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Using mobile health to expedite access to specialty care for youth presenting to the emergency department with concussion at highest risk of developing persisting symptoms: a protocol paper for a non-randomised hybrid implementation-effectiveness trial

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ABSTRACT

Introduction Paediatric concussion is a common injury. Approximately 30% of youth with concussion will experience persisting postconcussion symptoms (PPCS) extending at least 1 month following injury. Recently, studies have shown the benefit of early, active, targeted therapeutic strategies. However, these are primarily prescribed from the specialty setting. Early access to concussion specialty care has been shown to improve recovery times for those at risk for persisting symptoms, but there are disparities in which youth are able to access such care. Mobile health (mHealth) technology has the potential to improve access to concussion specialists. This trial will evaluate the feasibility of a mHealth remote patient monitoring (RPM)-based care handoff model to facilitate access to specialty care, and the effectiveness of the handoff model in reducing the incidence of PPCS.

Methods and analysis This study is a non-randomised type I, hybrid implementation-effectiveness trial. Youth with concussion ages 13–18 will be enrolled from the emergency department of a large paediatric healthcare network. Patients deemed a moderate-to-high risk for PPCS using the predicting and preventing postconcussive problems in paediatrics (5P) stratification tool will be registered for a web-based chat platform that uses RPM to collect information on symptoms and activity. Those patients with escalating or plateauing symptoms will be contacted for a specialty visit using data collected from RPM to guide management. The primary effectiveness outcome will be the incidence of PPCS, defined as at least three concussion-related symptoms above baseline at 28 days following injury. Secondary effectiveness outcomes will include the number of days until return to preinjury symptom score, clearance for full activity and return to school without accommodations. The primary implementation outcome will be fidelity, defined as the per cent of patients meeting specialty care referral criteria who are ultimately seen in concussion specialty care. Secondary implementation outcomes will include patient-defined and clinician-defined appropriateness and acceptability.

Ethics and dissemination This study was approved by the Institutional Review Board of the Children's Hospital of Philadelphia (IRB 22-019755). Study findings will be published in peer-reviewed journals and disseminated at national and international meetings.

Trial registration number NCT05741411.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Recruitment from the emergency department will allow for the enrolment of a socioeconomically and demographically diverse sample of youth with concussion.
⇒ Using both the daily chat and phone, text and email follow-up will serve to maximise retention to assess outcomes.
⇒ The mixed methods approach with qualitative interviews will allow a comprehensive assessment of the acceptability and appropriateness of the intervention.
⇒ It is possible that clinicians and/or patients do not find our novel care pathway either acceptable or appropriate, impacting utilisation and our effectiveness assessment.
⇒ Some participants may be seen in concussion specialty care outside of our network, making it difficult to evaluate the effectiveness of our intervention without knowing the management strategies employed by outside specialists.

INTRODUCTION

Nearly 2 million paediatric concussions occur each year.[1] Outcomes following

youth concussion can vary depending on the mechanism of injury, symptom profile and interventions prescribed. Approximately 30% of youth with a concussion experience persisting postconcussion symptoms (PPCS), defined as symptoms that persist beyond 28 days following injury.[2 3] Prolonged recovery times can impact many domains, including academic performance, mental health, and visual and motor functions.[4–6] Recently, several important advances in concussion care, in particular, moving away from a passive strategy of rest to a more active management approach, have been evaluated. These include the prescription of targeted aerobic exercise therapy[7 8] and visio-vestibular training programmes.[9 10] There is evidence that seeing a concussion specialist, who can prescribe and monitor these multimodal approaches, early in the recovery course can reduce time to symptom resolution, particularly for those at risk for experiencing persisting symptoms.[11–13] For example, a study of 12–22-year-olds presenting to a US sports medicine medical care setting demonstrated that adolescents and young adults seen in concussion specialty care within 7 days were nearly six times less likely to experience extended recovery than those who presented 1–3 weeks postinjury.[11]

