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Rest Evaluation for Active Concussion Treatment (ReAct) Protocol: a prospective cohort study of levels of physical and cognitive rest after youth sports-related concussion

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ABSTRACT

Introduction Although current guidelines for the early clinical management of sports-related concussion (SRC) call for a gradual return-to-activity, the optimal level of rest needed to promote recovery remains unknown. This paper describes the protocol of the Rest Evaluation for Active Concussion Treatment (ReAct) study which objectively measures physical and cognitive rest following SRC and its relation to recovery among youth athletes.

Methods and analysis Youth athletes aged 11–17 years are recruited preinjury and enrolled within 72 hours following a physician-diagnosed concussion. Injury information and acute clinical presentation are assessed at the time of injury. Youth participants are prospectively followed to objectively monitor daily physical and cognitive rest using two electronic devices: ActiGraph (to measure physical rest and sleep) and Narrative Clip (to measure cognitive rest), along with self-reported postconcussive symptoms using daily surveys. Other concussion outcomes, including functional outcomes, are assessed by surveying youth and their parents at three time points: (1) within 72 hours of injury, (2) at day 7 postenrolment and (3) at symptom resolution (or a maximum of 45 days postconcussion).

Ethics and dissemination This study has received ethical approval from the Institutional Review Board (IRB) at the participating institution (IRB at Nationwide Children's Hospital, IRB16-00613). The results of the study will be presented at national and international scientific conferences and published in peer-reviewed journals.

INTRODUCTION

Sports-related concussion (SRC) is a major public health problem in the United States, affecting approximately two million children each year.[1–3] Concussions can temporarily disrupt brain function and result in detrimental effects on youths' developing brains, which may affect their short- and long-term physical, cognitive, emotional and sleep health.[4–6] In most children, concussion symptoms resolve within one to 3 weeks post-injury.[6] However, evidence suggests that up to one-third of concussed children exhibit persistent postconcussion symptoms or other functional impairments which can last months to years after injury.[7–10] Current guidelines for the early clinical management of SRC call for a brief period of rest during the acute phase (24–48 hours) postinjury, followed by a gradual and progressive increase in activities while staying below cognitive and physical symptom-exacerbation thresholds (ie, activity level should not bring on or worsen symptoms).[11–13] However, these guidelines are not strongly evidence-based.

Animal models of concussion have shown that a period of rest immediately following concussion is beneficial as it reduces physical

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Strengths and limitations of this study

► This study fills critical knowledge gaps by objectively monitoring both physical and cognitive rest/activity among youth following a sports-related concussion.

► The study design allows for the gathering of data on physical and cognitive rest and other study measures within 72 hours of injury.

► Cutting-edge computer techniques are used to match the data collected by an ActiGraph and Narrative Clip, which minimises data processing time.

► Quantifying cognitive rest is challenging, although data on cognitive activities are documented.

► The cognitive activities participants engage in during school hours are not measured due to privacy concerns of wearing the Narrative Clip at school.

and cognitive demands and frees up energy for significantly increased metabolic needs during recovery.[14–18] Evidence from humans suggests that engaging in high levels of physical activity prematurely after a concussion can exacerbate symptoms, increase symptom duration and lead to greater neurocognitive and functional impairments.[19–23] However, emerging research has begun to highlight the potential benefits of both moderate physical and cognitive activity postconcussion.[24–27] A recent randomised controlled trial (RCT) of 88 individuals with concussion (aged 11–22 years) treated in a paediatric emergency department (ED) showed that 5 days of prescribed strict rest did not offer additional benefits compared with prescribed standard care.[28] In fact, Thomas and colleagues (2015) found that 5 days of 'complete' rest (ie, avoidance of all physical and cognitive activities) following a concussion could exacerbate symptoms.[28] Others have reported that a period of 'complete rest' postconcussion may be impractical or unnecessary for some individuals.[28–30] However, the optimal level and timing of postinjury physical and cognitive rest needed to promote recovery is unknown.[9 11]

Previous studies that measured physical and cognitive rest postconcussion have been limited by the use of self-report data.[19–22] Some studies have only measured prescribed rest while others have failed to distinguish between physical and cognitive rest.[19–22] The definition of physical and cognitive rest used in previous studies has also varied widely, from complete rest to decreased duration and frequency of cognitive and physical activities.[19–21] A comprehensive, prospective study using objective measures is necessary to identify the optimal level of physical and cognitive rest for youth after SRC, so that individually tailored and effective care can be provided to these youth.[31–33]

Objectives

The aims of the Rest Evaluation for Active Concussion Treatment (ReAct) study are to: (1) objectively measure the levels of physical and cognitive rest following SRC, (2) describe levels of physical and cognitive rest in relation to postconcussion symptoms and functional outcomes (ie, functional disability and quality of life) and (3) examine such relationship among youth with high- versus low-risk concussions (defined based on initial symptom and likelihood of prolonged recovery).[34 35] We hypothesise that the relationship between levels of physical and cognitive rest and postconcussion symptoms and functional outcomes will be curvilinear (eg, U-shaped), such that youth engaging in optimal levels of physical and cognitive rest following SRC will experience less severe postconcussion symptoms and functional outcomes as compared with youth whose level of rest is below or above the optimal level. We also hypothesise that postinjury levels of physical and cognitive rest will be more strongly related to postconcussion symptoms and functional outcomes among youth with high-risk concussions than among those with

low-risk concussions. This paper is a description of the methods to address these hypotheses.

