Title

Comparison of inguinal fist compression versus commercial windlass tourniquet for reduction in femoral artery blood flow by untrained providers: a protocol for a superiority, assessor-blinded, cross-over, randomised controlled trial

Names protocol contributors

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Abstract

Background/Problem:
Effective haemorrhage control is crucial in cases of limb trauma involving arterial injury, such as shark attacks, to prevent potentially fatal outcomes. International first aid consensus recommends the use of arterial tourniquets (proprietary or makeshift) as a primary treatment for life-threatening external bleeding. Manual pressure applied directly over a major artery proximal to the injury, such as Inguinal Fist Compression (IFC), is more accessible in a first-aid situation, but currently not recommended due to limited evidence. However, it is unclear whether the application of IFC is superior to commercial windlass tourniquets (CWTs) in reducing blood flow in the femoral artery when performed by untrained bystanders.

Methods:
Stopping Haemorrhage by Application of Randomised Compression or Tourniquet (SHARC-Two) is a superiority, assessor-blinded, cross-over, randomised controlled trial conducted with healthy untrained adult volunteers in non-clinical settings. Participants will be rotated as providers and recipients of both IFC and CWT, with providers randomised to the order that they perform the techniques. Providers will be exposed to an educational infographic before applying that technique to a recipient behind a drop sheet. A sonographer, blinded to the technique, will measure the peak systolic velocity (PSV) of blood flow in the superficial femoral artery (SFA) using Doppler ultrasound at baseline and then during application of each technique for five minutes.

Discussion:
Based on a recent pilot study with a similar protocol, there is the potential that IFC will achieve a greater reduction in femoral blood flow than CWT when applied by untrained bystanders after brief infographic exposure. Complete occlusion of the femoral artery with IFC may also be achieved more frequently and be faster and easier to apply than CWT. If IFC is found to be superior to CWT for reducing femoral artery blood flow, the findings shoulde play a significant role in shaping future guidelines for first aid management of massive arterial haemorrhage from limb trauma.

Trial registration:
Prospectively registered with ANZCTR on XX XXX 2024 (ACTRNXXXXXXXXX)

Keywords

Arterial tourniquet, bleeding, femoral artery, haemorrhage, lower limb, leg, manual compression, shark attack, pressure point

Title {1}	Comparison of inguinal fist compression versus proprietary arterial tourniquet for reduction in femoral artery blood flow by untrained providers: a

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Name and contact information for the trial sponsor {5b}	Research Service Officer, Bond University Phone: (07) 5595 1320 Research@bond.edu.au
Role of sponsor {5c}	The funding body and sponsor played no role in the study design, data collection, interpretation of data, report writing or decision to submit for publication.

Introduction

Background and rationale {6a}

Massive external haemorrhage from an arterial injury following a marine fauna encounter or shark attack can be fatal. The Surf Life Saving Australia 2023 Coastal Safety Briefing on marine fauna found that in Australia shark attacks are responsible for an average 2.44 deaths per year[1] with the incidence of non-fatal encounters likely to be much higher than this. In catastrophic exsanguination following trauma, a primary goal of prehospital medical management is to reduce blood loss to preserve organ function and reduce the need for blood product administration [4]. Current international first aid consensus recommends [8] the use of a windlass tourniquet (commercial or makeshift) as a first line treatment to control life threatening extremity bleeding, with direct wound pressure recommended where a tourniquet is not available [18]. However, there is no reference to arterial pressure point techniques (APPTs), such as the inguinal fist compression (IFC) technique.

Windlass tourniquets exist in two forms; commercially manufactured windlass tourniquets (CWTs); or improvised devices created with materials in the field. Several types of CWT exist but to date none has been robustly evaluated against IFC in untrained bystanders. IFC is novel technique that requires no specialised equipment to employ. The aim of this study is to investigate the efficacy of the general population, educated with an infographic, on their ability to occlude the femoral artery using two different techniques 1: application of IFC and 2: application of a CWT.