Unfortunately, not every concussion patient who would benefit from early specialty care has access to concussion specialist. Prior studies have demonstrated that the vast majority of youth with concussion are evaluated in acute or primary care, rather than specialty care, settings.[14] Follow-up from these care settings can be challenging for youth with concussion; fewer than 50% of patients with concussion initially seen in an emergency department (ED) have any follow-up visit with another medical provider.[15 16] The inconsistent follow-up is not evenly distributed across youth with concussion, however. Among patients evaluated for concussion by their primary care provider, non-Hispanic Black youth and those with public insurance are less likely to be able to complete care recommendations.[17] Disparities extend to access to concussion specialty care. An evaluation of location whereby patients with concussion enter into the healthcare system across a regional healthcare network found that specialty care patients are more likely to be non-Hispanic White (compared with non-Hispanic Black or Hispanic) and have private (compared with public) insurance.[14] While such disparities exist across multiple areas of specialty care in paediatrics in general, some appear to be more pronounced in concussion; when compared with musculoskeletal injuries, Hispanic and publicly insured youth with concussion are less likely to be evaluated by a specialist.[18] Thus, there is a critical need for improved access to specialty care for youth with concussion evaluated in ED settings, particularly those at risk for developing persisting symptoms.

Mobile health (mHealth) and remote patient monitoring (RPM) are digital strategies that represent avenues to begin addressing these issues. Previous work from our team has demonstrated the feasibility of using RPM to track patients with concussion from the ED setting. In a pilot study using an mHealth RPM tool to track daily concussion symptoms and physical activity, we found that >90% of adolescents interacted with the mHealth tool, with >75% responding to prompts on at least 14 of 21 study days.[19] Particularly with the emergence of telehealth as a method to remotely evaluate patients with concussion,[20–22] mHealth has the potential to begin to bridge equity gaps in concussion specialty care access. In other disease entities, mHealth has been shown to improve patient communication and outcomes[23 24]; however, such an approach has yet to be evaluated for youth concussion.

Therefore, the goal of this study is to evaluate the effectiveness (hastened recovery times) and feasibility (fidelity in connecting to concussion specialty care) of a novel mHealth intervention, designed to reduce disparities in access to specialty care through the use of RPM to facilitate care hand-off from ED to concussion specialty care. This move from a passive 'push' referral process, where the burden is on the patient to schedule follow-ups and appointments are scheduled without attention to the risk of PPCS, to an active 'pull' process, where the care team receives real-time data on symptoms and can target and prioritise concussion specialty care, represents a radical shift in the approach to concussion care. We hypothesise that the mHealth intervention will have high fidelity (>75% of patients meeting specialty care referral criteria will engage with the concussion specialist team) and compared with historical controls, improved effectiveness in mitigating concussion symptoms (a reduction in the incidence of PPCS).

METHODS AND ANALYSIS

Patients and population

Study procedures are reported in line with the SPIRIT statement for clinical trials (see online supplemental file 1).[25] The study will enrol from March 2024 through approximately March 2026. Study participants will be recruited from the ED of the Children's Hospital of Philadelphia (CHOP) healthcare network (see figure 1 for flow diagram of enrolment). The CHOP ED is located in urban west Philadelphia, with a diverse patient population; of those diagnosed with concussion, approximately 70% of patients are under-represented minorities (including non-Hispanic Black and Hispanic youth), 50% are publicly insured and 50% are female.[14 26] All participants will be aged 13–18, own a smartphone, present with a head injury that meets the criteria for concussion as defined by the sixth International Consensus Statement on Concussion in Sport[27] and present within 72 hours of injury to be eligible. Of note, prior research has shown that 95% of adolescents possess smartphones, without differences by race, ethnicity or sociodemographic status (specifically, 93% of teenagers in lowest-income households possess smartphones).[28] Those with evidence of moderate or severe traumatic brain injury (including Glasgow Coma Scale score <13 and findings of intracranial

