

RESEARCH PROTOCOL

The use of intermittent short-term selective head-neck cooling for the management of acute concussion and post-concussion syndrome

Purpose

The goal of this research is to:

- (a) Investigate changes that occur following the use of intermittent short-term selective head-neck cooling in acute concussion on the sideline of sports teams; and
- (b) Investigate changes that occur following the use of intermittent short-term selective head-neck cooling in the management of post-concussion syndrome; and
- (c) Monitor changes following intermittent short-term selective head-neck cooling in conjunction with the Sports Concussion Assessment Tool version 5 (SCAT5); and
- (d) Monitor changes following intermittent short-term selective head-neck cooling in conjunction with the King-Devick saccadic and balance tests; and
- (e) Monitor changes following intermittent short-term selective head-neck cooling in conjunction with the Brain Gauge somatosensory tool.

Sample

Sports Participants

Players from the Hutt Old Boys Marist Rugby Football Club women's club aged 18 years and older, will be invited to participate in the research. All players in the team covered by the lead researcher as the team medic / primary care provider will have baseline concussion assessments conducted as part of their pre-season assessment and these players will be invited to participate in the research. Should players elect to not participate in the research they will still be covered as part of the sideline medical care provided for the teams.

Post-Concussion Syndrome

People referred to the Post-Concussion Syndrome clinic aged 16 years and older, will be invited to participate in the research. All people who present to the clinic will have assessments done as part of their initial analysis. Those electing to participate in the research will undertake the assessments and be provided with information on the intermittent short-term selective head-neck cooling. Those electing not to participate in the research will be offered the opportunity to be part of the control group. Those who elect not to participate will still receive standard post-concussion syndrome management.

Procedure

Sports participants (see Figure 1)

During the preseason / pre-competition period all players will be reviewed, and baseline concussion assessments will be conducted. These will be utilised should there be a concussion identified or suspected throughout the season.

Recruitment and inclusion / exclusion criteria

Inclusion criteria is that the players are members of the Hutt Old Boys Marist Rugby Football Club women's team and are aged 18 years and older. All players tested preseason / pre-competition will be offered the opportunity to enrol in the study. Players declining to participate will have their baseline assessments maintained throughout the competition season. Players electing to enrol in the study will be asked:

- (a) To complete a player medical history form;
- (b) To identify if they have had a concussion in the preceding six (6) months; and
- (c) If they are on any prescription / over-the-counter / herbal or complimentary medicines.

This data will be collected on a player history form and transferred to an Excel spreadsheet for collating following the study period.

Enrolled players to receive:

- (1). Player information sheet
- (2) Copy of the consent form (signed). Copy to be retained by researcher

Measurement

At baseline all players will complete the King-Devick Saccadic reading and balance test and the SCAT5 (see Figure 2).

During the season, all players will be observed during matches for any signs of receiving a direct blow to the head, and/or if they are slow to rise from a tackle or collision or appear to be unsteady on their feet following a collision, will be assessed on-field for a concussive injury. Any signs of delayed answering, incorrect answers to questions or, if the player appears to be impaired in any way, will result in the player being removed from the activity and rested on the sideline.

A reassessment of the player will be undertaken approximately five minutes later utilising established guidelines. The player will also complete a sideline King-Devick saccadic reading test and, if they fail this and they are enrolled in the research, they will be asked to complete the Post-Concussion Symptom Score assessment and then provided with an intermittent short-term selective head-neck cooling device to wear for ten minutes. Following this ten-minute period, they will again be asked to complete the Post-Concussion Symptom Score assessment. Players not enrolled in the research will be managed in accordance with standard concussion management guidelines.

Any player losing consciousness will be treated for a cervical spine injury, immobilized and transferred to a hospital for further assessment and management irrespective of whether the player denies any mid-line cervical spine tenderness once they are responsive. All concussions will be referred to a health practitioner for further assessment and management. All players diagnosed with a concussion will stand down in accordance with the Accident Compensation Corporation Concussion protocol, will be required to undertake a graduated return to play program and must compete a full medical clearance before they could return to full training and match-play.

Players enrolled in the research will, in addition to the procedure outlined above, undertake routine post-match King-Devick saccadic reading and Balance tests, SCAT5 and Brain Gauge assessment until medically cleared, the player returns to their baseline score on the King-Devick, achieves a 92% corticometric score on the Brain Gauge and they are symptom free.