METHODS

Study design and overview

The ReAct study uses a prospective cohort design, with repeated measures. Eligible youth aged 11–17 years and a parent/legal guardian ('parent') are invited to participate in the study either preinjury during preseason team meetings or following a concussion. Youth and parents ('dyads') are screened for study eligibility following their physician-confirmed SRC, and then enrolled after providing written assent and consent, respectively (figure 1).

Injury information and acute clinical presentation (signs and symptoms, mental status, balance, neuropsychological function) are assessed at the time of injury or at the time of the initial clinic visit as part of routine clinical care. Participants are followed throughout their recovery by a trained research team member ('researcher'), and complete assessments of postconcussion symptoms, functional outcomes and other study outcomes (eg, quality of life) at three time points: (1) within 72 hours of injury (assessment 1), (2) 7 days after enrolment (assessment 2) and (3) at symptom resolution or 45 days postinjury (assessment 3), whichever occurs first (figure 1). Symptom resolution is defined as being symptom-free or as having symptoms return to premorbid levels as confirmed by a certified athletic trainer (AT) or physician. Physical and cognitive rest (the inverse of activity) are monitored for a 7-day period following the first assessment using two electronic devices: an ActiGraph and a Narrative Clip. The ActiGraph (with an accompanied heart rate sensor) records 24 hours physical activity (eg, steps) and sleep cycles. The Narrative Clip records daytime activity (outside of school time) by taking a photo every 30 s, allowing us to code their cognitive activities. Additionally, youth participants complete a hard-copy or online daily survey, which assesses their physical and cognitive activities, postconcussion symptoms and pain throughout their enrolment in the study.

The first assessment lasts about 1 hour, and the two follow-up assessments last about 30 min each. Most measures, described below, are drawn from the National Institutes of Health Common Data Elements for Paediatric Traumatic Brain Injury and Sports-related Studies.[36] The study began on 1 September 2016 and will end on 31 August 2019.

Study population

Youth aged 11–17 years must have sustained a direct or indirect force(s) to the brain during an organised or recreational sport activity, and received a physician-confirmed diagnosis of concussion.[11 37] The dyad must be able to meet a researcher within 72 hours of injury.

Youth are excluded if any of the following apply: (1) the concussion occurred during participation in a
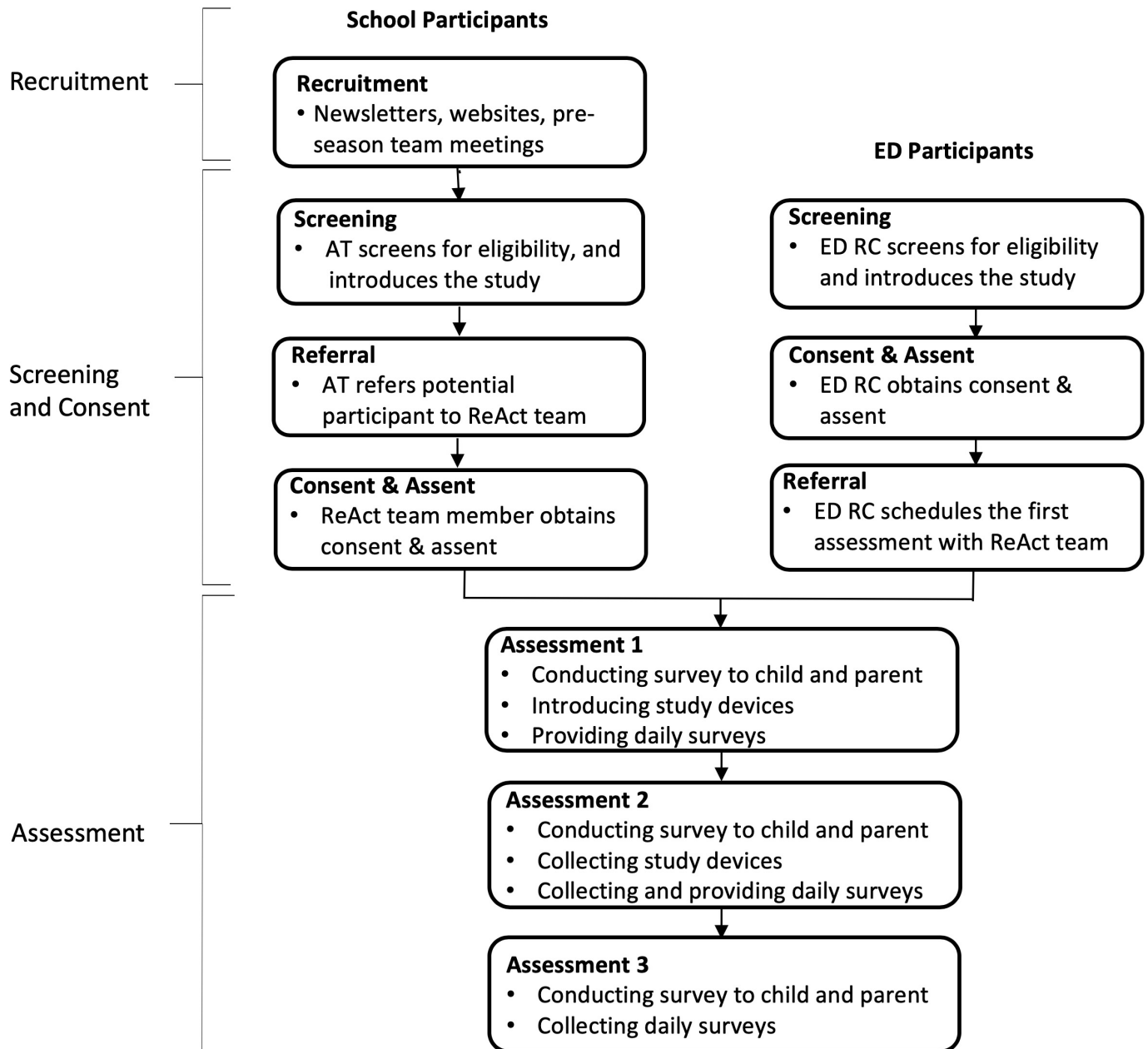
School Participants