Objectives {7}

The primary objective of the Stopping Haemorrhage by Application of Randomised Compression or Tourniquet (SHARC-TWO) trial is to determine whether IFC is more efficacious than a CWT in reducing

femoral artery blood flow (as percentage reduction in PSV) at five minutes in healthy volunteers, applied by untrained adults after reading an infographic. Secondary objectives are to determine if IFC has a higher frequency of complete occlusion at five minutes, has a faster time to application and is the preferred intervention by providers and recipients.

Trial design {8}

SHARC-Two is a superiority, assessor-blinded, crossover randomised controlled trial (RCT), based on a pilot study from the same authors with a similar protocol. The protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement.

Methods: Participants, interventions and outcomes

Study setting {9}

Recruitment and data collection will be conducted at several venues, such as sporting clubs in Gold Coast, Queensland, Australia. The equipment required for the trial will be transported to the venue and set up in a location that maintains the privacy of the participants.

Eligibility criteria {10}

There are three stages in ensuring eligibility is met, and safety maintained.

1. Screening. Potentially eligible participants will be approached and invited to take part in the trial by a research team member at coordinated data collection sessions. An information sheet outlining the research trial will then be provided which will include a list of eligibility screening questions (Appendix A). Those who are screened and excluded will be recorded with reasons documented.

2. Review. Volunteers who satisfy initial screening will be asked to present to the nominated venue at a specified time (if not already on site), a review of complete eligibility criteria by a member of the research team will then take place. The inclusion criteria are modelled to represent an untrained adult bystander in Australia (Table 1.) The exclusion criteria seek to ensure participant safety by identifying medical issues that could be exacerbated by providing or receiving either IFC or CWT techniques (Table 1). If eligible and written consent is obtained, the participant will proceed in the trial as a provider.

3. Assessment. Prior to proceeding as a recipient, participants will undergo visual inspection of their groin and lower limbs, examining for pathologies as outlined in Table 1. A targetted sonographic assessment will then be performed to exclude vascular anomalies or undiagnosed peripheral vascular disease as outlined in Table 1. If an abnormality is detected in the assessment of the lower limb, the participant will not progress as a recipient. They will be informed of the findings and be referred to their General Practitioner with a letter recommending further evaluation. Given that the recruitment and data collection will take place in groups, participants may be required to be a recipient more than once (this will be documented).

Table 1. Eligibility criteria

Inclusion criteria	Exclusion criteria (Provider)	Exclusion criteria (Recipient)

- Aged between 18-59 years (inclusive) - English language fluency (including as a second language) - No formal medical training beyond first-aid - No training in arterial tourniquet application	- Diagnosis, or evidence of, conditions that could potentially be exacerbated by participation as a provider: ○ Musculoskeletal e.g., carpal tunnel syndrome, previous shoulder dislocation or surgery (e.g. reconstruction), recent injury	- Diagnosis, or evidence of, conditions that could potentially be exacerbated by participation as a recipient ○ Musculoskeletal e.g. previous groin surgery (e.g. hernia repair, hip replacement), recent injury ○ Vascular e.g. arterial venous malformation or aneurysmal disease of the femoral artery; peripheral vascular disease, including PSV of the SFA outside the normal reference range [20] ○ Neurological e.g. peripheral nerve disease ○ Haematological e.g.hypercoagulability, coagulopathy or anticoagulation ○ Dermatological e.g. severe dermatitis, infection or sunburn -

Table 1. List of inclusion/exclusion criteria

Who will take informed consent? {26a}

Once volunteers are deemed eligible for the trial, a member of the research team will check their understanding of their involvement in the trial, based on the written information provided. Written consent will then be obtained from the volunteer willing to participate in the trial.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

There are no provisions for future ancillary studies using the data collected in this trial.

