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Impact of Early Activity and Behavioral Management on Acute Concussion Recovery: A Randomized Controlled Trial

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Abstract

Objective: To determine the efficacy of early physical activity and behavioral management for acute concussion in pediatric patients.

Study design: A multicenter, prospective, 2 × 2 factorial randomized controlled trial was conducted among patients aged 11-24 years who presented within 72 hours of injury. Participants were randomized into 4 groups based on early physical activity (or usual care [UC]) and behavioral management (or none). The early activity (EA) group was encouraged to meet step targets despite symptoms. The primary outcomes were postconcussion symptom severity and quality of life at 14 days postenrollment.

Results: A total of 239 participants were randomized, and 210 completed all study procedures. The EA group demonstrated higher daily step counts compared with the UC group. However, no significant differences were observed in postconcussion symptom severity or quality of life at 14

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days between groups. The EA group experienced higher daily postconcussion symptom severity during the first 7 days and took longer to recover compared with the UC group. Behavioral management showed no effect on outcomes.

Conclusions: Early prescribed physical activity and behavioral management did not improve postconcussion outcomes in the first 2 weeks following injury. Early prescribed activity despite symptoms was associated with delayed symptom resolution.

Trial registration: [ClinicalTrials.gov NCT03869970](https://clinicaltrials.gov/ct2/show/study/NCT03869970).

Mild traumatic brain injury (mTBI) affects nearly 2 million youths annually in the US, with most recovering within a month.¹ Optimizing acute management is essential as both physiological and psychological factors influence recovery, with psychological factors gaining prominence over time. Accurate injury assessment and outpatient guidance can reduce recovery time and complications. Current guidelines recommend up to 48 hours of relative rest, followed by a gradual subsymptom return to physical and cognitive activity.² Prolonged strict rest (eg, ≥ 5 days) has been associated with greater symptom burden and delayed recovery.³ A recent meta-analysis found that active interventions slightly increased symptoms without significantly affecting recovery time, raising concerns about the quality and quantity of existing clinical trials.⁴ Cohort studies suggest early light physical activity promotes recovery, while prescribed individualized subsymptom threshold exercise has been successful in clinical settings.^{5–8} The efficacy of standardized activity instructions despite symptoms vs individualized symptom-guided activity after acute concussion diagnosis has not been established. Given the role of psychological factors, cognitive behavioral interventions improve symptoms and quality of life, with face-to-face psychoeducation reducing fatigue, symptoms, and post-traumatic stress in children.^{9–11} Yet, evidence supporting mobile health (mHealth)–based behavioral interventions is limited.^{12,13}

This study aims to evaluate the efficacy of standardized physical activity, behavioral management, or both, vs usual care (UC) discharge instructions in youth with acute mTBI presenting to an emergency department (ED) or concussion clinic. We hypothesized that early activity (EA) and behavioral management would be beneficial (ie, result in lower symptom scores, more rapid and complete recovery, and higher quality of life [QoL] scores) at 14 days (primary time point) and at one and 2 months (secondary time points) postenrollment.

Methods

Study Design

This was an unblinded, phase II factorial, multisite randomized controlled trial (RCT) of patients with acute (< 72 hours) mTBI.¹⁴ Participants were recruited from pediatric EDs and concussion clinics at 2 sites: Children's Wisconsin (Medical College of Wisconsin) and Children's Hospital of Pittsburgh (University of Pittsburgh Medical Center). mTBI was defined using the Acute Concussion Evaluation-ED.¹⁵ The study enrolled participants from June 11, 2019, to June 22, 2023, with final follow-up completed on August 11, 2023, and primary analysis performed on December 14, 2023. This trial is registered on

[Clinicaltrials.gov \(NCT03869970\)](https://clinicaltrials.gov/ct2/show/study/NCT03869970) and was approved by the Medical College of Wisconsin Institutional Review Board (IRB#PRO33221).

Study Sample

Eligible patients were aged 11-24 years and met mTBI criteria within the past 72 hours (ie, signs, symptoms, and/or impairment following direct or indirect brain trauma). Exclusions included non-English speakers, conditions impairing assessment or consent, history of mTBI within past 6 months, need for hospital admission, orthopedic injuries limiting activity, history of moderate-severe TBI or brain surgery, developmental delay, substance abuse, major psychiatric disorders (except anxiety or depression), or lack of smartphone access. Neuroimaging was obtained at clinicians' discretion.

Study Procedures

Participants completed baseline assessments of demographics, injury details, symptoms, physical activity, and QoL. They were randomized into 1 of the following 4 groups: 1) UC; 2) EA; 3) UC plus mHealth; or 4) EA plus mHealth. All participants received standardized discharge instructions covering postconcussion self-care, symptom recognition, reasons for ED return, and school reintegration. They were advised to avoid high-risk and sport-specific activities until cleared by a health care provider. Each site provided printed, comic-based and video instructions tailored to group assignment. Research coordinators guided families through study procedures, assisted with baseline assessments, and observed discharge process using a structure checklist to ensure consistency across sites. Participants received Fitbit trackers (Flex or Inspire 2; Fitbit, Inc) and the active injury management app to track symptoms, cognitive activity, and compliance, both validated in preliminary studies. Follow-ups occurred at 3-5 days, 14 days (in person or virtual), and at 1 and 2 months (See Figure 1 for study overview).