Recruitment

> **Recruitment**
> • Newsletters, websites, pre-season team meetings

ED Participants

Screening and Consent

> **Screening**
> • AT screens for eligibility, and introduces the study

> **Screening**
> • ED RC screens for eligibility and introduces the study

> **Referral**
> • AT refers potential participant to ReAct team

> **Consent & Assent**
> • ED RC obtains consent & assent

> **Consent & Assent**
> • ReAct team member obtains consent & assent

> **Referral**
> • ED RC schedules the first assessment with ReAct team

Assessment

> **Assessment 1**
> • Conducting survey to child and parent
> • Introducing study devices
> • Providing daily surveys

> **Assessment 2**
> • Conducting survey to child and parent
> • Collecting study devices
> • Collecting and providing daily surveys

> **Assessment 3**
> • Conducting survey to child and parent
> • Collecting daily surveys

Figure 1. Overview of Study Procedures

Figure 1 Overview of study procedures. AT, athletic trainer; ED, emergency department; RC, research coordinator; ReAct, Rest Evaluation for Active Concussion Treatment.

non-sports-related activity (eg, motor vehicle crash, fall), (2) individuals with multiple trauma (eg, face, neck injury, broken bone(s)), (3) the concussion involved a penetrating injury, (4) the child requires neurosurgical intervention or hospital admission, (5) the injury was associated with illicit drug or alcohol use, (6) the child has an associated injury that is likely to interfere with neuropsychological testing (eg, injury that affects eyesight) or (7) the participant is physically unable to wear the study devices. Designated physicians review potential participants' information to ensure that they meet the study eligibility criteria.

Study procedures
Recruitment and consent
Participants recruited from middle schools and high schools
Youth are identified at three middle schools and 15 high schools, all of which have contracts for athletic training services with Nationwide Children's Hospital (NCH). All ATs in these schools are NCH employees and some also work at NCH concussion clinics.

ReAct study information (ie, study email address, phone number, other contact information) is distributed via participating schools' newsletters, on NCH's and participating schools' websites, and at preseason

team and parent meetings. At preseason team and parent meetings, our research team presents a brief overview of the study to students, parents and coaches. Soon after a physician-confirmed diagnosis of concussion, school ATs, who have been trained on study protocols, reintroduce the study to potential participants and then notify our research team if the family is interested. A researcher then contacts the family to confirm eligibility, and schedules an in-person meeting with the concussed youth and a parent within 72 hours of injury at a location that is convenient for the child and parent (eg, clinic, participant's home, school or library). During this initial meeting, the researcher answers any questions, obtains informed written consent and assent from the youth and parent, respectively, and completes enrolment procedures and the first assessment.

Participants recruited from ED

Prospective participants are identified from youth who present to the ED at NCH and receive a physician-confirmed diagnosis of SRC. ED recruitment started in 25 April 2017 to help increase enrolment of study participants within 72 hours of injury. Soon after a physician-confirmed diagnosis of SRC, an ED clinical research coordinator, who has been trained on study protocols, screens for eligibility and introduces the study to eligible participants. The ED clinical research coordinator obtains written informed consent and assent from those interested in participating, completes enrolment procedures, schedules the first assessment within 72 hours of injury and provides the research team with the contact information of the enrolled participant and their preferred method of contact via a secure email. A member of the ReAct research team then contacts the family to confirm the date, time and location of the first assessment.