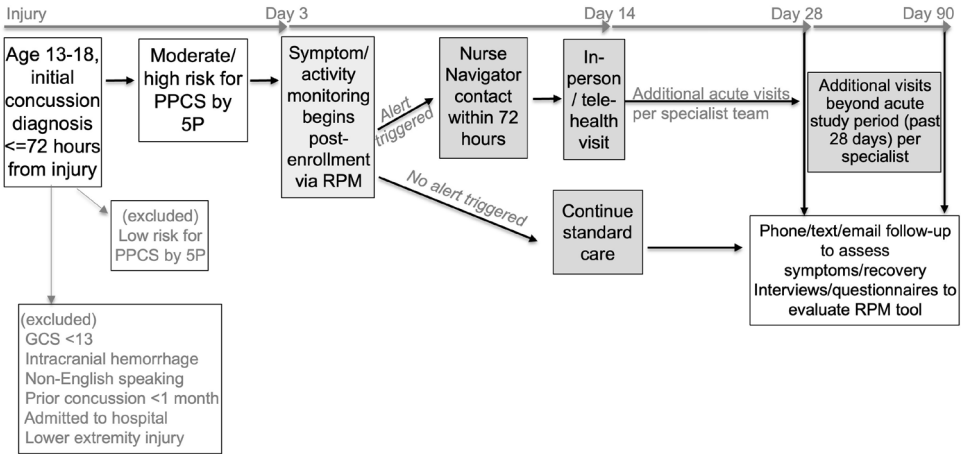

Figure 1 Flow diagram of patient enrolment and procedures 5P, predicting and preventing postconcussive problems in paediatrics; ED, emergency department; GCS, Glasgow Coma Scale; PPCS, persisting postconcussion symptoms; RPM, remote patient monitoring.

haemorrhage on neuroimaging), non-English speaking participants, those with a prior concussion within the preceding month, those admitted to the hospital, those with lower extremity injury precluding aerobic activity and those previously enrolled in the study will be ineligible. Following an initial screening, patients will be risk stratified using the predicting and preventing postconcussive problems in paediatrics (5P) risk stratification model, a rule for PPCS derived and validated across multiple North American EDs and concussion programmes.[2 3 29] The rule stratifies youth with concussion to low, moderate and high risk for PPCS; in light of the high sensitivity of those deemed to be low risk (>90%) in excluding PPCS,[2] those designated as low risk by 5P will also be excluded. Participant/parent informed consent and child assent (where appropriate) and HIPAA authorisation will be obtained prior to study enrolment by research team members. Enrolment is planned to begin in March of 2024.

Intervention

Study participants will enrol in a secure, web-based chat platform to complete study procedures. Following enrolment, the platform sends a link daily (either via text message or email with the method chosen by the participant) to participants containing a secure, HTML-based chat. The chat guides participants through completing the Postconcussion Symptom Inventory (PCSI), a scale of 21 concussion-related symptoms that participants rate on a 7-point Likert scale ranging from 0 (not a problem) to 6 (severe problem), for a total symptom score of 0–132.[30] Additionally, the chat asks the participant questions on sleep, medication utilisation and daily activity. Participant responses are integrated into the electronic health record (EHR) of our healthcare system. Alerts are triggered by the symptom information entered, based on findings such as a high overall total symptom score, an increasing total symptom score, a plateauing total symptom score or a high emotional symptom subcomponent of the PCSI. The triggering of an alert immediately notifies the concussion specialty care team, who will subsequently reach out to the family to obtain further information about the clinical course and schedule a specialty care visit. Using information from symptom trajectory, physical activity, cognitive activity, sleep activity, as well as patient/family preference and/or geographic location, the specialty team will schedule a visit with a CHOP concussion specialist either via telehealth or in-person (at locations that include urban and suburban clinics). Beyond obtaining symptom and activity information, the chats will also serve to provide reminders related to the benefit of light aerobic activity, appropriate use of analgesics, sleep and cognitive activity. At the end of each chat, participants are reminded of the phone number and hours of the CHOP specialty care concussion call centre if needed. Participants will receive links to the chats daily for up to 28 days after enrolment. If the participant is cleared by a clinician, or goes 14 days without triggering a flag that would warrant specialty evaluation, they will no longer be asked to complete daily chats (see figure 1).