Interventions

Prescribed Activity. UC participants followed standard recommendations of 48 hours of rest followed by a symptom-guided return to activity. EA participants were instructed begin light-to-moderate physical activity with the goal of reaching daily step targets (eg, aiming for 10 000 steps per day for 3 days in the first week and 5 days in the second week). EA participants were instructed specifically to increase activity regardless of current symptoms but should not push through worsening symptoms. They were encouraged to engage in low-risk activity (eg, walking) while avoiding activities that may increase reinjury risk (eg, biking, sports). Pedometer-based programs have shown that 10 000-step goal effectively improves health and increase physical activity in adolescents.^{16,17} This simple clear target is accessible to all patients, regardless of health literacy, and real-time feedback provides continuous motivation.

Behavioral Management. mHealth participants used the SuperBetter app to foster a positive recovery framework. SuperBetter is a gamified app designed to build psychological resilience, promote social and emotional learning, and reduce anxiety and depression. The app engages users with game mechanics (eg, points, levels, "power-ups") to encourage mental, physical, social, and emotional resilience represented as a resilience score. The

app provides preprogrammed and customizable goals (eg, deep breathing, hydration, social interaction) to reinforce progress and create a positive recovery mindset. SuperBetter has been shown to improve depression, anxiety, and postconcussive syndrome in clinical trials and outpatient pediatric concussion populations.^{18,19} The EA + mHealth group received both interventions, integrating physical activity goals into the SuperBetter app. Groups not assigned to mHealth had no access to the application.

Outcome Measures

Compliance. Compliance with the activity intervention was assessed using participants' Fitbit step counts over the first 7 days postenrollment. This was specifically defined as whether participants met step goals 3 or more days within the first 7 days. Step counts below 1000 steps per day were excluded as incomplete. Step count averages were calculated using data from complete days within the first 7 days. Compliance with the behavioral management intervention was gauged by evaluating weekly resilience scores on the Superbetter app over the 14-day assessment period. Achievement of treatment goals was reviewed by analyzing Fitbit step counts and Superbetter resilience scores.

Efficacy. The primary study outcomes were the total symptom burden and QoL scores at 14 days. Symptom burden was determined using the Post-Concussive Symptoms Scale (PCSS), which measures 22 self-reported symptoms from 0 (none) to 6 (severe).²⁰ QoL was assessed using the Pediatric Quality of Life Inventory (PedsQL), featuring 23 items rated on a 4-point scale, providing total PedsQL scores and domain scores for physical, emotional, social, and school functioning.²¹

The secondary outcomes used to determine patient-centered outcomes included symptoms at 3 days; neurocognitive, balance, and vestibular/ocular motor impairment; and symptom resolution at 14 days (defined as a PCSS ≤ 7)²²; PedsQL measures; time to symptom resolution; and return to normal activity at 1 and 2 months. All outcome measures were National Institute of Neurological Diseases and Stroke Common Data elements for mTBI.²³

Neurocognitive. Neurocognitive performance was assessed using the ImPACT Quick Test, a 5-7 minute iPad-based tool evaluating symbol matching, letter sequences, and attention tracking, with age- and gender-adjusted percentile scores for memory, motor speed, and attention.²⁴

Balance. Balance was assessed using the modified Balance Error Scoring System, measuring errors in 3 stance conditions (double leg, single leg, tandem) on firm flooring. Scores were the sum of errors across 3 trials (0-30).²⁵

Vestibular. Vestibular/ocular impairment was assessed with the Vestibular Oculomotor Screen, including 7 tests (eg, saccades, vestibular reflex, and motion sensitivity). Symptoms were rated on a 10-point scale, and average near point of convergence distance was measured.²⁶

Additional Assessments Included. The International Physical Activity Questionnaire short form²⁷ which measures physical activity recall over the last 7 days, Brief Symptom

Inventory- 18²⁸ which measures internalizing psychopathology (depression, anxiety, and somatization), and Somatization Subscale of Child Behavior Checklist²⁹ which captures somatic symptoms.

Randomization and Blinding: The randomization schema was generated by the study statisticians (C.N.S., C.G.P.) with permuted blocks stratified by site using SAS sampling procedures. The schema was submitted to the data manager who uploaded the list into an electronic database for implementation to preserve allocation concealment. Participants and clinical providers could not be masked and clinical research team conducting follow-up were not explicitly blinded from group assignment during follow-up as assessment of compliance required knowledge of group assignment. Other study team members including data analysis and principal investigators were blinded from group assignment as best as possible.

Statistical Analysis

Sample Size Calculation. A priori, we calculated a total sample size of 388 participants to detect differences among the 4 groups in the PCSS over time (day 0, 5, 10, 14, 30, and 60) among those deemed high-risk accounting for repeated measures within person and 20% attrition. We assumed 60% of participants were high-risk (eg, history of somatization, migraines, or multiple concussions) and the PCSS had a SD of 10.¹⁵ In October 2022, due to lower-than-expected recruitment, the lead statistician conducted a revised power analysis to evaluate the main effects of each intervention given the recruitment rate and expected enrollment stop date. With a total sample size of $n = 190$ and complete data, the study would achieve 90% power to detect half a SD between 2 groups for symptom burden and QoL ($\alpha = 0.05$). As a result, the analysis plan was adjusted to focus on the main effects of EA vs UC and mHealth vs no mHealth, without prioritizing the high-risk subgroup analysis.

