcome time 2 assessment. Figure 2F displays the box and violin plots for CISS at each time point.

Table 2 provides additional data showing the number and percentage of participants in the two treatment groups classified as successful or improved for the CISS at the outcome time 1 and 2 assessments. These percentages were based on using the CISS-validated cut-off values used in previous studies (CISS<16 (adolescent), CISS<21 (adult)).^{37 45} For the CISS score alone at outcome time 1 assessment, 26/52 (50%) of the participants were classified as successful compared with 5/52 (10%) in the

delayed group. After completing the full 16 sessions of the OBVAM protocol, as measured at outcome time 2 assessment, the immediate group had 27/52 (52%) successful participants and the delayed group had 31/50 (62%) successful participants.

Comparison of CISS Score between 'preinjury' to the outcome time 1 and 2 assessments

Since the convergence disorder was related to concussion, we were able to ask participants to recall their preinjury symptoms. The comparison from preinjury to outcome allowed us to use each participant as their own control. Participants had relatively similar preinjury CISS scores (immediate group=15.4 points (95% CI: 12 to 18.8 points), delayed group=12.8 points (95% CI: 10.3 to 15.4 points)). Similarly, participants' mean CISS scores at baseline were close to each other (immediate group=34.7 points (95% CI: 31.8 to 37.6 points), delayed group=34.6 points (95% CI: 31.6 to 37.6 points)). At the outcome time 1 assessment, the CISS score in the immediate group decreased (less symptoms) to 19.2 points (95% CI: 15.7 to 22.8 points), while the CISS score remained elevated in the delayed group at 30.6 points (95% CI: 27.1 to 34.1 points). The mean difference between the preinjury CISS score and the outcome time 1 assessment CISS score was 2.5 points ($p=1.00$) versus 12.0 points ($p=0.002$) for participants assigned to the immediate and the delayed groups, respectively (95% CI: -3.6 to 8.5 points (immediate group) versus 95% CI: 6.1 to 17.9 points (delayed group), see [table 3](#)).

The results demonstrate that, at the outcome time 1 assessment, 22/52 (42%) of the immediate group participants were at or below their preinjury symptom level compared with 6/52 (12%) of the participants in the delayed group. When evaluating the data as reaching preinjury scores or changing by ≥ 10 points (being less symptomatic), the results demonstrate that at the outcome time 1 assessment, 41/52 (79%) of the participants had CISS scores \leq preinjury CISS score or changed by 10 points or more points (less symptomatic). This was substantially greater than in the delayed group, where only 7/52 (13%) reached their preinjury scores or changed by more than 10 points (less symptomatic). At the outcome time 2 assessment, when all participants had 16 sessions of OBVAM, 26/52 (50%) returned to the preinjury level or better within the immediate group and 24/50 (48%) within the delayed group. At the outcome time 2 assessment, the percentage of the immediate group that reached their preinjury score or changed by 10 points (less symptomatic) was 42/52 (81%) compared with 43/50 (86%) within the delayed group.

Benefit of four additional therapy sessions

The second clinical aim was to determine whether there was a benefit in dosing with additional therapy sessions by comparing outcome time 1 (12 sessions of OBVAM) versus outcome time 2 assessments (16 sessions of OBVAM) for the immediate group. After the outcome time 1 assessment, participants in the immediate group received 2 more weeks (four sessions) of OBVAM. This was an opportunity to determine if the additional sessions led to any clinically meaningful changes in the individual measures of NPC, PFV and CISS, as well as the composite primary outcome measurement. No statistically significant differences were identified for mean values of NPC and PFV at outcome time 2 compared with the outcome time 1 assessment in the immediate group. NPC improved 0.9 cm (95% CI: -0.1 to 1.9 cm; $p=1.00$) and PFV improved 1.7 Δ (95% CI: 1.2 to 4.5 Δ ; $p=1.00$). No significant differences were identified for CISS at