Safety procedure

In addition to the procedures above, all players identified with a concussion injury will be assessed by a health professional and not allowed to return to full participation until medically cleared. All players with any injury will be required to undertake the appropriate rehabilitation process before being allowed to return to sporting activities. In the case of any untoward event, the player will be taken to the nearest hospital / acute medical facility for further assessment and management.

Follow-up

Should a player not return to baseline scores on the SCAT5, the King-Devick saccadic reading and Balance test, or have symptoms that are prolonged, the player will be referred for a further

medical assessment with the possibility of a referral for post-concussion assessment and management and be stood down from match and training activities until medically cleared.

Should a player (irrespective of whether enrolled in the study or not) incur a second concussive injury during the same competition season they will be stood down from participating in any further matches and, until medically cleared to do so, any subsequent training activities.

Post-season players will be requested to complete the King-Devick saccadic reading test.

Post-Concussion Syndrome (see Figure 3)

People presenting to the post-concussion syndrome clinic will have baseline tests conducted as part of their assessment. These tests will be utilised to allow comparisons to be conducted as they progress through the rehabilitation process.

Recruitment and inclusion / exclusion criteria

Inclusion criteria is that the participants had presented for assessment and rehabilitation of post-concussion syndrome at concussion clinic. Participants electing to enrol in the study either as controls or the intervention group will be asked:

- (a) To complete a concussion history form;
- (b) If they have had a concussion in the preceding six (6) months; and
- (c) If they have been medically diagnosed as having Post-Concussion Syndrome.

This data will be collected on a concussion history form and transferred to an Excel spreadsheet for collating following the study period.

Enrolled participants to receive:

- (1). Player information sheet
- (2) Copy of the consent form (signed). Copy to be retained by researcher

Measurement

At the initial assessment all people presenting to the post-concussion clinic will complete a Brain Gauge and a King-Devick Eye-Tracker assessment. Should they consent to participating in the research, they will be provided with the intermittent short-term selective head-neck cooling device to utilise as part of their post-concussion management and provided with a 'Use Diary' to complete. Should they just consent to be in the control group, they will go through routine King-Devick tests and the Brain Gauge assessments.

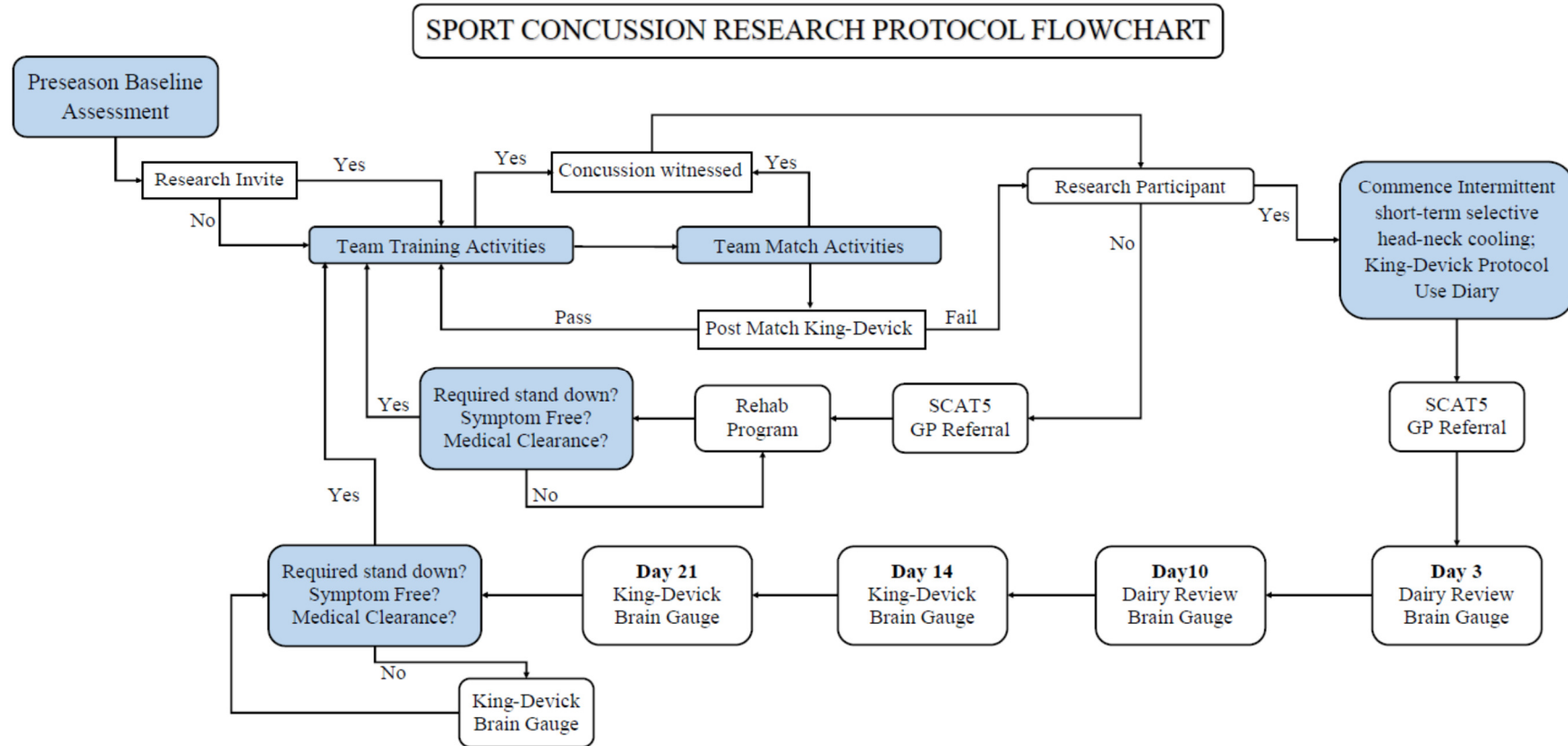
Each subsequent visit, all people in the research (control & intervention) will complete a King-Devick Eye Tracker, Balance tests, Post-Concussion Symptom Scale and Brain Gauge assessment. These will be compared to their previous assessments. For the intervention group, the Use Diary will be reviewed to identify the frequency and duration of the intermittent short-term selective head-neck cooling that the participant undertook.