Analysis Plan. All efficacy analyses used an intention-to-treat approach. Adjusted mean differences with 95% CIs were calculated using baseline constrained linear mixed models, including fixed effects for site, time point, and group time point interaction, and a random participant effect, in which baseline outcomes were included in the outcome vector while assuming treatment means are equal at baseline.³⁰ Unstructured and AR(1) covariance structures were considered with model selection based on Akaike Information Criterion and the Bayesian Information Criterion. The unstructured covariance matrix was chosen as it provided a better model fit based on these criteria. Analyses focused on main effects of each factor (two-sided $\alpha = 0.05$, no multiple comparison adjustment) with exploratory testing of EA-mHealth interactions. Kaplan-Meier plots assessed time to reach PCSS ≤ 7 over 2 weeks, with group comparisons via log-rank test. All analyses were performed in SAS 9.4 (SAS Institute Inc).

Results

Demographics

Out of 719 screened patients, 549 met the inclusion/exclusion criteria (see Figure 2 Consort diagram). Of these, 310 patients declined participation and 239 were randomized (UC = 59, EA = 60, UC/mHealth = 60, and EA/mHealth = 60). Follow-up was 90.8%, 85.8%, and

81.2% at 14 days, 1 month, and 2 months, respectively; 85% of participants were recruited from the pediatric ED, while 15% were recruited from concussion clinic. For the factorial analysis, 118 participants were given UC recommendations compared with 117 given EA recommendations, while 117 participants were given the mHealth intervention compared with 118 who did not (Figure 3). Each group was approximately 50% female with an average age of 14.5 years (SD 2.3 years). There were no clinically meaningful differences among our intervention groups at time of evaluation including PCSS total score, mechanism of injury, symptoms at presentation, previous mTBI, acute evaluation, and acute treatment (Table I).

Compliance

Participants who were prescribed EA were more likely to achieve the prescribed step goal of 10 000 steps per day for 3 days in the first week (33/86 [38%] vs 10/81 [12%]; $P < .01$) and have higher average Fitbit step counts over the first 7 days compared with those prescribed UC ($n = 99$; 7008 steps/day [SD = 2968] vs $n = 94$; 5697 steps/day [SD = 2595]; $P < .01$). Participants prescribed mHealth interacted with the app a median of 5 days (IQR = 6), with half of participants meeting recommended treatment goals (Superbetter resilience score goals met in week 1 = [49%] and week 2 = [50%]).

Outcomes

We did not detect differences in primary outcomes (PCSS and PedsQL) at 14 days between the EA and UC. However, participants prescribed activity experienced more symptoms in the first 7 days postinjury (see Figure 4, A) and were less likely to achieve early symptom resolution (see Figure 4, B). Participants prescribed UC had lower mean balance errors compared with participants prescribed EA (4.7 [2.6] vs 6.1 [4.1] $P = .02$) (Table II). No differences were detected in neurocognitive, vestibular/oculomotor, or anxiety/depression outcomes between the EA and UC groups. Similarly, there were no differences in primary outcomes or symptom trajectory between mHealth and no mHealth groups (see Figure 4, C [PCSS], Figure 4, D), nor in any secondary outcomes. No interaction was detected for the 2 factors (mHealth, activity) over time for either primary outcome (PCSS $P = .24$; PedsQL $P = .66$).

Adverse Events

There were 4 patients who experienced adverse events during the trial. In the UC group, 1 participant reported suicidal ideation on Brief Symptom Inventory-18. Within the UC/mHealth group, 1 participant fainted and another participant sustained a subsequent head injury, both requiring return visits to the ED. The only study related adverse event was in the EA group, when 1 participant, overexerted themselves attempting to exceed step count recommendations, exacerbating symptoms and consequently returned to the ED.

Discussion

This study found no added benefit of prescribed EA or mHealth interventions over UC for acute concussion in youth. Although our findings did not support a positive effect of EA, multiple RCTs have shown that controlled, subsymptom threshold aerobic exercise initiated