outcome time 2 compared with the outcome time 1 assessment in the immediate group. The CISS was reduced (less symptomatic) 4.5 points (95% CI: 1.0 to 7.9 points; $p=0.305$). However, reviewing the individual participant data for the primary outcome measure (the clinical composite of NPC and PFV defined in the Participants and Methods section), we observed 17 reclassifications. Of the reclassifications, 14 were positive and three were negative changes when comparing outcomes for the immediate group at outcome time 1 assessment to outcome time 2 assessment. For the positive reclassifications, 11 participants changed from improved to success classification, one participant changed from non-responder to improved and two participants changed from non-responder to success. For example, a participant could have experienced a change in their NPC by more than 4 cm and a change in their PFV by more than 10 Δ but not reached clinical normal values at outcome time 1 assessment. When four more OBVAM sessions were administered, the participants may have reached the defined success criteria for reaching normal clinical values and clinically meaningful changes. For the negative reclassifications, one participant changed from improved to non-responder, one changed from success to improved and another participant changed from success to non-responder. For the participant who changed from success to non-responder, this participant suffered a head trauma the day of the outcome time 2 assessment, which is speculated to have caused the change in classification. Using the primary measure of composite NPC and PFV, the percentage of participants categorised as successful was 32/52 (62%) at the outcome time 1 assessment (12 OBVAM sessions) and rose to 42/52 (81%) at the outcome time 2 assessment (16 OBVAM sessions).

Impact of six-week delay on effectiveness of OBVAM

The third clinical aim was to assess whether an additional delay of OBVAM with 6 weeks since study enrollment of watchful waiting (10 to 30 weeks since last concussion) impacted therapeutic effectiveness. This third aim was assessed by comparing the primary outcome measure of the clinical composite of NPC and PFV at the outcome time 2 assessment. At the outcome time 2 assessment, the immediate group had 42/52 (81%) classified as successful, 49/52 (94%) improved and 3/52 (6%) non-responder. Similar percentages were observed in the delayed group at the outcome time 2 assessment, with 41/50 (82%) successful, 48/50 (96%) improved and 2/50 (4%) non-responder. There was not a significant difference between the immediate and delayed groups after both groups received 16 OBVAM sessions, even when one group had an additional 6 week delay till treatment ($\chi^2(2)=0.17$; $p=0.9$), see [table 2](#).

Compliance with home-based therapy

Compliance with the home-based HTS2, monitored electronically via the software, was poor in both groups. In the immediate group, compliance was only 16% of the prescribed sessions, and 21% did not use the programme at all. In the delayed group, only 11% of the prescribed sessions were completed, and 24% did not use the programme at all.

Comparison to previous studies of TYP-CI

Although previous RCT data are not available for CONC-CI, multiple previous studies that use similar eligibility criteria (except for the presence of concussion), assessment tools and therapy protocol for TYP-CI do exist. Online supplemental table 4 compares the CONCUSS outcome results with results from previous studies with TYP-CI participants. Instead of a delayed

group, previous studies used a placebo control group. This table shows that both the mean change and mean outcome values were very similar for both NPC and PFV for these RCTs.

DISCUSSION

Primary outcome measure

We compared the effectiveness of immediate OBVAM to delayed therapy for the treatment of symptomatic, CONC-CI in participants 11–25 years old with persisting postconcussive symptoms, 4–24 weeks post injury. For clinicians, the key clinical outcome after treatment of convergence insufficiency is the successful normalisation and clinically meaningful change of both NPC and PFV, the two key diagnostic signs of convergence insufficiency. Using this composite change in both NPC and PFV, we found a statistically significant difference in the predefined classification of success between the immediate and delayed groups, with a 62% success rate in the immediate group, compared with 6% in the delayed group at the outcome time 1 assessment. The success rate improved to 81% after 16 sessions of OBVAM therapy during outcome time 2 assessment for the immediate group, which is virtually the same as 82% for the delayed group after they had 16 sessions of OBVAM for the outcome time 2 assessment. While natural recovery within 6 weeks did occur in this study, it was rare. These data indicate that the OBVAM therapy protocol used was effective in this study and should be generalised to patients in this age group with similar clinical findings.