Data collection

During the first assessment, conducted in-person within 72 hours of injury, the researcher administers the first survey to the youth and the parent. The survey asks about demographic information of the dyad, postinjury concussion symptoms and functional outcomes of the youth, and postinjury events (eg, return to school, return to play [RTP]). In addition, the parent is asked to retrospectively rate the premorbid functioning of the youth.

Following the completion of the survey, the family is provided with the two study devices (Narrative Clip and ActiGraph with the accompanied heart rate sensor, see description below) and a laptop computer. The researcher activates the devices and shows the dyad how to use them. The ActiGraph is initialised based on the participating youth's height, weight, age and preferences for wearing the device (ie, wrist vs ankle, left vs right side, dominant vs non-dominant hand/foot). After the ActiGraph is initialised, it automatically connects to the heart rate sensor (which the participant

is instructed to wear around their torso) via Bluetooth. The youth participant is instructed to wear these waterproof devices 24 hours a day for the next 7 days. Next, the Narrative Clip and its use are explained to the participating youth and his/her parent. Specifically, the youth participant and the parent are shown how to wear the Narrative Clip with the custom-designed headband, and how to connect the Narrative Clip to the laptop via a universal serial bus (USB) cable. The youth participant and the parent are instructed to do this each night. Once the Narrative Clip is connected to the laptop, the data (ie, photographs) are automatically uploaded to the computer and the Narrative Clip begins to charge. Additionally, the youth is instructed to complete a daily survey each night, either online via REDCap or a pen-and-paper survey, based on his/her personal preference. The daily surveys include questions about activities related to the sport in which the injured youth is returning to soon after recovery, as well as physical and cognitive rest and postconcussion symptoms. At the end of the first assessment, the youth participant and parent receive detailed written instructions regarding their daily study responsibilities and the contact information of the researcher if they have questions. A researcher contacts the family within 48 hours of the first assessment to see how the participant is feeling and to ensure device use is going smoothly.

Seven days after the first assessment, the researcher meets with the participating family to complete the second assessment. During this assessment, the dyad completes a survey, with similar questions to the first survey, and returns the study devices. The youth participant is instructed to continue completing daily surveys until symptom resolution. After data are downloaded, the study devices are reset (wiped of all data and photographs) by a designated information technology professional at NCH, sanitised and made available for future participants.

Once the youth's symptoms resolve or they reach 45 days postinjury, whichever occurs first, the dyad complete the third and final assessment that includes the completion of a survey with similar questions as the two previous surveys.

To ensure data quality and participant compliance, the researcher frequently checks-in with the participating family to ensure that there are no problems with completing the daily surveys and the uploading of photographs to the computer. The daily surveys also include a prompt for participants to upload the data from the Narrative Clip to the computer. To encourage participant compliance, participants are compensated (eg, gift cards) for completing assessments, device usage, photograph upload and daily survey completion.

Study variables and measures

Study variables and measures included in this study organised by the data source, time and method of data collection are summarised in table 1.

Table 1 Measures organised by domain, location of assessment, source of data and day of assessment

Domain measures	Reported by	Postinjury					
		Day$_0$	Day$_{\leq 3}$	Day$_{3-7}$	Day$_{7-7a}$	Day$_{7-45a}$	Day$_{45a}$
Variables and measures collected as part of routine clinical care							
Acute signs and symptoms							
Injury report form	Care provider	X					
Acute mental status							
Standardized Assessment of Concussion*	Care provider	X					
Neuropsychological functioning							
Cogstate Computerized Cognitive Assessment Tool*†	Care provider		X		X		X
Balance							
Balance Error Scoring System*	Care provider	X					
Variables and measures included in the daily survey							
Physical rest							
ActiGraph-Energy Expenditure/Sleep	Y			———————→			
Daily Physical and Cognitive Rest Survey‡	Y			———————→			
Cognitive rest							
Narrative Clip-Cognitive Rest Video Clips	Y			——————————————→			
Daily Physical and Cognitive Rest Survey‡	Y			——————————————→			
Pain							
Pain intensity rating	Y			——————————————→			
Postconcussive symptoms							
Post-Concussive Symptom Scale*	Y			——————————————→			
Variables and measures included in the three assessments							
Functional outcomes							
Functional Disability Inventory*	Y and P		X		X		X
Pediatric Quality of Life Inventory*	Y and P		X§		X		X
Potential confounders							
Premorbid child functioning							
Behavior Assessment System for Children*	P		X§				
Concussion risk	Y		X				
Demographic information and postinjury events	Y and P		X		X		X

Day$_0$: Day of injury.
Day$_{\leq 3}$: Date of 1st assessment (within 72 hours of injury).
Day$_{7a}$: Date of second assessment (between 7–10 days after injury).
Day45a: Date of third assessment.
*Adopted in the Common Data Elements for Pediatric Traumatic Brain Injury. Administered at any time during recovery.
†Evaluated by physician during a clinic visit(s) as needed as part of routine care.
‡Data collection until the acute symptoms resolve.
§Retrospective ratings by parents at the first assessment to assess premorbid functioning.
P, parent; Y, youth.