within 24–48 hours can facilitate recovery.^{6,8} These studies emphasize that structured aerobic exercise, rather than general physical activity, is the key factor, with causality well established, though the underlying mechanisms remain unclear.³¹ Current guidelines recommend gradual return to activity as symptoms improve, a strategy supported by trials favoring subsymptom threshold exercise over passive rest. However, prior studies often involve small sample sizes (16–118 participants), clinic-based recruitment, and a focus on subacute or chronic recovery, limiting applicability to the acute phase.^{32–34} Few RCTs have specifically evaluated exercise interventions within the first 72 hours postinjury in youth. In a 2019 RCT by Leddy et al,⁵ 103 adolescents seen in 2 community sports medicine clinics within a week of sport-related concussion were assigned to 20 minutes of daily subsymptom threshold aerobic exercise or a placebo-like stretching program. Exercise intensity was individualized using the Buffalo Concussion Treadmill Test, targeting 80% of the heart rate threshold for symptom exacerbation. The aerobic exercise group recovered significantly faster compared with the stretching group. A 2021 follow-up RCT replicated these findings across multiple sites with an intention-to-treat analysis, confirming that early (within 10 days) tailored aerobic exercise accelerated recovery and reduced risk of persistent symptoms.³⁵ Our study differed in several ways. We recruited from pediatric EDs within 72 hours of injury and provided standardized activity goals regardless of symptom status, rather than prescribing individualized, subsymptom threshold exercise. In contrast to the structured protocols used in prior trials, our general activity recommendations were unsupervised and not symptom-guided. A similar ED-based trial by Ledoux et al³⁶ randomized 456 youth to resume activity at 72 hours postinjury or follow UC. Although the primary analysis showed no group differences at 2 weeks, a per protocol analysis revealed that those who adhered to activity recommendations had fewer symptoms. Adherence, therefore, may be key. In our trial, although the activity group increased average daily step counts, only 38% met target step goals. This high nonadherence likely limited potential benefits and raises questions about the practicality of broadly recommending EA in acute care. Unlike structured, supervised exercise programs with tailored, subsymptom activity, both our study and Ledoux et al relied on general activity guidance without supervision or adjustments, which may explain the variability in outcomes. Additional differences, such as patient population (acute ED vs outpatient), timing of intervention (hours vs days postinjury), broader inclusion criteria, and differing outcome measures, may have contributed further to contrasting findings. Notably, our activity group transiently reported increased symptoms, which resolved by day 14, while the UC group showed better balance scores at follow-up. Together, these findings suggest that while physical activity is an essential component of concussion recovery, its benefits depend on timing and individualization. Prescribing a fixed activity level shortly after injury, without adjusting for symptom response, may be suboptimal. Current evidence supports tailored symptom-guided subsymptom threshold exercise after a brief period of relative rest.³⁷

Regarding the behavioral intervention, our commercially available mHealth app self-guided program showed no benefit, with only half the patients engaging with the app for a median of 5 days and meeting resilience goals. This limited acceptability suggests a need for more engaging or personalized digital tools. In addition, our mHealth programming lacked concussion-specific goals, symptom monitoring, recommendations, or direct health care

team communication. While this approach did not show benefit, the app also did not cause harm, which contrasts with evidence suggesting increased screentime postpediatric mTBI may worsen symptoms.³⁸ Future concussion-specific programs integrating symptom-guided return to activity could prove beneficial. A planned subanalysis of a high-risk populations and a per protocol analysis may clarify further the benefits of prescribed activity or behavioral intervention.

Our study supports the current standard of care for acute concussion management. mTBI triggers a neurometabolic cascade leading to a brain energy crisis and functional impairments.³⁹ Rest theoretically restores brain energy stores. In our prior trial comparing prolonged rest (5 days) with UC (24-48 hours), prolonged rest worsened symptom outcomes without affecting neurocognitive outcomes.³ DiFazio et al⁴⁰ noted psychological and physical deconditioning effects contributing to symptom persistence in youth post-mTBI. Our study found 24-48 hours of rest followed by symptom-guided return to activity led to faster symptom resolution compared with early, symptom-independent activity. Combined with existing literature, these findings suggest personalized concussion guidance postinjury could prevent excessive rest or premature return to activity. Most patients can naturally increase activity as symptoms improve over 10-14 days postinjury. For those with variable symptoms or slow recovery, early referral to primary or specialty care may ensure smooth recovery and timely interventions. Future studies should focus on tailoring interventions to individual symptom thresholds, such as developing methods to determine personalized subsymptom threshold activity goals in acute care settings or utilizing remote patient monitoring to provide timely symptom-guided recommendations.

Our study was not without limitations. This trial encountered challenges common to studies conducted during the COVID-19 pandemic. Recruitment and retention difficulties prompted adaptations such as enhanced compensation and flexible follow-up options (eg, in-home and remote assessments), which were necessary for social distancing but limited our ability to capture secondary outcomes. Changes in care-seeking behavior during the pandemic may also have influenced our sample. Increased loss to follow-up may have introduced attrition bias, impacting the robustness of findings. Requiring smartphone ownership excluded 7% of eligible participants. Outcome assessors were not blinded, which may have introduced bias. Most participants were recruited from the ED or a specialty clinic within 72 hours of injury, whereas many adolescents with concussion present to primary care days to weeks later, limiting generalizability. Symptom resolution was self-reported and not confirmed with objective balance or oculomotor testing, potentially missing residual deficits. Adherence to early physical activity recommendations was low, and most injuries occurred in nonsport settings, in contrast to RCTs showing benefit in athletic populations.

Overall, our study found no evidence that early prescribed activity or mHealth interventions added benefit over standard care for youth with acute concussion. While prior work, including Ledoux et al's per protocol analysis, suggests that individualized goal-directed exercise may support recovery, high nonadherence in our study limits conclusions about efficacy. These findings raise concerns about universal recommendations to resume physical activity within 72 hours postinjury, regardless of symptom burden. Instead, they support an individualized approach that emphasizes early, light physical activity below the symptom-

exacerbation threshold to avoid both excessive rest and premature return to full activity. Despite 2022 Amsterdam Consensus guidance recommending on light activity within 24 hours, real-world adherence remains a barrier.² Future work should refine strategies to improve both effectiveness and uptake of tailored interventions.

Declaration of competing interest

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Data Statement

Data sharing statement available at www.jpeds.com.