Interventions

Explanation for the choice of comparators {6b}

Current international guidelines on first aid management of major limb haemorrhage include the use of arterial tourniquets applied by trained personnel [18], however, this relies on the availability of CWTs and trained personnel able to apply them. Emerging evidence suggests that untrained members of the community may be able to provide more effective reduction in femoral artery blood flow in healthy adult volunteers with the application of IFC compared to CWTs [10,11,12,13,14,19]. In a trauma setting, larger reduction in femoral artery blood flow would lead to lower volumes of blood loss and better patient outcomes. Given the time-critical nature of extremity arterial haemorrhage, IFC could be rapidly provided as first aid by bystanders while awaiting the attendance of emergency services.

Intervention description {11a}

Inguinal Fist Compression (IFC)

The provider will place the fist of their dominant hand at the midpoint of the recipient's inguinal canal, midway between the anterior superior iliac spine and the pubic symphysis (Figure 1). The leg used (left or right) for each data collection session will be determined by the ergonomics of each testing space and will be recorded. Maximal pressure will then be applied over the compression point as per the technique reported by Taylor and Lamond [13].

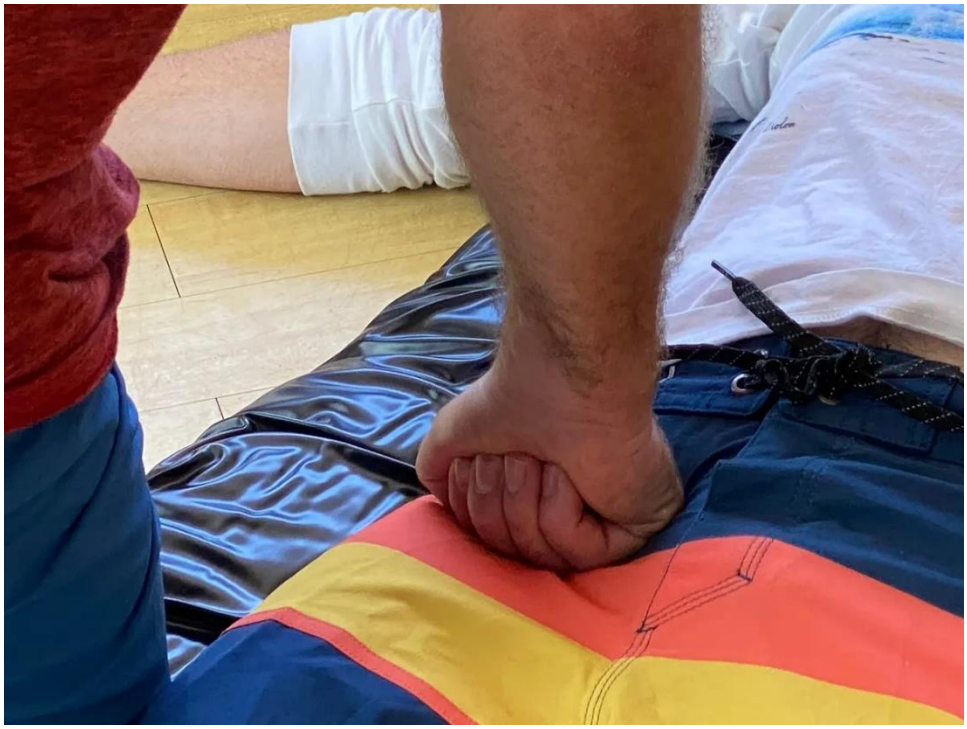

Figure 1. Inguinal Fist Compression (IFC) technique

Commercially manufactured windlass tourniquet (CWT)

The CWT used will be the Combat Application Tourniquet manufactured by C-A-T Resources (Figure 2.). The provider will apply the CWT to the upper thigh of the recipient and the windlass rotated to and locked at the maximum tolerable tightness for the recipient. Application of the CWT will be over clothing as to emulate real world ultilsation.

Figure 2. Combat Application Tourniquet

Infographics

Separate infographics were developed for the IFC and CWT which outline step-by-step instructions on the application of each intervention (Figure 3a and 3b). The IFC infographic was adapted from the that used in the study conducted by Taylor and Lamond [13]. The CWT infographic was adapted from the manufacturer's instructions [21]. Both infographics were tested in an initial pilot study and further developed with input from a consumer advisory group with members of the general population.