Variables and measures collected as part of routine clinical care

Acute signs and symptoms

Acute signs and symptoms are measured using a standardised injury report form completed by the certified AT or ED physician. Injury details and acute signs and symptoms (ie, loss of consciousness, post-traumatic amnesia, neurological status and other clinical features) are collected and verified by an attending physician.

Acute mental status

The Standardized Assessment of Concussion (SAC), used to measure acute mental status,[38 39] is completed by the certified AT or an attending physician. The SAC provides a rapid assessment of orientation, attention and immediate and delayed memory, as well as acute postconcussion symptoms. SAC has been used extensively in research on SRCs in youth.[39 40]

Neuropsychological functioning

Neuropsychological functioning is evaluated by an attending physician using Cogstate Computerized Cognitive Assessment Tool (CCAT), which uses computerised card games to test cognitive ability.[41–43] The CCAT is currently used at the seven NCH concussion clinics as part of routine clinical care. It measures four simple tasks with standard scores (M=100, SD=10): (1) processing speed, (2) attention, (3) learning and (4) working memory. The CCAT has been validated among youth and has excellent psychometric characteristics.[43] The CCAT data collected by the NCH concussion clinics as part of routine clinical care will be available to the study team. Baseline data is also available via prior health records.

Balance

Balance is assessed by the certified AT or an attending physician using the Balance Error Scoring System (BESS), a widely used tool.[44] The BESS has participants perform three stances (narrow double leg, single leg and tandem) on two footing surfaces (firm surface/floor vs medium density foam). Each stance is held, with hands on hips and eyes closed, for a period of 20 s. The errors (eg, opening eyes, lifting hands off hips or stumbling) committed during each condition are counted and recorded. The BESS has shown satisfactory reliability in youth and adolescents.[44]

Variables and measures included in daily survey

Physical rest

Physical rest is defined as not engaging in physical activity beyond activities of daily living.[14] In this study, we measure the duration and quality of sleep, and the duration and intensity of physical activity, using an ActiGraph (Model GT3XP-BT), which is a 4.6x3.3x1.5 cm, validated, non-invasive, wrist-watch-like device with a Bluetooth-paired strap that records heart rate ('ActiGraph').[45] The ActiGraph continually measures rest cycles with an Actimetry sensor. The device can store up to 2 GB of data for up to 25 days. Actigraphy has been shown to provide accurate biometric data, including energy expenditure, activity intensity, heart rate, sleep duration and sleep efficiency.[45] In this study, Actigraphy provides data on sleep duration (number of sleep hours) and sleep quality (the ratio of deep- to light-sleep). Actigraphy also provides data on the intensity of the physical activities in which the youth participant engages, expressed as the ratio of energy expenditure to basal energy expenditure (number of calories burned in the resting state), adjusting for participant age, sex, height and weight.[46] Actigraph has been used in monitoring physical activity and sleep in youth following concussion.[47 48] In this study, the level of physical rest for each day is measured as the inverse of the participant's summary score, which is scored as the total duration of various physical activities multiplied by the corresponding intensity of these physical activities (duration x intensity) across a whole day. Additionally, self-reported physical rest data, including sport activity specific to the participant's sport, are collected via the daily surveys throughout the participant's enrolment.

Cognitive rest

Cognitive rest is defined as not engaging in activities requiring attention or concentration.[14] In this study, cognitive rest is monitored using a Narrative Clip which is a 36×36×9 mm wearable camera weighing 20 g.[49] The camera silently and automatically captures high-resolution digital images every 30 s. This device can store up to 4000 digital images, and has a 2-day battery life.

Participants wear the Narrative Clip for a 7-day period following enrolment. They are asked to wear the Narrative Clip as much as possible during this 7-day period. To ensure the Narrative Clip captures a normal visual field, a three-dimensional (3D) printed wedge (figure 2) was custom-designed to hold the Narrative Clip in place at a specific angle. Participants are instructed to attach the Narrative Clip to the 3D printed wedge, which is attached to a band, and then wear it around their forehead. Participants are instructed to cover the camera lens or take off the Narrative Clip as needed (eg, when the participant is using the bathroom). Additional instructions are to: (1) not wear the Narrative Clip to school or while sleeping, (2) plug the Narrative Clip into the laptop at the end of each day using the USB cable provided (ie, automatically upload and charge the device) and (3) review and delete any photos that contain sensitive information.

We classify intensity of every cognitive activity recorded by the Narrative Clip into three ordinal categories (ie,
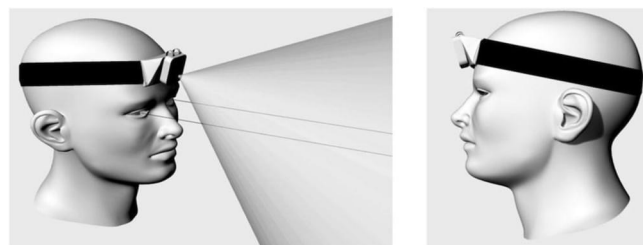

Figure 2 Narrative clip wedge.