Data Sharing Statement:

Deidentified individual participant data (including data dictionaries) will be made available, in addition to study protocols, the statistical analysis plan, and the informed consent form. The data will be made available upon publication to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal. Proposals should be submitted to Danny G Thomas (dthomas@mcw.edu).

Glossary

EA	Early activity
ED	Emergency department
mHealth	Mobile health
mTBI	Mild traumatic brain injury
PedsQL	Pediatric Quality of Life Inventory
PCSS	Post-Concussive Symptoms Scale
QoL	Quality of life
RCT	Randomized controlled trial
UC	Usual care

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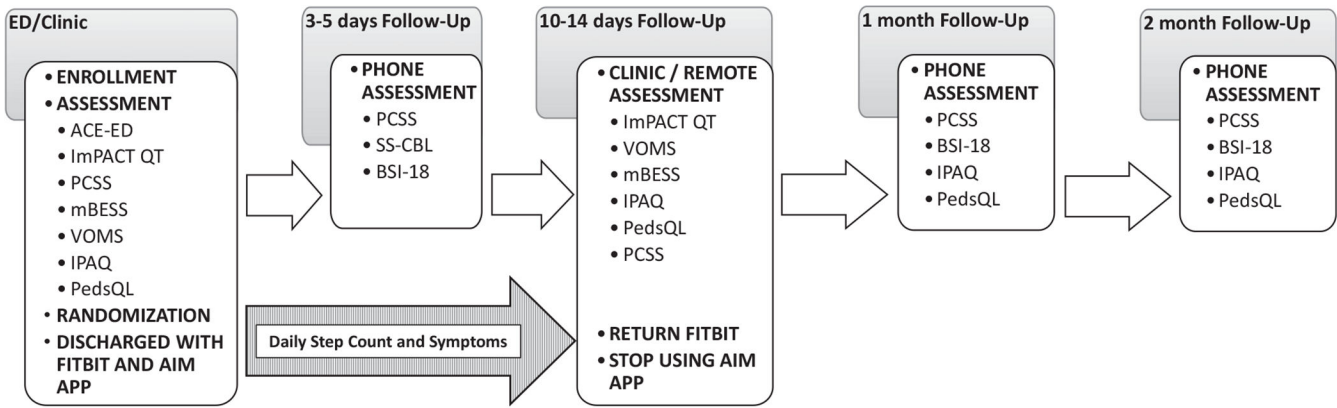
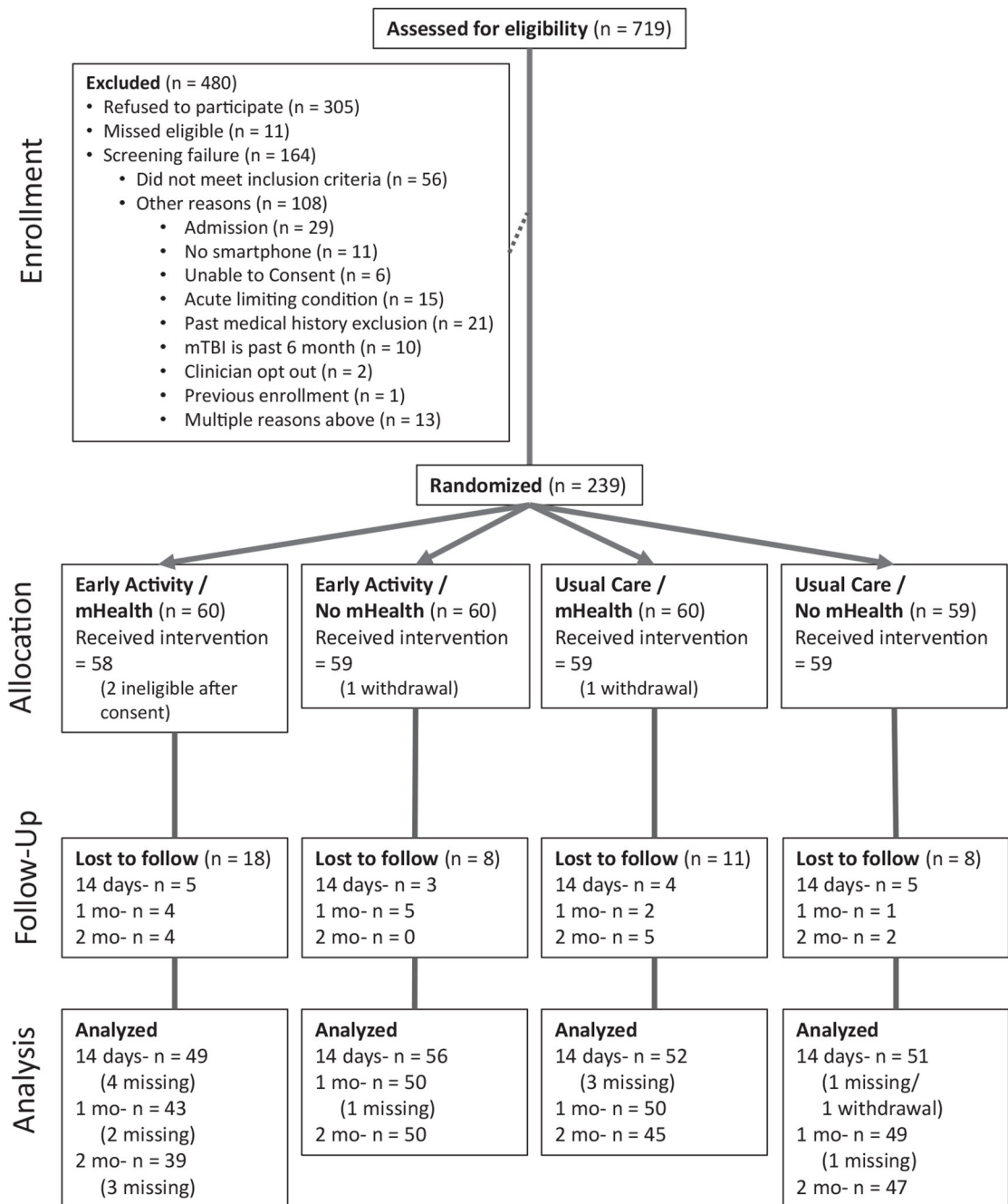