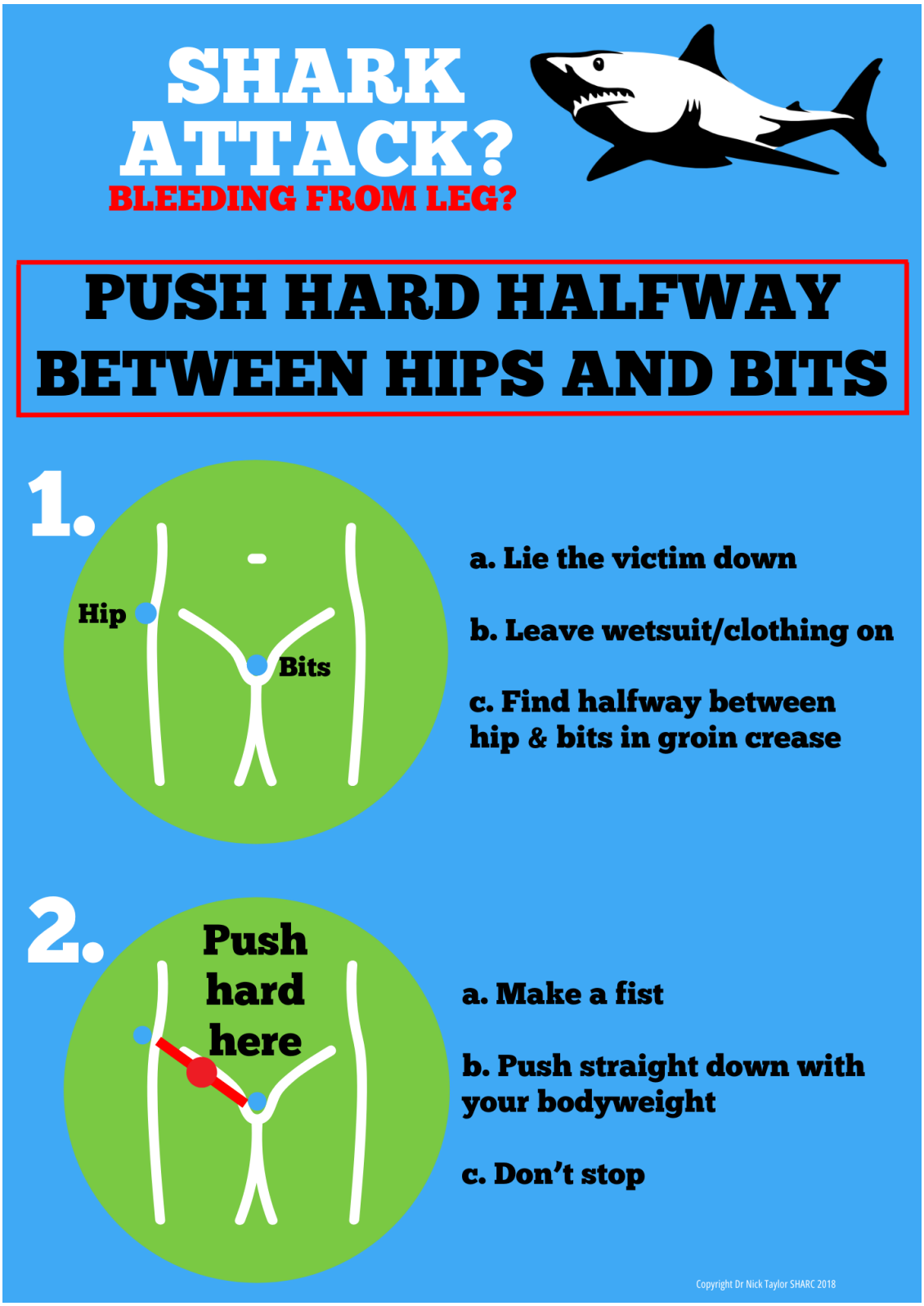

Figure 3a. IFC infographic

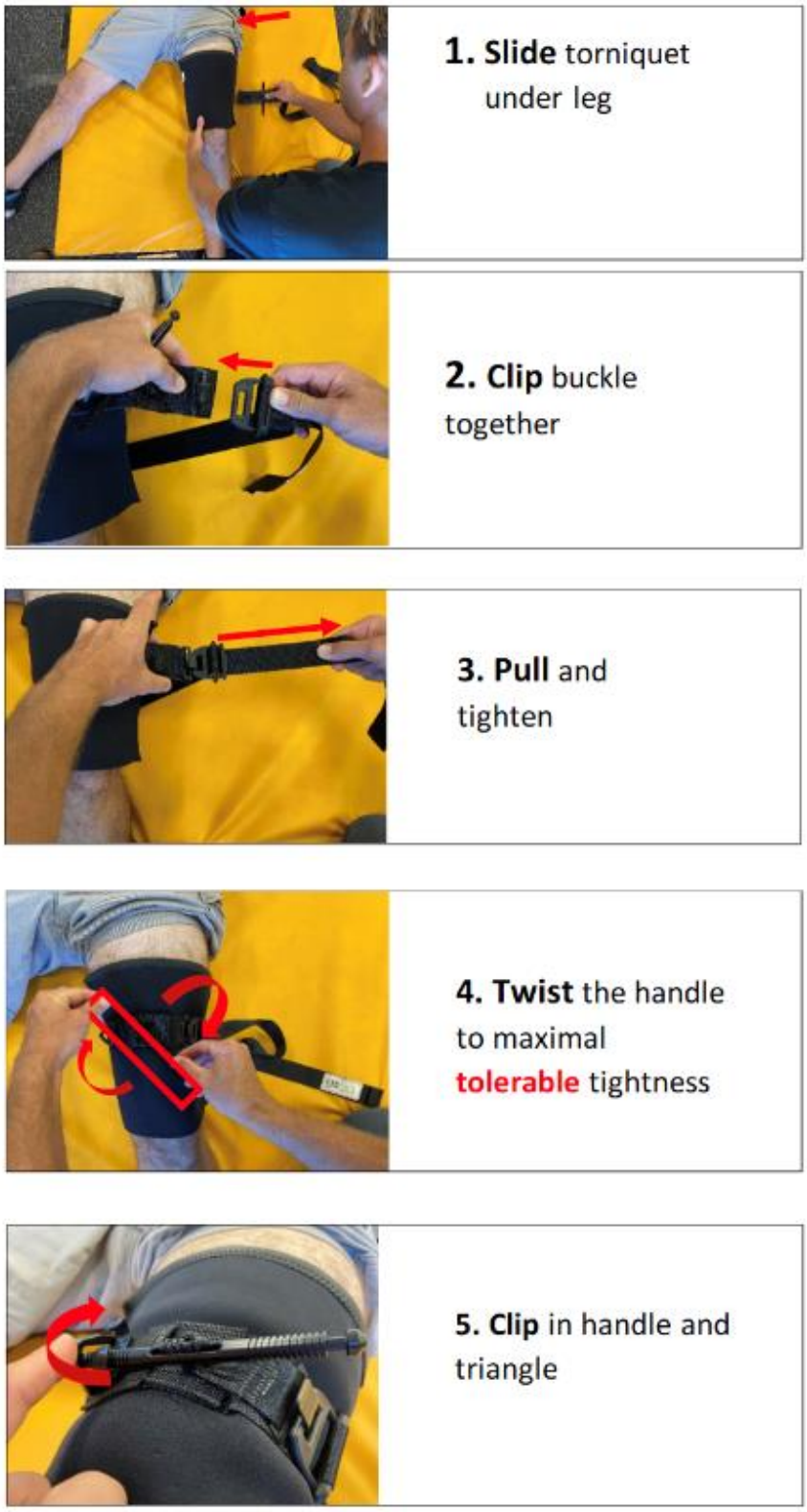

Figure 3b. CWT infographic

Criteria for discontinuing or modifying allocated interventions {11b}

Should the recipient verbally indicate at any stage that the intervention being applied is not tolerated, the provider will immediately release it. A member of the research team will also intervene to release the intervention if they deem that the recipient is experiencing excessive pain.