Near point of convergence results

We also analysed several secondary outcomes to understand the clinical relevance of the study results. In clinical practice, it is important to understand the effect of therapy on the individual clinical measures of NPC and PFV. We found that the change in the mean NPC break from baseline to the outcome time 1 assessment (6 weeks, 12 OBVAM sessions) in the immediate group was significantly improved compared with the delayed group. The NPC break improved to normal levels by the outcome time 1 assessment (4.1 cm). Previous studies have established that a change in the NPC ≥ 4 cm is clinically meaningful, and the magnitude of change in this study was 7.3 cm.¹⁸

Positive fusional vergence results

PFV is one of the key clinical findings in the diagnosis of convergence insufficiency, representing the ability to compensate for the exodeviation at near (40 cm along midline). The change in the PFV from baseline to the outcome time 1 assessment (6 weeks, 12 OBVAM sessions) in the immediate group was significantly improved compared with the delayed group. The mean PFV break improved to normal levels by the outcome time 1 assessment (27.8 Δ), and the magnitude of change was clinically meaningful (17.5 Δ). Previous studies^{18 21} indicate that a change of $\geq 10\Delta$ is clinically meaningful.

CISS results

In previous RCTs studying TYP-CI, investigators have used CISS as a clinical outcome for symptoms.^{18 20–22} Since TYP-CI is a developmental condition, it is unrealistic to ask a participant to try to remember a time when they did not have the condition. Thus, in previous studies, investigators administered the survey at the baseline examination using the following instructions: ‘Please answer the following questions about how your eyes feel when reading or doing close work.’ However, in CONC-CI, we asked participants to complete the survey based on how they felt before the concussion. Since we had these preinjury symptom

data, this study aimed to return the participant to their preinjury level of symptoms rather than using existing expected findings for the CISS. A recognised limitation of the CISS is that a high symptom level does not necessarily indicate that a vision problem is responsible for the symptom level.^{57 58} Using the comparison from preinjury to outcome allowed us to analyse each participant as their own control. After OBVAM, the majority of participants reached the preinjury scores. We also calculated the change in the CISS from baseline (post-injury score) to the outcome time 1 assessment. We found a statistically significant change in the mean CISS score between the two groups, with a greater change in the immediate group compared with the delayed group at outcome time 1 assessment.

Persistence, stability, natural course and frequency of resolution with watchful waiting

An outstanding question in the concussion literature is whether any form of medical treatment is necessary for CONC-CI compared with ‘typical rest followed by graded exertion’.⁵⁹ In a systematic review of treatment following sports-related concussion, Schneider *et al* conclude that cervicovestibular rehabilitation is recommended for adolescents and adults with neck pain, dizziness or headaches that persist past 10 days post injury.⁵² Similar reviews do not exist for the accommodative or oculomotor dysfunctions for patients with persisting postconcussive symptoms. In a recent consensus statement on visual rehabilitation in mild traumatic brain injury (mTBI), the authors conclude, ‘Visual symptoms may occur in patients with mTBI, and most patients note spontaneous symptom resolution’.³² In the American Academy of Pediatrics (AAP) Policy Statement on Vision and Concussion, the authors conclude that ‘academic accommodations for school that account for possible vision problems after concussion may be helpful to children during recovery from concussion’.⁶⁰ These consensus and policy statements imply that watchful waiting and school-based or work-based accommodations are all that is needed, with the assumption that, with time, problems associated with concussion-related vision disorders, such as convergence insufficiency, resolve without any direct treatment. The results of this study provide evidence indicating that watchful waiting (6 weeks from study enrolment) is highly unlikely to lead to the resolution of the concussion-related vision problem, leading to prolonged recovery. In the CONCUSS RCT, recovery categorised as a successful remediation was only present in about 6% of the participants in the delayed group at outcome time 1 assessment. While it is true that with more time additional recovery may have occurred, 6 weeks since study enrolment (10–30 weeks post-injury) is a significant amount of time in the life of an adolescent or an adult struggling at school or work and may have a negative emotional impact on the individual who is unable to fully return to academic, work or other extracurricular activities.

Comparison to previous trials on TYP-CI

Due to the differences in mode of onset (gradual in TYP-CI versus sudden in CONC-CI) and types of symptomatology, one might hypothesise that OBVAM might be less effective for CONC-CI. In contrast, the outcomes achieved for NPC in this study with CONC-CI were comparable to those of previous studies on vergence/accommodative therapy in TYP-CI.^{16–18 20 21} Prior studies report a mean improvement of NPC ranging from 6 cm to 10.4 cm, which is similar to the change in NPC of 7.9 cm observed within the CONCUSS RCT for CONC-CI. Similarly, the resultant changes in PFV in this study were comparable to

those found in previous trials with TYP-CI. For PFV, the mean improvements in previous studies ranged from 17.3Δ to 23.2Δ in TYP-CI compared with 17.5Δ in the CONCUSS study for CONC-CI.