A Study Safety Committee comprised of three physicians (DJC, CLM, JJZ) and the lead research coordinator will monitor all participants during the study. An alert will occur if total symptom score for these patients increases by either 20 points (on a scale of 0–132) or 20% in a single day, or continuously increases on 3 consecutive days. Given our previous work, we expect daily symptoms to fluctuate within a 20-point range in this period.[19 31] Symptom profiles will then be reviewed, and the subject will be promptly contacted for additional evaluation. A symptom-based score of risk factors for increased intracranial pressure (headache, vomiting and mental status change) will also be calculated,[32] and an increase in that score by >20% on a single day will prompt additional evaluation. Since the study procedures are not greater than minimal risk, serious adverse events are not expected. If any unanticipated problems related to the research involving risks to participants or others happen during the course of this study, they will be reported to the CHOP

Institutional Review Board (IRB) in accordance with IRB guidelines.

Following the acute study period, semi-structured interviews will be conducted with patient/parent dyads. All participants will be offered the opportunity to participate in the interview until thematic saturation is reached. We anticipate enrolling 30 dyads to achieve saturation in themes identified by participants.[33] During these interviews, open-ended questions will assess facilitators and barriers to the RPM-facilitated referral model within the range of categories of health determinants, focused on the individual (using RPM to increase engagement and symptom awareness) and healthcare system (RPM and mHealth to reduce access barriers) levels.[34] To assess the appropriateness and acceptability of risk stratification and utilisation of the RPM tool at the provider level, semi-structured interviews will be conducted with both paediatric ED and concussion specialty providers (including attending physicians and advanced practice providers) following the completion of the enrolment period. Providers will be recruited via email. Interviews will be conducted using techniques developed by Sitting and Singh surrounding communication and organisational and human factors related to technology implementation, using multiple sociotechnical model dimensions.[35] We expect enrolling 30 providers (approximately 20 ED and 10 specialists) to achieve thematic saturation.[33]

Variables and outcomes

We will collect the following demographic and historical variables on enrolment via patient and/or caregiver self-report as well as from the EHR: injury mechanism, age at injury, biologic sex, self-identified race and ethnicity, concussion history and co-morbid conditions associated with PPCS, including anxiety, depression, migraine history, somatization disorders, attention deficit hyperactivity disorder, learning disabilities and motion sickness.[36–38] Insurance status and child opportunity index (COI) scores will be abstracted from the EHR as neighbourhood measures of socioeconomic status and opportunity.[39] On enrolment, a preinjury PCSI will be collected for outcome determination, in line with previous predictive studies of PPCS.[2] In addition to daily PCSI scores collected during the study period via RPM, we will collect information daily on physical activity (amount of exercise performed), cognitive activity, sleep and analgesic medication use.

As a type I, hybrid implementation-effectiveness study, the study will have both effectiveness and implementation aims; this study design was chosen given the lack of knowledge of both the improvement in symptom burden that results from and the feasibility of obtaining early referral to specialty care.[40] The primary effectiveness outcome of this study is the incidence of PPCS, defined as the presence of at least three concussion-associated symptoms (from the PCSI) above baseline at 28 days following injury.[2 3] Regardless of participation in RPM chats, at 28 days, all participants will be contacted by either phone, text message or email to complete a PCSI, which will be compared with the preinjury PCSI score. Secondary effectiveness outcomes include number of days until return to baseline (preinjury) symptom score, number of days until clearance for full/unrestricted activity and number of days until return to school without accommodations. These will be assessed at the 28-day follow-up; for those who have not yet met all recovery criteria, a 90-day follow-up also be performed to assess symptom, activity and school return/recovery. The primary implementation outcome will be fidelity, defined as the per cent of patients meeting criteria for referral to specialty care who ultimately are seen by the concussion specialty team, at either an in-person or telemedicine visit. Secondary implementation outcomes include appropriateness (the perceived fit of a new practice),[41 42] assessed using the System Usability Scale,[43] and acceptability (the perception that an innovation or practice is agreeable),[41 42] assessed using a Technology Acceptance Model (TAM)-derived questionnaire.[44] Appropriateness and acceptability will also be assessed among participants, guardians and clinicians (including ED and concussion specialty care) via semi-structured interviews.