Safety procedure

In addition to the procedures above, all participants will be assessed in accordance with the Post-Concussion Syndrome rehabilitation process and managed accordingly. If any distress is identified in the assessment process, the results will be advised to the management team.

Follow-up

All participants will undergo the programme as prescribed by the Accident Compensation Corporation for the assessment and management of Post-Concussion Syndrome. They will stay within the programme until the management team identify that they are recovered or referred onto other services for further rehabilitation.



Research Participants:

Clearance to return to full training requires: (1) Symptom Free [PCSS]; **AND** (2) Baseline or faster King-Devick test; **AND** (3) Brain Gauge >92% 'Corticalmetric'; **AND** (4) Medical Clearance

Non-Research Participants:

Clearance to return to full training requires: (1) Symptom Free [PCSS]; **AND** (2) Baseline or faster King-Devick; **AND** (3) Medical Clearance

Figure 1: Sport Concussion Research Protocol for amateur women's domestic rugby union participants

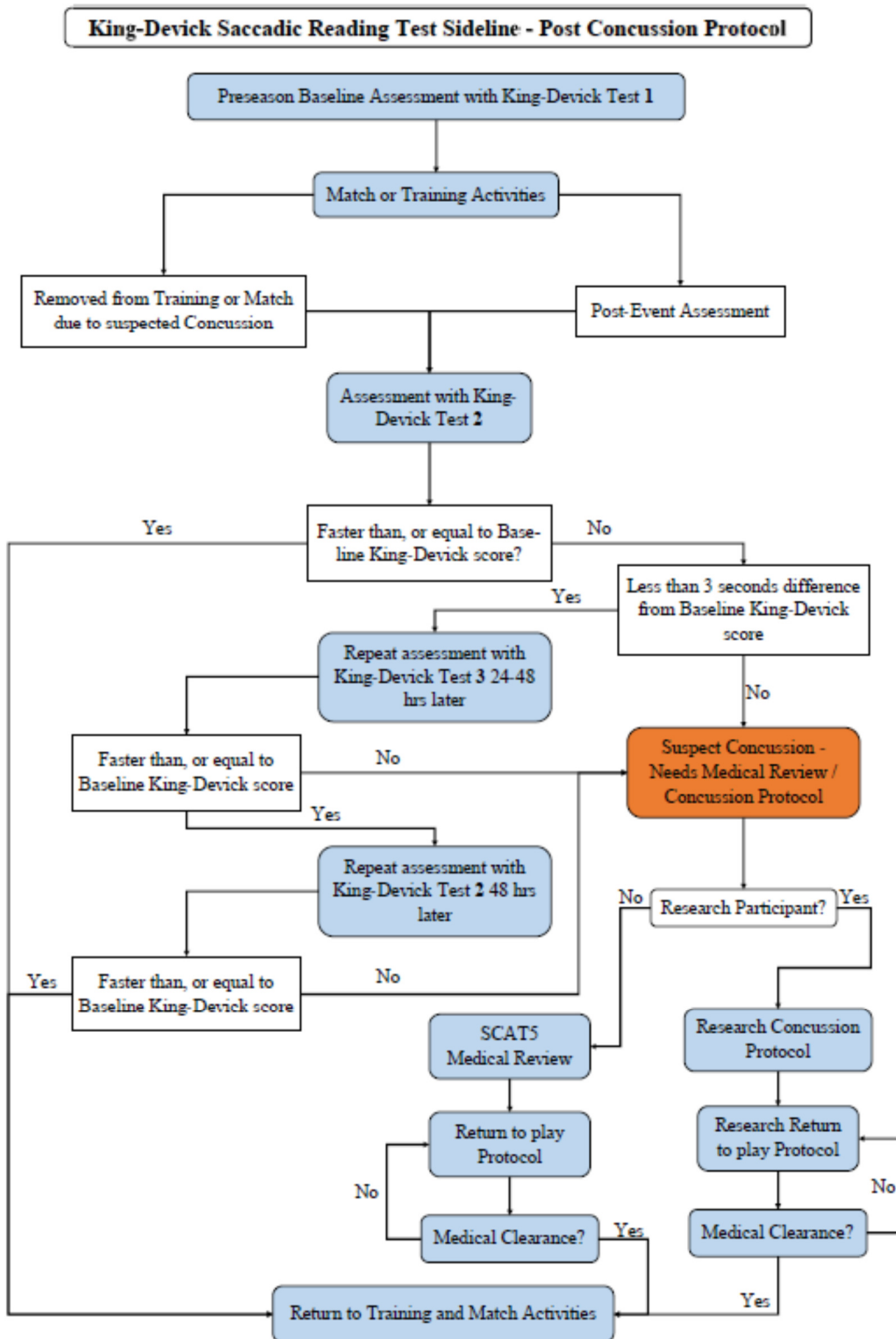
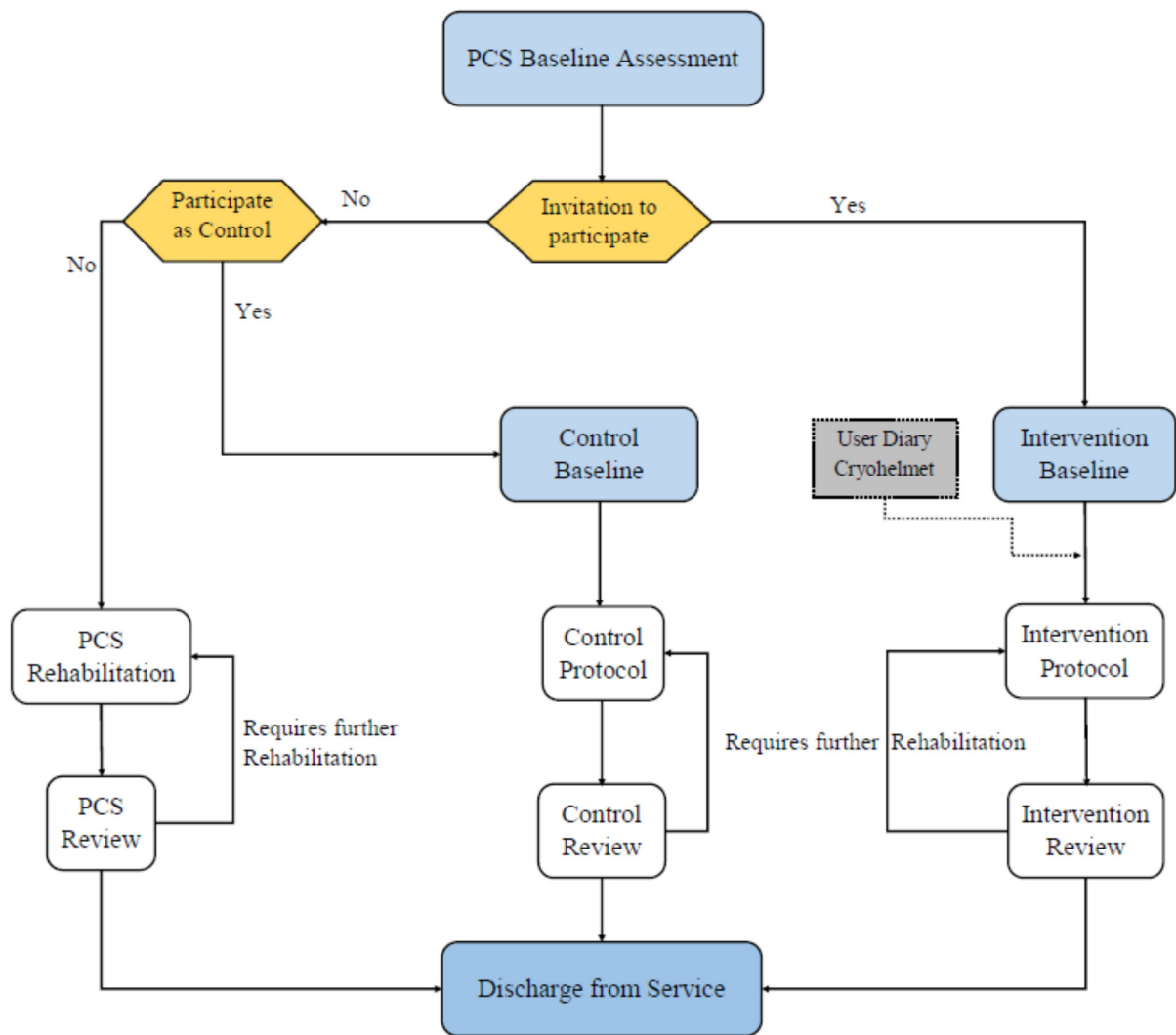