Figure 1. Study overview. *ACE-ED*, acute concussion evaluation-ED; *BSI-18*, brief symptom inventory-18; *ED*, emergency department; *ImPACT QT*, immediate post-concussion assessment and cognitive test; *IPAQ*, International Physical Activity Questionnaire; *mBESS*, modified balance error scoring system; *PedsQL*, pediatric quality of life inventory; *PCSS*, post-concussive symptoms scale; *SS-CBCL*, somatization subscale of child behavior checklist; *VOMS*, vestibular oculomotor screen.

**Figure 2.**

Consort diagram. *mHealth*, mobile health; *mTBI*, mild traumatic brain injury.

<u>Treatment Groups</u>		<u>Factorial Analysis:</u> Activity
USUAL CARE N = 59	USUAL CARE & mHEALTH N = 59	Usual Care: N = 118 Rest for 24-48 hrs then symptom guided activity
EARLY ACTIVITY N = 59	EARLY ACTIVITY & mHEALTH N = 58	Early Activity: N = 117 Low intensity activity regardless of symptoms
<u>Factorial Analysis:</u> Behavioral Management	No mHealth: N = 118	mHealth: N = 177 Use of "Resilience" app

Figure 3.
Randomization groups.

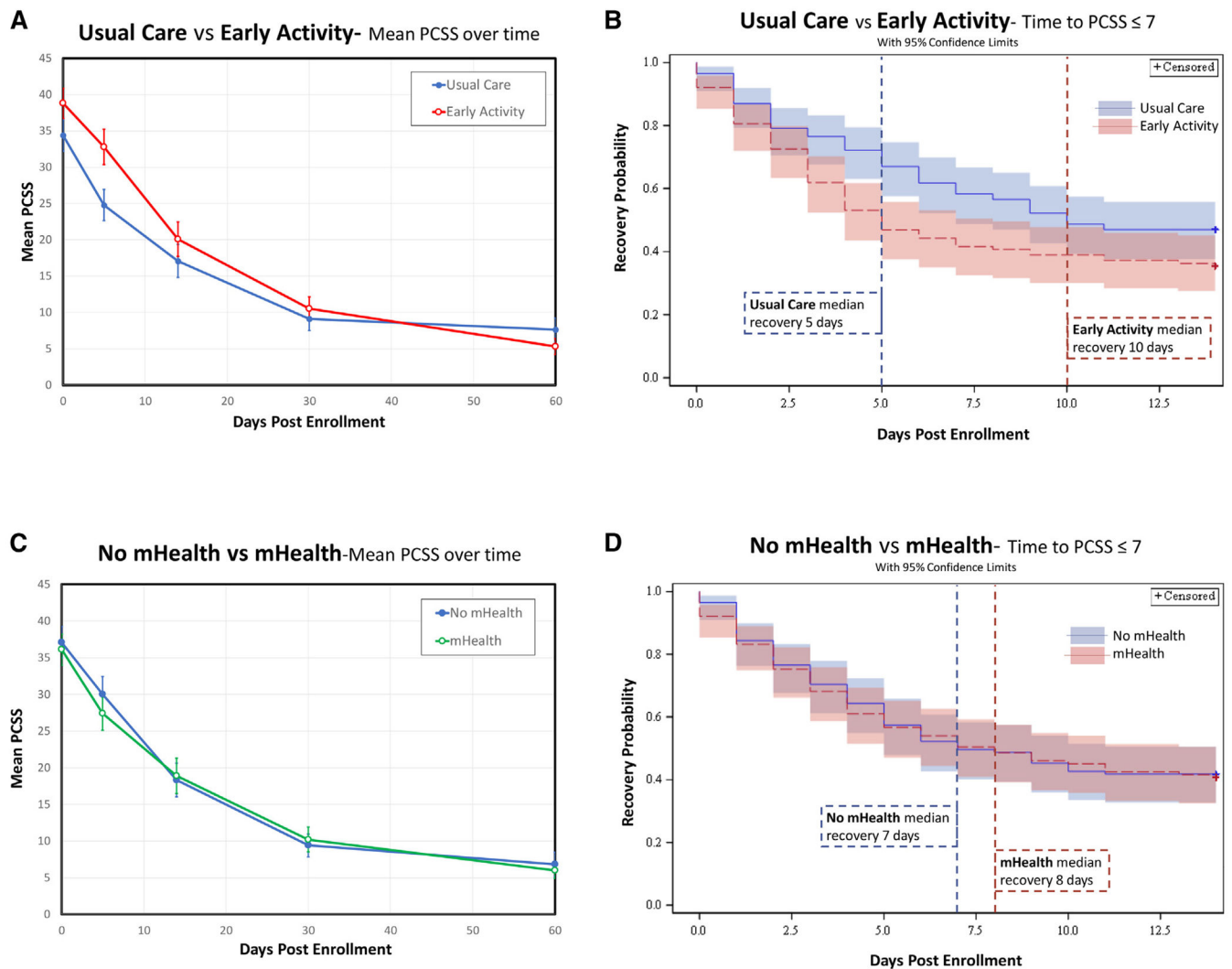


Figure 4.