1=*low*, 2=*moderate* and 3=*high*) according to published mental activity diary metrics.[22 29] Detailed descriptions of the procedure used to code intensity of cognitive activity is included in online supplementary appendix A. We also measure the duration of each of these activities in minutes based on the number of photos taken by Narrative Clip. The level of cognitive rest for each day is measured as the inverse of the summary score that sums the duration of various cognitive activities multiplied by the corresponding intensity of these cognitive activities (duration x intensity) across a whole day. Using established protocols, two trained coders will code the photo image data collected by the Narrative Clips for intensity and duration of each cognitive activity. Inter-rater reliability will be established before the coding. Any discrepancy in coding will be reviewed and discussed by the two coders until consensus is reached. Additionally, self-reported cognitive rest data are collected daily throughout study participation via the daily surveys and will be compared with the Narrative Clip data.

Postconcussive symptoms

Postconcussive symptoms are assessed daily by having youth complete the Post-Concussive Symptom Scale (PCSS) based on current symptoms.[50] The PCSS consists of 22 symptoms ranging from 0 (no symptoms) to 6 (severe symptoms). The total PCSS score is the sum of the ratings (range 0–132). The PCSS is the most commonly used concussion assessment tool among clinicians, with established reliability and normative data.[50]

Pain

Pain is self-reported daily by youth participants based on the severity of the pain they experienced on that given day using an 11-point numerical rating scale (0=*no* pain to 10=*worst pain possible*).[51]

Variables and measures included in the three assessments
Functional outcomes

Functional outcomes are evaluated during each postinjury assessment using the Functional Disability Inventory (FDI)[52] and Pediatric Quality of Life Inventory (PedsQL).[53–55] Youth and his/her parent complete the FDI and PedsQL at all three time points to assess activity limitations attributable to the SRC, as well as the youth's overall quality of life.[53–55] The FDI asks participants to rate perceived activity limitations due to physical health problems, while the PedsQL assesses broader aspects of quality of life, measured in terms of physical, emotional, social and school functioning. The PedsQL generates psychosocial and physical summary scores, as well as a total score.[53–55] During the first assessment, retrospective ratings of preinjury functioning are obtained using the PedsQL.

Potential confounders
Premorbid child functioning

Premorbid child functioning is retrospectively rated by parents at the first assessment using the Behaviour Assessment System for Youth, second edition.[56] The Behavioural Symptoms Index provides a summary measure of premorbid behavioural adjustment, and the Adaptive Skills Composite score provides a summary measure of premorbid adaptive functioning.

Concussion risk

For the purposes of this study, we define a high-risk concussion as one surpassing an empirical threshold for acute symptoms on the PCSS.[34 35 50] Specifically, we will classify concussions with an acute total PCSS score of 13 or higher as high-risk.[35]

Demographic information and postinjury events

Demographic variables include age, sex, grade in school, sport, school, number of previous concussions, years of experience in the sport, prescribed rest, diet, device wear time and times from injury to return to school, start of the graded RTP protocol, completion of the RTP protocol and acute symptom resolution.

Data management
Time-lapse photo-motion match data

All ActiGraph and Narrative Clip data are automatically time and date stamped. After participants return study devices, data on postinjury physical and cognitive activity collected on the devices are transferred to a protected research server. Data on the protected server are only accessible to a designated subgroup of study staff, and are only accessible from systems connected internally to the organisation's network. We first use computer visualisation methods, including automatic extraction, analysis and image understanding, to process and analyse the metadata collected by the Narrative Clip (eg, total photographs taken, number of photographs deleted and time each photograph was taken). Custom developed software is then used to create time-coded, time-lapse photo-motion matched data based on the data collected from the Narrative Clip and ActiGraph, respectively (figure 3). Finally, we use algorithms to streamline analysis of the matched data (ie, Narrative Clip photograph and ActiGraph motion) by identifying the matched data points with similar characteristics, which significantly reduces data processing and coding time. For example, 12 hours of images from the Narrative Clip (roughly 1440 photos) can be condensed to a 24 s long (30 frames per second, 1 minute time-lapse) video (figure 3). Using predefined criteria established by the research team (online supplementary appendix A), two trained research staff then review the photo-motion matched data to code and validate the intensity and duration of the cognitive activities captured by the Narrative Clip (described above).