Figure 2: King-Devick Saccadic Reading test protocol for amateur women’s domestic rugby union participants

Procedure for intermittent short-term selective head-neck cooling concussion research Women's rugby 2019-2020

1. Baseline assessment of participants
 - a. All participants complete baseline testing x 2 with KD-rapid number test
 - i. Fastest time is baseline
 - ii. Utilised for comparison
 - b. All participants complete baseline testing with 1 x KD-Balance test
 - i. Incorporate into SCAT5 in-lieu of mBESS
 - c. All participants complete baseline SCAT5
 - i. Include KD Balance test
 - ii. Utilised for post-injury comparison
2. Post-match assessment
 - a. KDT
 - i. Random player numbers selected each week (random.org) (n=5)
 - ii. Player(s) with suspected head injury
 1. Post-Concussion Symptom Scale
 2. Commence intermittent short-term selective head-neck cooling for 10 minutes
 3. Post-Concussion Symptom Scale
 - iii. Player(s) with witnessed concussive event
 1. Post-Concussion Symptom Scale
 2. Commence intermittent short-term selective head-neck cooling for 10 minutes
 3. Post-Concussion Symptom Scale
3. Post-concussion assessment
 - a. Undertake formal medical evaluation (SCAT5)
 - b. Intermittent short-term selective head-neck cooling for 2 days
 - c. 2-day post injury Brain Gauge
 - d. Undertake stepwise graduated return-to-play protocol
 - e. Testing to be done
 - i. KDT (Days 0, 3/4, 7, 10/11, 14, 21 & 28)
 - ii. SCAT5 (Days 0, 3 (PCSS), 7, 14, 21, 28)
 - iii. Brain Gauge (Days 3, 7, 14, 21 & 28)
4. Return-to-play assessment
 - a. Baseline achieved on KDT
 - b. SCAT5 return to baseline
 - c. Brain Gauge metric >92%

PCS MANAGEMENT RESEARCH PROTOCOL FLOWCHART



PCS Baseline: As prescribed by Accident Compensation Corporation for service provided

Control & Intervention Baseline: King-Devick Eye-Tracker; King-Devick Balance; Brain Gauge