Impact of OBVAM effectiveness with six-week treatment delay

An interesting result is that while watchful waiting rarely leads to resolution of the underlying concussion-related vision problem and symptoms, delaying therapy did not have a negative impact on the effectiveness of OBVAM after completion of the 16 therapy sessions. The clinical implication is that even if therapy has been delayed for some reason, OBVAM therapy is still likely to be effective. While the delayed treatment did not impact the overall effectiveness, a 6-week delay where patients are still symptomatic does have a negative impact on academic performance, work, leisure activities and social interactions. Clinicians should evaluate these considerations when deciding when to refer for treatment.

Four additional sessions and the number of weeks of therapy

The primary outcome measure was comparing the two groups after 6 weeks (12 1-hour therapy sessions of OBVAM in the immediate group versus watchful waiting in the delayed group). However, we administered two more weeks (four additional OBVAM sessions) to learn if the additional four sessions had any additional benefit. A previous study of TYP-CI was designed to evaluate the effectiveness of either 16 versus 12 sessions of OBVAT and found that participants who had unsuccessful NPC and PFV values at the end of 12 sessions of office-based vergence and accommodative therapy had positive results after 16 sessions.²¹ The additional four sessions led to the following reclassification: 66% of the unsuccessful participants for NPC and 25% of the unsuccessful participants for PFV were classified as successful after four more sessions. Since CONC-CI is more complicated because of its sudden onset and other symptoms such as light and motion sensitivity, we designed this study to assess the value of four additional sessions. The mean changes in the NPC and PFV were not statistically significant or clinically meaningful. However, an evaluation of the individual participants demonstrates that four additional sessions led to more positive reclassifications for those who did not achieve a successful outcome at 12 OBVAM sessions. There were positive reclassifications in 14 of the 17 participants who had reclassifications, such as a change from non-responder to success or improved.

Another important outcome of this study was that 8 weeks of bi-weekly vergence/accommodative therapy appears to be as effective for treating CONC-CI as 16 weeks of weekly therapy sessions in TYP-CI. A reasonable hypothesis would have been that CONC-CI is more complicated because of the co-occurrence of additional symptoms associated with concussion, and more therapy hours over a longer period might be required to rehabilitate CONC-CI than TYP-CI. We chose bi-weekly sessions primarily based on ethical concerns. Study investigators wanted to minimise the delay time for the control group (those in the delayed OBVAM treatment) and expedite return to school, work or sports. As illustrated in online supplemental table 4, this study's results are comparable to those of previous studies with TYP-CI.

Clinical implications

For physicians and other healthcare professionals who treat patients with concussions, the results have significant clinical

implications. For patients with persisting postconcussive symptoms 4–24 weeks post injury, vision problems should be assessed, as is recommended in the recent American Academy of Pediatrics (AAP) Policy Statement.⁶⁰ At a minimum, a screening (NPC and accommodative amplitude) for the two most common concussion-related vision problems, convergence insufficiency and accommodative insufficiency, should be performed. If persisting postconcussive symptoms are observed, especially those summarised within this research, a referral for a comprehensive sensorimotor vision exam to a professional who can provide vision rehabilitation should be considered. To be enrolled in this study, participants had to be 4–24 weeks post their most recent concussion. If a patient was randomly assigned to the delayed group, then the natural recovery was participant-dependent and was between 10 weeks and 30 weeks following the last concussion. Our results show that if a participant is at least 4 weeks post concussion and has a diagnosis of CI, then it is rare for the CI to remediate naturally. Furthermore, the CONCUSS RCT provides evidence that successful treatment is available to help patients return to school, work and sports relatively quickly. A minimum of 10 weeks (at least 4 weeks post injury plus 6 weeks of watchful waiting) is a significant period for students aged 11–25 years old or for an adult in the workforce to try and function with the symptoms associated with CONC-CI. The results of this RCT demonstrate that watchful waiting is unlikely to be a successful approach, and that CONC-CI is a condition that can be successfully treated in 6–8 weeks.