Missing data

To handle missing data, we will first examine patterns of missing data and identify missing data mechanisms. We will then use approximate Bayesian Bootstrap or Markov Chain Monte Carlo methods in our main analyses if the assumption of missing completely at random or missing at random
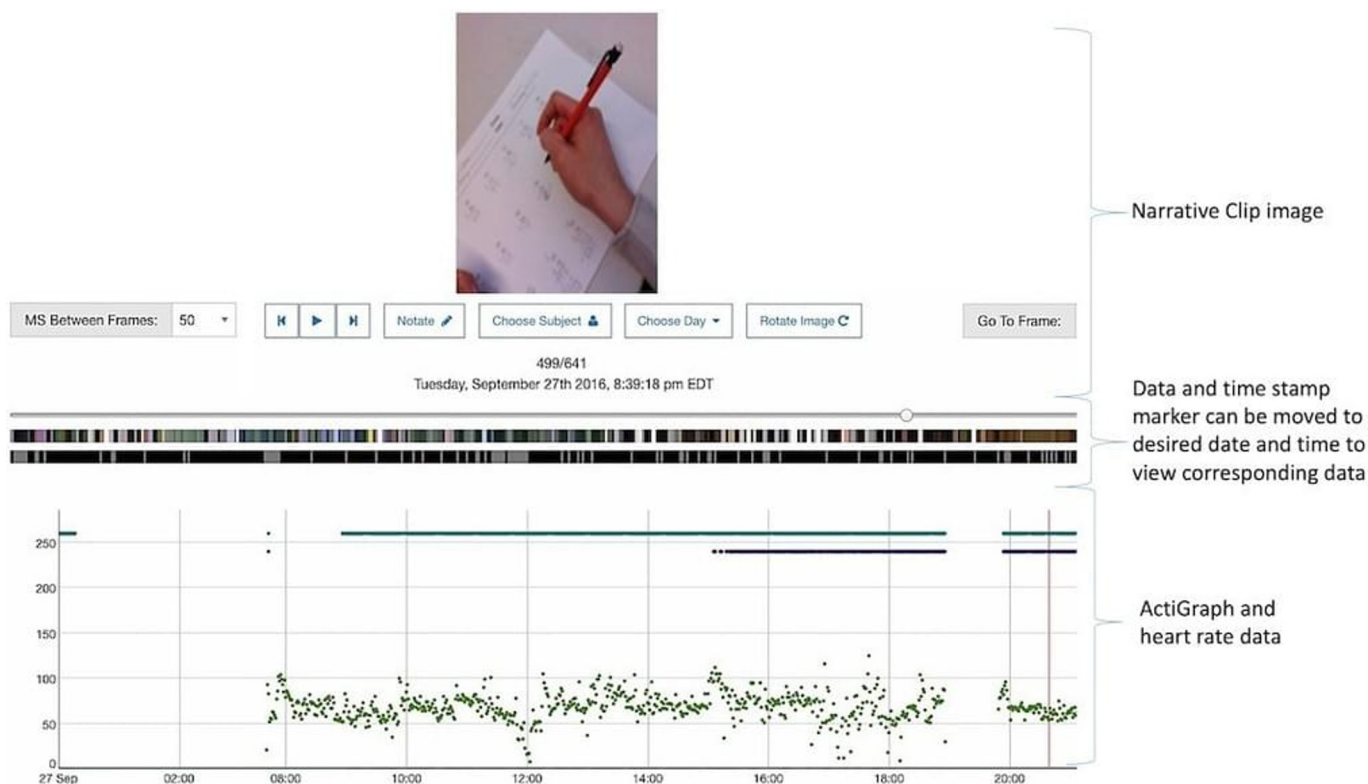
Figure 3 Time-lapse photo-motion matched data from the Narrative Clip and ActiGraph.

is met, respectively. We will use multiple imputation by fully conditional specification in our main analyses, followed by a sensitivity analysis if the assumption is violated.[57]

Data analyses
Descriptive analyses
We will describe the distributions of daily physical and cognitive rest by duration, intensity and levels (duration x intensity). We will report descriptive statistics and illustrate distributions of rest using Kernel density estimation. Comparisons will be made across subgroups, based on age, sex and concussion risk (high vs low) using analysis of variance or Kruskal-Wallis equality-of-populations rank test, as appropriate. We will compare the difference between rest type (physical vs cognitive) using paired t-test or Wilcoxon matched-pairs sign rank test. We will also examine the consistency between prescribed rest and actual rest, and objectively measured physical and cognitive rest and self-reported physical and cognitive rest, using Pearson correlation or Spearman rank correlation analysis.

Primary analyses
We will use Cox proportional hazards models to identify the duration, intensity and levels (duration x intensity) of physical and cognitive rest after SRC in relation to the number of days from injury to symptom resolution, censored or to the end of the study at day 45, whichever comes first.[58] Propensity scores will be used to mimic the homogenous or balanced condition for high levels versus moderate levels, as well as low levels versus moderate levels, of physical and cognitive rest,

respectively, accounting for all covariates, including demographics, sport and school characteristics, acute clinical variables, injury severity, premorbid conditions and pain.[59] Using a novel approach ('restricted cubic splines' in the Cox models),[60] we will first test whether the relationship between physical and cognitive rest and the outcome of interest are linear or non-linear. If a U-shaped or J-shaped (non-linear) dose-response relationship is found, we will then identify the optimal dosage (ie, duration, intensity or levels of physical and cognitive rest). We will assess the proportional hazards assumption with graphical methods, and by adding time-by-covariate interaction terms in the models. If the assumption of proportional hazards is violated, we will consider other alternatives, such as Poisson regression.

To identify the duration, intensity and postinjury levels of physical and cognitive rest in relation to continuous variables of functional outcomes, we will construct a 2-level linear mixed model with repeated outcome measures at the three assessments (level 1), nested in individuals (level 2) using a restricted maximum likelihood method.[61] We will use the same restricted cubic splines approach and propensity score methods described above to evaluate the duration, intensity and levels of physical and cognitive rest.