Intervention Protocol: Intermittent short-term selective head-neck cooling; K-D tests; Brain Gauge; Use Diary

Control Protocol: K-D tests; Brain Gauge

All participants tested at least once a week for the duration of the process

Figure 3: Post-Concussion Syndrome research protocol

**Protocol for intermittent short-term selective head-neck cooling concussion
research
Post-Concussion Syndrome 2019-2020**

1. Baseline assessment of participants
 - a. All participants complete baseline testing x 1 with KD-Eye Tracker
 - i. Utilised for post-cooling comparison
 - b. All participants complete baseline testing with 1 x KD-Balance test
 - i. Utilised for post-cooling comparison
 - c. All participants complete baseline PCSS of SCAT5
 - i. Utilised for post-cooling comparison
 - d. All participants complete baseline Brain Gauge
2. Post-cooling intervention – initial assessment
 - a. All participants complete post testing x 1 with KD-Eye Tracker
 - b. All participants complete post testing with 1 x KD-Balance test
 - c. All participants complete post PCSS of SCAT5
 - d. All participants complete post Brain Gauge
3. Follow up assessments
 - a. All participants complete 1 x KD-Eye Tracker
 - b. All participants complete 1 x KD-Balance test
 - c. All participants complete 1 x PCSS of SCAT5
 - d. All participants complete 1 x Brain Gauge

Appendix I: King-Devick tests

King-Devick saccadic reading test

Based on the time to perform rapid number naming, the King-Devick test takes less than two minutes to administer.^{9, 10} The King-Devick test involves participants reading aloud a series of random single-digit numbers from left to right. The test includes one practice (demonstration) card and three test cards that vary in appearance (see Fig 4). Players will be asked to read the numbers from left to right across the card as quickly as they can without making any errors using standardized instructions. The time will be kept for each test card, and the King-Devick summary score for the entire test will be based upon the cumulative time taken for the participant to read all three test cards. The number of errors made in reading the test cards will be recorded. Baseline King-Devick times for all participants will be established either during the preseason or when the participants joined the team after the season had commenced. The best time (fastest) of the two trials without errors becomes the established baseline King-Devick test time.⁹ When head trauma is suspected the King-Devick test will be utilised as a screening tool to assess for possible concussive injury as part of a series of concussion assessments. The King-Devick test has not been recommended for use as a standalone diagnostic tool^{11, 17} and the King-Devick will be utilised in conjunction with other concussion assessment tools as a sideline screening tool as previously recommended.^{17, 36} Previous studies have reported on the use of the King-Devick in mixed martial arts and boxing,⁹ rugby league,^{26, 32} rugby union,³² ice hockey,¹³ collegiate American football³³ and has been identified to assist in the identification of sports-related concussion when combined with the Sports Concussion Assessment Tool (SCAT).^{12, 36}