A, The mean difference in PCSS over time between usual care and early activity demonstrates a difference in PCSS for the first 5 days, which is no longer statistically significant after day 14. **B**, The usual care group median symptom resolution time of 5 days compared to early activity group median symptom resolution time 10 days ($P = .03$). **C**, There were no mean differences in PCSS between the mHealth and non-mHealth teams, nor **D**, were there differences in time to symptom resolution. *mHealth*, mobile health; *PCSS*, Post-Concussive Symptoms Scale.

Table 1.

Demographics and ED variables

	All n = 235	Activity		Behavioral management	
		Usual care n = 118	Early activity n = 117	No mHealth n = 118	mHealth n = 117
Demographics					
Female sex, n (%)	114 (51)	55 (47)	59 (50)	54 (46)	60 (51)
Age, mean (SD)	14.5 (2.3)	14.6 (2.2)	14.3 (2.4)	14.5 (2.3)	14.5 (2.3)
Race					
Black; n (%)	52 (22)	25 (21)	27 (23)	22 (19)	30 (26)
White; n (%)	176 (75)	90 (76)	86 (74)	93 (79)	83 (71)
Other* ; n (%)	6 (3)	3 (3)	3 (3)	2 (2)	4 (3)
Not reported; n (%)	1 (0)	0 (0)	1 (1)	1 (1)	0 (0)
Ethnicity					
Hispanic; n (%)	22 (9)	11 (9)	11 (9)	12 (10)	10 (9)
Unknown; n (%)	12 (5)	5 (4)	7 (6)	5 (4)	7 (6)
Concussion history					
Previous concussion; n (%)	60 (26)	30 (25)	30 (26)	25 (21)	35 (30)
Unknown; n (%)	1 (0)	1 (1)	0 (0)	1 (1)	0 (0)
Mechanism of injury					
Sports; n (%)	84 (36)	36 (31)	48 (41)	46 (39)	38 (32)
Fall; n (%)	68 (29)	35 (30)	33 (28)	38 (32)	30 (26)
Motor vehicle collision; n (%)	12 (5)	6 (5)	6 (5)	5 (4)	7 (6)
Pedestrian vs motor vehicle; n (%)	2 (1)	1 (1)	1 (1)	0 (0)	2 (2)
Assault; n (%)	17 (7)	7 (6)	10 (9)	6 (5)	11 (9)
Other; n (%)	50 (21)	32 (27)	18 (15)	22 (19)	18 (24)
Unknown; n (%)	2 (1)	1 (1)	1 (1)	1 (1)	1 (1)
Presentation					
Concussion clinic; n (%)	35 (15)	12 (10)	23 (20)	18 (15)	17 (15)
Reported signs/symptoms					
PCSS, mean (SD)	36.6 (23.1)	34.4 (23.4)	38.8 (22.6)	37.1 (22.9)	36.1 (23.3)
PedsQL, mean (SD)	83.8 (14.7)	83.0 (14.4)	84.5 (15.0)	84.3 (15.0)	83.2 (14.5)

	All n = 235	Activity		Behavioral management	
		Usual care n = 118	Early activity n = 117	No mHealth n = 118	mHealth n = 117
Immediate symptoms [†] , n (%)	105 (44)	48 (41)	57 (49)	50 (42)	55 (47)
Loss of consciousness, n (%)	53 (23)	33 (28)	20 (17)	24 (20)	29 (25)
Anterograde amnesia, n (%)	77 (33)	44 (38)	33 (28)	38 (32)	39 (34)
Retrograde amnesia, n (%)	34 (14)	18 (15)	16 (14)	16 (14)	18 (15)
Seizure, n (%)	1 (0)	1 (1)	0 (0)	1 (1)	0 (0)
Acute evaluation					
Head imaging obtained, n (%)	8 (3)	4 (3)	4 (3)	4 (3)	4 (3)
Acute treatment					
Analgesic, n (%)	111 (47)	58 (49)	53 (45)	56 (47)	55 (47)
Antiemetic, n (%)	50 (21)	25 (21)	25 (21)	26 (22)	24 (21)

* Other includes: American Indian/Alaska Native, Asian, and Native Hawaiian/Other Pacific Islander.

[†] Experienced one or more of the following: dazed or stunned, confused about events, answers questions slowly, repeats questions, or forgetful.

Table II.