Strategies to improve adherence to interventions {11c}

The infographics used in this trial are modified versions of those used in the pilot study. Feedback from the Gold Coast Hospital and Health Service Consumer Advisor Group has been used to enhance the readability of both infographics for this study. From the participant perspective, the researcher team will ensure that participants area aware that both interventions have the potential for discomfort.

Relevant concomitant care permitted or prohibited during the trial {11d}

No other concomitant intervention or treatment that may alter femoral artery blood flow in the recipient is permitted during data collection.

Provisions for post-trial care {30}

Recipients will be evaluated following both interventions for complications and to assess for the return of normal SFA blood flow, both clinically and using doppler ultrasound, immediately after their participation. Although no participants from the pilot study encountered any adverse event or complication, further medical evaluation will be arranged at a local hospital for any participant who requires it. All participants will be provided with a standardised letter outlining their involvement in the study should they need it for medical purposes as well as the contact details of the principle investigator. Participants will be made aware that they may experience localised bruising or mild pain following their involvement in the study, but anything beyond this will likely require further medical evaluation. Volunteers will also be telephoned, text messaged or emailed by the research team within 48 hours to assess for any complications or adverse outcomes.

Outcomes {12}

The trial's primary outcome is the reduction in PSV of the SFA at 5 minutes post application of the intervention (IFC or CWT), expressed as a percentage. This was chosen as it determines the efficacy of the intervention for reduction in blood flow, that the provider has sustained for a reasonable period as a first-aid measure. A qualified sonographer will perform Doppler ultrasound of the SFA blinded to the intervention.

Secondary outcomes will include:

- Time to apply intervention: recorded as time from infographic exposure until application of intervention, as indicated by the provider. A member of the research team will use a stopwatch to record this duration in seconds.
- Blood flow reduction: PSV measurements will be taken at baseline (preintervention), immediately post application of the intervention (0 minutes), and at minutely intervals until 5 minutes (i.e. 1, 2, 3, 4, 5 minutes).
- Complete occlusion: the proportion of recipients with complete occlusion of blood flow (i.e PSV = 0cm/s) at 5 minutes will be compared between interventions. The duration of complete occlusion (number of PSV measurements with complete occlusion) will also be compared.Effect of provider

characteristics, including age, biological sex, gender, first-aid training, level of education, English as second language and grip strength, on the primary outcome of percentage PSV reduction at five minutes

- Effect of recipient characteristics, including age, biological sex, gender, clothing type and mid-thigh circumference, on the primary outcome of percentage PSV reduction at five minutes

- Provider reported:

    - level of difficulty of applying the intervention, rated on a Likert scale from 0-10 (0 = no difficulty, 5 moderate difficulty, 10 most difficult).
    - ability to sustain the application of the intervention, rated on a Likert scale from 0-10 (0 = very easy to 10 = very difficult).
    - preference for technique (IFC, CWT or no preference)

These will all be manually recorded by the provider on a data sheet after they provided both interventions

- Recipient reported:
    - Maximal level of discomfort for applied technique, rated on a Likert scale from 0-10 (0 = no discomfort, 5 = moderate discomfort, 10 = extreme discomfort)
    - preference for technique received, rated on a Likert scale with from 0-10 (0 = IFC preferred, 5 = equal/no preference for technique, 10 = CWT preferred).

These will all be manually recorded by the recipient on a data sheet after they have received both interventions.

- Any adverse outcomes from the intervention, with recipients asked immediately afterwards and at follow-up within 48 hours by phone call, text message or email. Participants will also have the contact details of the lead author to report any adverse events.