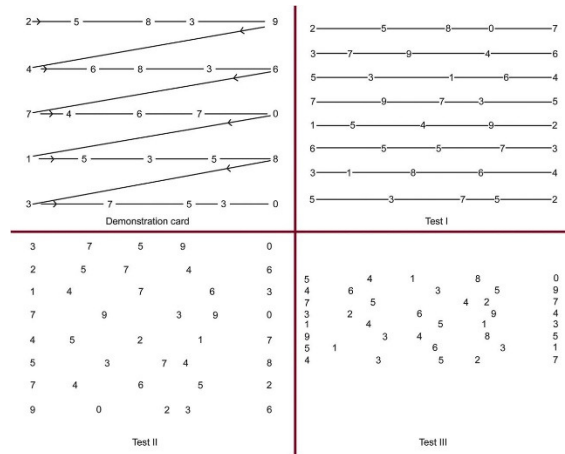


Figure 4: Demonstration and test cards for the King-Devick Test

The test will be administered once using the same standardized instructions, and the time and errors will be recorded then compared to the participant's own baseline score. Worsening of time and/or errors identified on the sideline or post-match King-Devick test have been associated with concussive injury,^{5, 9, 10, 13, 25, 26, 36} and players with any changes from their baseline scores will be referred for further medical assessment. The King-Devick test performance has been previously shown to be unaffected in various noise levels and testing environments.⁴⁵ The King-Devick has also been reported to have significant correlations ($p < 0.0001$) with the visual motor speed (VMS), reaction time (RT), verbal memory (VEM) and visual memory (VIS) of the Immediate Post-concussion Assessment Cognitive Test (ImPACT®)⁴⁷ computerised concussion evaluation system. Worsening of the King-Devick times from baseline¹⁶ have been associated with changes in the Standardised Assessment of Concussion (SAC) ($r = -0.37$; $p < 0.0001$) and total symptoms ($r = 0.24$; $p = 0.0002$). The King-Devick has also been reported to have a high test-retest reliability (ICC's between 0.86 and of 0.97) in a variety of adolescent and adult athletic populations.^{1, 9, 33, 34, 40} The current King-Devick tests utilised will be the v4.2.2 (<http://www.kingdevicktest.com>) on an iPad2. The iPad2 version enables the use of the King-Devick test with three different test platforms and these will be varied over the duration of the study. The baseline will be assessed with platform 1 and the post-match tests will be conducted with either platform two or platform three randomly alternated.

King-Devick Saccadic Reading Test Eye Tracker

A further development of the King-Devick test is the addition of eye-tracking to allow for real-time automated eye movement data and output using measures of fixations, saccades, blinks and pupillary dynamics (see Fig 5). This eye tracking technology brings objective tools to the clinical management of oculomotor dysfunctions while allowing quantifiable measurement of impairment severity and status over progression and remediation. All

participants completed one trial of a novel digitized version of the King-Devick eye tracker test under objective, video-based, infrared oculography (EyeTech VT3 Mini, EyeTech Digital Systems, Mesa, AZ, USA). The K-D card images were imported into the eye tracking software with maintenance of stimulus matching (e.g. numbers presented, spacing between numbers).^{42, 43}



Figure 5: King-Devick Eye Tracker computer set-up

King-Devick Balance Test

The King-Devick Balance test is an FDA-cleared balance assessment software application that provides an objective measurement of balance performance aiming to improve the quality of commonly used clinical balance tests. The King-Devick Balance test runs on an iPhone and it is secured to the participant's upper chest with a hands-free device holder. The location of the device is along the line of the participant's center of gravity which is optimal for detection of postural movement. The King-Devick Balance test utilizes the tri-axial coordinate data from the internal accelerometers of the mobile device to calculate a quantitative balance score. Scores closest to zero demonstrate no postural movement during the assessment. The King-Devick Balance test instructs the examiner with step-by-step instructions through the test protocol in order to maintain consistency with each test administration. The King-Devick Balance test consists of three separate stances. These are the: 1) Double-leg (feet together); 2) Tandem stance right foot forward; and 3) Tandem stance left foot forward. The King-Devick Balance test does not include any single leg stances in the testing procedure due to the variability in single leg stance measures recorded in a normal population.

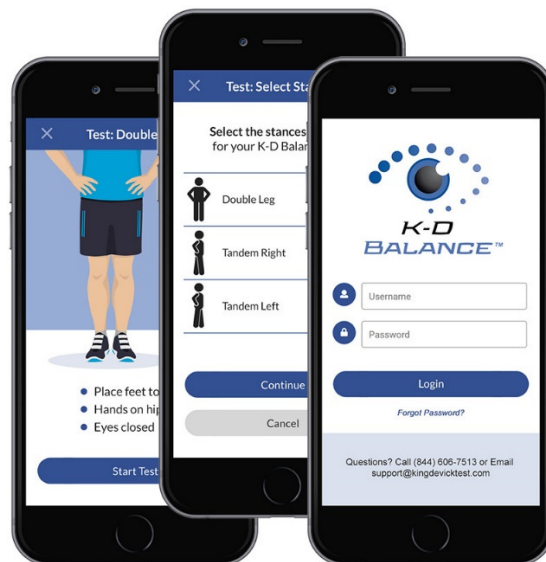


Figure 6: Screenshots of the King-Devick Balance Test

Appendix II: Sports Concussion Assessment Tool 5th Edition (SCAT5)

The SCAT5^{7, 38} is a tool developed by combining existing concussion assessment tools.³⁷ Established as having face validity, the SCAT5 reliability and change scores have not been reported to date. The SCAT5 is an updated version of the previously published SCAT3^{6, 14, 15} and consists of both subjective and evaluative components consisting of the Post-Concussion Symptom Scale (PCSS), modified Maddock's questions, cognitive assessment and neurological screening. The cognitive assessment consists of a five-word immediate (upon hearing the words) and delayed (following concentration tasks) recall assessment, reciting the months of the year in reverse order and repeating single digits in reverse order.