Statistical analysis and power calculation

Our primary effectiveness outcome, the incidence of PPCS, will be presented as a proportion with a 95% CI. We will compare the incidence of PPCS in our sample, via one-sided Wald testing,[45] to that of a population estimate in those meeting 5P criteria for moderate-to-high risk, in both patients previously evaluated for concussion across our healthcare system (from the Minds Matter Concussion Registry)[26 46 47] and the sentinel 5P data.[2] We anticipate the PPCS incidence in our control comparison groups to be between 30% and 35%.[2 48] Over 2 years of enrolment, we plan to enrol approximately 150 participants. With 80% power, a significance level of 0.05, using a one-sided Wald test with a null incidence of 30%, we would be able to detect a 9% decrease in the incidence of PPCS in our intervention group. In our pilot study of RPM from the ED, approximately 77% of subjects responded to prompts on at least 14 of 21 days[19]; if we use a similar rate to estimate those who will be lost to follow-up, we will be powered to detect a 10% decrease in the incidence of PPCS (approximately 20% incidence of PPCS in the intervention group). This decrease is in line with interventional trials evaluating the effectiveness of early, targeted, active management of concussion.[7] Following marginal bivariate analyses, we will plan to conduct a multivariate logistic regression evaluating the effect on the incidence of PPCS of injury, sociodemographic and neighbourhood-level economic variables, including race, ethnicity, sex, insurance, mechanism of injury and COI, as well as known factors associated with PPCS, including age, concussion history and co-morbid conditions.[36 38] Secondary effectiveness outcomes, including days until return to symptom baseline, clearance for full activity and return to school without accommodations will be

compared with historical control data using Wilcoxon Rank Sum tests, assuming non-linearity of the recovery times.[38] Missing data (under a Missing at Random assumption) for symptom score in determining PPCS will be handled using multiple imputation via logistic regression, where results are pooled over different imputed datasets using Rubin's rule.[49 50] In each case, sensitivity analyses will compare complete-data-only model fits to imputed data model fits.

Our primary implementation outcome, fidelity, will be presented as a proportion with a 95% CI. Based on our pilot study, we will assume approximately 67% of enrolled participants will be flagged for specialty evaluation.[19] If we assume a similar rate of interaction with our RPM tool as in our pilot study, using an alpha of 0.05, enrolling a sample of 150 participants (100 of whom would meet a flag to see specialty care), would allow us to detect the true proportion of fidelity with a 8% margin of error.[51] In addition to our point estimate, we will perform a multivariate logistic regression evaluating the effect on fidelity of injury, sociodemographic and neighbourhood-level economic variables, including race, ethnicity, sex, insurance, mechanism of injury and COI. For our secondary implementation outcomes, results from the SUS and TAM scores will be presented as means or medians, where appropriate. Qualitative data from semi-structured interviews will be analysed using a grounded theory approach, including segmenting and developing coding schemes, following an iterative process of running text queries and code revision for final thematic identification.[52 53]

Changes to initial protocol

Based on discussion from initial team meetings, following the initial protocol development but prior to the commencement of participant enrolment, we made two minor changes to the protocol. We had initially planned to recruit for the study from both primary care and ED sites; however, due to feasibility issues, we decided to enrol exclusively from the ED. In addition, to ensure capture of study endpoints in as many participants as possible, we decided to add an additional follow-up contact, at 90 days, for those participants who did not meet recovery as defined by the three secondary effectiveness outcomes. These changes are reflected in the current clintrials.gov record.

In summary, data from this trial will be critical in evaluating a promising intervention for decreasing the incidence of PPCS by reducing barriers to access to concussion specialty care clinicians, who can provide the most advanced concussion treatments for those patients at the highest risk of experiencing care inequities and persisting symptoms following youth concussion.

Patient and public involvement statement

The study intervention was based on pilot data collected from concussed adolescents presenting for acute care. In addition, we conducted cognitive interviews with adolescent patients with concussion to obtain feedback on the question structure in the RPM chat. Finally, feedback from study participants (including adolescents and their guardians) and clinicians across multiple disciplines will be elicited through questionnaires and qualitative interviews to assess the acceptability and appropriateness of our intervention.

ETHICS AND DISSEMINATION

This study was approved by the IRB of the Children's Hospital of Philadelphia (IRB 22–019755) (online supplemental file 1). Study findings will be published in peer-reviewed journals and disseminated at national and international meetings.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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