For eye care specialists, this study provides high-quality evidence that OBVAM is an effective treatment for CONC-CI and that 16 therapy sessions over 8 weeks are a reasonable estimate of the time necessary to treat a high percentage of patients with CONC-CI effectively. Since CONC-CI patients experience a high level of symptoms, one might hypothesise that patients may be unable to tolerate two sessions a week. This study's very high adherence rate provides evidence that for participants 11–25 years of age, the twice-weekly treatment is well-tolerated.

The CONCUSS home therapy compliance was similar to the CINAPS RCT investigating TYP-CI, which used the same home reinforcement and quantitative assessment of percent time used.²⁰ However, home compliance was lower than CITT and CITT-ART on TYP-CI, which may be partly due to the qualitative assessment of home compliance or the evaluation of home-based only interventions.^{21 61} Home-based gaming protocols can also vary widely. Studies on other vision dysfunctions report a 22% compliance rate when using one game on an iPad.⁶² Meanwhile, a similar team on a similar population reports 47% compliance with using another game on an iPad.⁶³ The difference in compliance between these studies suggests that participant engagement in the game/activity is critical to compliance, as is how compliance is measured (subjective versus objective) and whether home-based therapy is used as a reinforcement or is the primary therapy being evaluated. Future research is recommended to enhance and streamline home-based treatment compliance, which could have a broader impact on patients who may be unable to receive treatment due to financial constraints or difficulties in finding a clinic that offers treatment. Home-based therapy could objectively measure eye movements to improve the evaluation of progress.^{64–66}

Limitations

There are some limitations to this study. The strengths of this study include an adequate sample size, randomisation, use of a masked examiner, well-defined diagnostic and treatment protocols, study-certified therapists and a low loss of data during time assessments.

The first limitation is that one might argue that a longer delay in treatment might have led to a higher degree of resolution. We considered a longer delay, but the study physicians are ethically uncomfortable with any delay longer than 6 weeks in treatment. A second limitation is the 4–24 week post injury inclusion criterion. We considered only 4–8 weeks post-injury, but based on recruitment for previous studies, we felt that this would make recruitment challenging. We recognise that with participants enrolled from 4 weeks to 24 weeks post injury, the time without treatment will vary; however, we are unaware of any studies that have prospectively followed a cohort of untreated patients with CONC-CI for any length of time. The length of time since injury was used as a covariate within our statistical model to address this limitation. Another covariate is the number of prior concussions, where the immediate and delayed groups are balanced; however, the inclusion of this variable adds variance to the dataset, which is a limitation. To aid participant recruitment, we did not exclude participants with multiple concussions but did record how many concussions each participant had before enrolment. Another limitation is that we did not determine the maximum effectiveness of OBVAM therapy since all treatments stopped after 16 therapy sessions. Additional sessions may have led to more success or improved classifications of participants.

Future research

Similar to all RCTs, some questions are answered, and others are raised. Future research ideas include:

- ▶ Comparison of office-based treatment to home-based therapy.
- ▶ Comparison of OBVAM to virtual reality gamified methods, either in the office or at home.
- ▶ Comparison of office-based therapy and base-in prism reading glasses.
- ▶ Determination of the number of sessions required to achieve maximum improvement.
- ▶ Determination of the long-term efficacy of OBVAM 1 year post-treatment.
- ▶ Determination of the underlying neural mechanism of OBVAM using sensorimotor vision signs, objective eye movement recording and fMRI datasets.

CONCLUSION

OBVAM was effective in improving the clinical signs (NPC and PFV) and symptoms in participants with concussion-related symptomatic convergence insufficiency. After 16 sessions of OBVAM at outcome time 2 assessment, 83/102 (81%) were classified as a success, and 97/102 (95%) were classified as improved using the primary outcome measure of a composite of NPC and PFV. At the outcome time 2 assessment, there was no statistically significant difference between the immediate and delayed groups' findings regarding NPC, PFV and CISS. A delay in providing OBVAM intervention may impede return to school, work, sports and other activities. However, this study's results demonstrate that OBVAM will benefit a patient to a similar degree whether implemented immediately or after a 6-week delay. Because only 6% of participants in the delayed group were categorised as a success, and only 8% were classified as improved after 6 weeks of watchful waiting from the time of study enrolment (10–30 weeks since the last concussion), it suggests that treatment should be considered as soon as it is evident that a CONC-CI is diagnosed. In most cases, such an approach will lead to successful outcomes, enabling a more rapid return to school, work, sports and other activities.

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