Primary and secondary outcomes measures

	Usual care vs early activity					mHealth vs no mHealth				
	Usual care		Early activity			No mHEALTH		mHEALTH		
	N	Mean (SD)	N	Mean (SD)	Adjusted mean difference and 95% CI	N	Mean (SD)	N	Mean (SD)	Adjusted mean difference and 95% CI
Primary outcomes										
PCSS										
Day 5	106	24.8 (22.3)	102	32.8 (24.9)	5.7 (0.6, 10.8)	103	30.0 (24.6)	105	27.4 (23.1)	-0.6 (-5.7, 4.6)
Day 14	100	17.1 (23.0)	105	20.1 (24.4)	1.4 (-4.5, 7.3)	106	18.3 (23.6)	99	18.9 (24.1)	1.7 (-4.2, 7.6)
Day 30	99	9.1 (15.9)	92	10.5 (15.7)	1.0 (-3.5, 5.4)	99	9.4 (15.3)	92	10.2 (16.3)	1.3 (-3.2, 5.7)
Day 60	92	7.6 (15.4)	89	5.3 (10.2)	-2.7 (-6.3, 1.0)	87	6.8 (15.4)	82	6.0 (9.9)	-0.7 (-4.4, 2.9)
PedsQL										
Day 14	102	80.1 (16.0)	104	81.0 (14.7)	0.02 (-3.6, 3.7)	106	81.3 (14.4)	100	79.7 (16.4)	-1.3 (-4.9, 2.3)
Day 30	99	87.8 (14.1)	91	87.7 (14.2)	-1.8 (-5.4, 1.8)	99	88.5 (12.8)	91	87.0 (15.4)	-0.7 (-4.3, 2.9)
Day 60	92	89.9 (13.2)	89	92.0 (11.3)	0.5 (-2.6, 3.4)	97	91.4 (11.3)	84	90.3 (13.5)	-0.4 (-3.4, 2.6)
Secondary outcomes										
Resolved symptoms at 14 days (PCSS ≤ 7)	N	%	N	%	Adjusted OR and 95% CI	N	%	N	%	Adjusted OR and 95% CI
Depression (BSI-18)	100	49%	105	45%	0.8 (0.5, 1.5)	106	46%	99	47%	1.1 (0.6, 1.8)
Day 30	99	1.2 (2.8)	91	1.2 (2.4)	-0.1 (-0.7, 0.5)	99	1.2 (2.8)	91	1.2 (2.3)	-0.2 (-0.7, 0.6)
Day 60	92	1.3 (2.8)	89	0.9 (2.2)	-0.5 (-1.2, 0.2)	97	1.1 (2.5)	84	1.1 (2.6)	-0.1 (-0.8, 0.6)
Anxiety (BSI-18)	N	Mean (SD)	N	Mean (SD)	Adjusted mean difference and 95% CI	N	Mean (SD)	N	Mean (SD)	Adjusted mean difference and 95% CI
Day 30	99	1.4 (2.9)	91	1.3 (2.7)	-0.5 (-1.2, 0.2)	99	1.5 (2.8)	91	1.3 (2.7)	-0.1 (-0.8, 0.5)
Day 60	92	1.3 (2.6)	89	0.8 (1.8)	-0.7 (-1.3, -0.5)	97	1.1 (2.4)	84	1.0 (2.0)	-0.2 (-0.8, 0.4)
Vestibular (VOMS)	N	Mean (SD)	N	Mean (SD)	P values	N	Mean (SD)	N	Mean (SD)	P values
Day 0 (baseline) Total score	92	79.7 (64.9)	84	86.7 (62.5)	.47	92	80.1 (68.5)	84	86.3 (58.2)	.50
Day 14 Total score	73	24.2 (41.9)	78	30.6 (47.0)	.37	75	28.9 (50.6)	76	26.0 (37.8)	.70
Balance (mBESS)	N	Mean (SD)	N	Mean (SD)	P values	N	Mean (SD)	N	Mean (SD)	P values
Day 0 (baseline) Total score	92	6.2 (4.0)	88	6.4 (4.2)	.60	93	6.3 (3.8)	87	6.3 (4.4)	.97
Day 14 Total score	73	4.7 (2.6)	76	6.1 (4.1)	.02	74	5.6 (3.3)	75	5.2 (3.7)	.43
Neurocognitive (ImpACT QT)	N	Mean (SD)	N	Mean (SD)	P values	N	Mean (SD)	N	Mean (SD)	P values

	Usual care vs early activity				mHealth vs no mHealth			
	Usual care		Early activity		No mHEALTH		mHEALTH	
Day 0 (baseline) Attention (%ile)	114	17.5 (3.3)	112	16.5 (5.0)	112	17.2 (4.1)	114	16.9 (4.4)
Day 0 (baseline) Motor spd (%ile)	114	14.2 (5.2)	112	13.2 (4.4)	112	13.7 (4.8)	114	13.7 (4.9)
Day 0 (baseline) Memory (%ile)	114	8.4 (3.1)	112	8.7 (2.8)	112	8.7 (2.8)	114	8.5 (3.0)
Day 14 Attention (%ile)	72	18.3 (2.8)	66	18.2 (2.6)	69	18.2 (2.9)	69	18.3 (2.5)
Day 14 Motor spd (%ile)	72	15.8 (5.4)	66	16.1 (5.3)	69	15.6 (5.2)	69	16.2 (5.5)
Day 14 Memory (%ile)	72	10.4 (2.3)	66	9.6 (2.7)	69	9.8 (2.8)	69	10.3 (2.2)

Baseline scores are presented in italics. Statistically significant differences are presented in bold.