The SCAT5 contains separate test domains to assess total number of symptoms (0-22; higher score=more symptoms), symptom severity (0-132; higher score=more severe symptoms); total Standardized Assessment of Concussion (SAC) (0-30; lower score=worse cognitive performance), and a modified Balance Error Scoring System (mBESS) of three stances on a hard floor (0-30; higher score=lower number of errors). The timed tandem gait measure and coordination test will not be included in the final analysis. The cognitive assessment in the SAC comprises four components: orientation (0-5), immediate memory (0-15), concentration (digits backwards and months in reverse order, 0-5) and delayed recall (0-5). The instructions for conducting the SCAT5 assessment will be read out to ensure continuity of assessment. To evaluate the SCAT5 components, the following guidelines for concussion assessment will be utilised:⁴⁴

- a. Symptom Evaluation;
 - a. Score (range 1-22): 3 or more symptoms from baseline; and/or
 - b. Severity (range 1-132): score of 11 or more.
- b. Cognitive Assessment;
 - a. Orientation (range 0-5): 1 less than baseline; and/or
 - b. Immediate Memory (range 0-15): 12 or less; and/or
 - c. Concentration (range 1-5): 3 or less for numbers reversed; and/or
 - d. Delayed recall (range 0-5): 3 or less.
- c. SAC (range 0-30): combined score of 27 or less; and
- d. Modified Balance Scoring System (range 0-30): more than three errors in double and/or tandem stance from baseline.

In addition to the symptom evaluation scales, symptom indices³⁹ will be applied to the symptom score and severity. The symptoms indices are the Global Severity Index (GSI) providing an overall summary measure of the symptoms on a scale from 0 to 6, and the Positive Symptom Distress Index (PSDI) to measure the intensity of the symptoms the player reports on a scale from 0 (no distress) to 6 (most distress).³⁹

The SCAT5 is the base form utilised for the assessment of concussion in the Match Concussion and Training Concussion Forms 2019-2021 (please refer to these for further information).

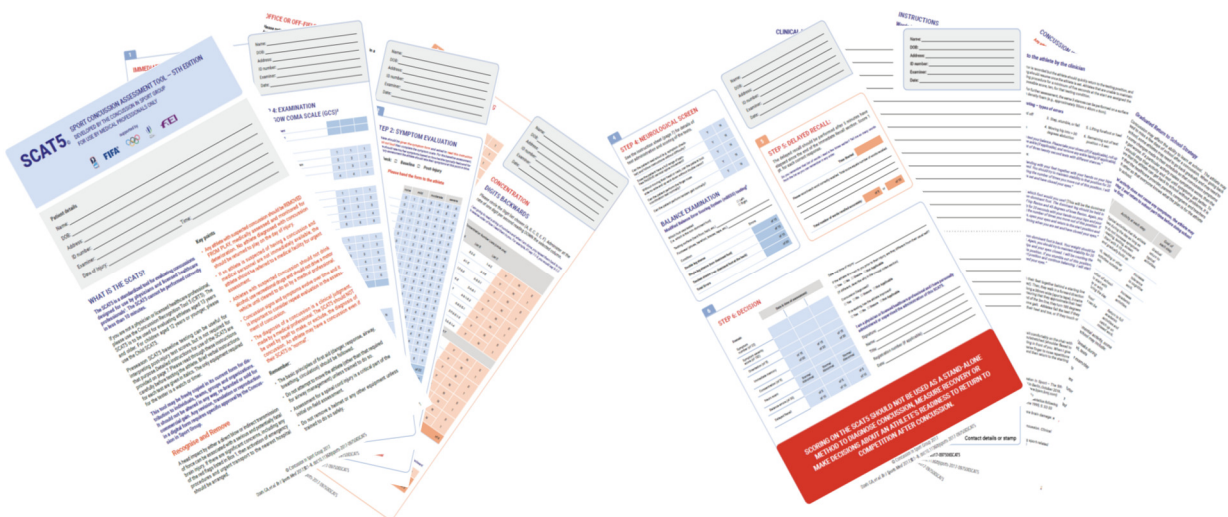


Figure 7: Sports Concussion Assessment Tool version 5 (SCAT5)