Secondary/exploratory analyses
Similar analyses will be conducted to test whether the duration, intensity and levels (duration x intensity) of physical and cognitive rest vary between youth with

high-risk and low-risk concussions. We will also test for interactions between concussion risk and levels of rest using a likelihood ratio test. If the interaction terms are statistically significant, we will report stratified results for youth with high-risk or low-risk concussions to illustrate differences in duration, intensity and postinjury levels of physical and cognitive rest.[61]

Statistical power

We calculated sample size and study power based on the log-rank test of two survival rates for simplicity.[62 63] We define the date of symptom resolution as the event of interest, and divide the summary scores of physical and cognitive rest into three groups: (1) below, (2) within and (3) above the optimal levels of physical and cognitive rest. Using the second category as the reference group and considering the multiple comparisons across the three groups, we will apply a Bonferroni adjusted alpha level of 0.025 [0.05/(3-1)]. Based on the results from our pilot study, we estimate that (1) 50% of participants are within the optimal level of rest and 95% of these participants' symptoms will resolve within 28 days, and (2) 15% are above and 35% are below the optimal level of rest and 75% of these participants' symptoms will resolve within 28 days. With a total sample size of n=110 and one-sided significance test, we have 86.8% power to detect a 20% decrement in recovery rate comparing the below to within optimal level of rest group. If we have up to 10% loss to follow-up, we still have at least 83.2% power to detect a decrement of 20% in recovery rate.

Patient and public involvement

The study protocol and instruments used in this study have been successfully pilot tested with concussed children and their parents and demonstrated feasibility. Prior to obtaining consent/assent, we explain the objectives, expected benefits of the study and type of information collected to interested dyads. Informed written consent/assent is then obtained from every participant. Data confidentiality is ensured and maintained throughout the study. The findings of this study (edited in lay language) will be disseminated to study participants through a newsletter. We will also disseminate our study findings at scientific conferences and by peer-reviewed publications.

ETHICS

No significant risks are associated with participation in the study, and participation does not affect the care provided to participants. Since participants are asked to wear a Narrative Clip that takes a picture every 30 s, the research team has worked very closely with the Privacy and Security Advisory Committee at NCH to identify potential risks to privacy and confidentiality, and developed procedures and technical controls to mitigate the potential risks. These strategies include blocking all uploaded data from the Narrative Clip cloud service, disconnecting laptops from the internet, only storing images on the laptop,

providing training to youth participants and their parent on proper device utilisation and photograph review, and establishing a 'chain of custody' for handling the laptop and devices. Further, youth are assured that only trained researchers will have access to the data.

DISSEMINATION

We will use common dissemination strategies to disseminate our study findings: (1) traditional academic outreach (eg, publications in peer-reviewed journals and presentations at professional conferences), (2) media outreach (eg, newspapers, radio, TV, social media) and the creation of related materials (eg, reports, special interest newsletters), (3) personal contacts (eg, professional networks), (4) key stakeholders and organisations (eg, youth sports leagues), and (5) creating actionable recommendations for concussion prevention programmes.

DISCUSSION

This prospective cohort study aims to objectively measure physical and cognitive rest following SRC and identify the level of rest that facilitates recovery and optimises postconcussion outcomes for youth with high-risk or low-risk SRCs. Engaging in high levels of activity too soon after concussion could exacerbate symptom duration and lead to greater neurocognitive and functional impairments.[19–23] Conversely, a period of 'complete' rest, especially for long periods of time, could negatively affect youth with concussion because of muscular deconditioning and withdrawal from school and sport activities, and may also be impractical or unnecessary after some concussions.[28–30] To the best of our knowledge, this study is the first of its kind to objectively measure and collect real-time data on the type, duration and intensity of physical and cognitive activities (and, conversely, rest) postconcussion. The study findings will therefore fill a critical knowledge gap, and will enable identification of the level of physical and cognitive rest needed following SRC to facilitate recovery based on concussion risk.[31 32]

The study has several limitations. First, quantifying cognitive rest is challenging. Although we document and track activities that require mental concentration using both objective and self-report data, we are not able to measure participants' actual mental engagement in each cognitive activity. Second, participants are instructed not to wear the Narrative Clip to school because of privacy concerns; thus, we are unable to document the cognitive activities that participants engage in during their time at school. Third, participants may opt out of wearing the devices, or their activities may not be recorded if they improperly wear the devices. Fourth, patient and injury characteristics may differ for youths recruited from local middle and high schools compared with those recruited from the ED.

Despite these limitations, the study will foster the development of better tools to objectively measure physical

and cognitive rest postconcussion. The results of the study will help move us beyond the current clinical practice of 'one-size-fits-all' rest plans,[34 35] and will provide evidence-based, individually tailored rest recommendations, which can be evaluated in a subsequent RCT. Finally, the results of the study will shape standards of care and inform treatment decisions about optimal levels of physical and cognitive rest for youth following SRC.

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