Participant timeline {13}

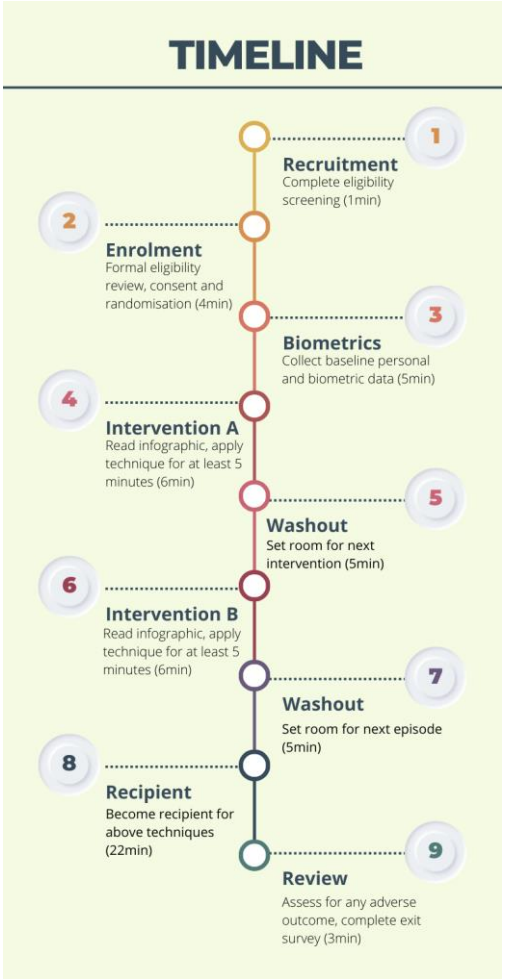

Figure 4b. Individual participant timeline, the first participant in each group will skip steps 4, 5 and 6.

Sample size {14}

This trial's sample size calculation was informed from the previous pilot study [19]. Sample size calculations were based on a superiority hypothesis of IFC compared to CWT with a primary outcome of PSV at 5 minutes post application of the intervention. Using the software G*Power and the pilot study mean difference of 40.0% and standard deviation of difference of 61.1 percent, with power 0.9 and significance level 0.05, a minimum sample size of 30 participants was calculated, which will provide 60 primary outcome data points (30 per intervention). This sample size also achieves power above 80% for the key secondary outcome of proportion of participants achieving complete occlusion, based upon pilot study data of 87.5% with IFC and 50% with CWT. To allow for any withdrawals or technical issues precluding primary outcome data collection, the goal will be for up to 40 participants to be recruited with 80 primary outcome data points i.e., 40 applications of each intervention (IFC and CWT).

Recruitment {15}

To ensure adequate recruitment to the trial, volunteers will be sought out from venues in the Gold Coast city region of South-East Queensland, Australia. This could include sporting groups, Surf Life Saving clubs, universities, or other community groups. Organisation gatekeepers will be given participant information sheets, which will outline all relevant details such as allocated time commitment for participants. Where possible, a member of the research team will conduct pre-screening of participants remotely via phone or email, to ensure efficiency for the scheduled data collection sessions. Data collection will either occur in those community venues or centrally at a designated room at Bond University.

Assignment of interventions: allocation

Sequence generation {16a}

The order of the interventions performed by each provider will be dictated by the web-based Griffith Randomisation Service (GRS)[22]. This is a centralised, computer-generated algorithm with randomisation performed in a 1:1 ratio.

Concealment mechanism {16b}

Described in 16a.

Implementation {16c}

After consenting, eligible participants will be enrolled into the trial by a member of the research team who will then allocate the order that the interventions will be applied, as determined by the Griffith Randomisation Service.

Assignment of interventions: Blinding

Who will be blinded {17a}

The trial will be conducted as an assessor-blinded study, with participants unavoidably aware of the intervention. The sonographer performing the PSV measurements will be blinded to the intervention using a drop sheet to visually conceal the intervention (Figure 5) and noise cancelling headphones to audibly mask any dialogue or sounds that might reveal the intervention. To enhance blinding of the intervention, the provider will remain beside the recipient during data collection, regardless of intervention. The statistician will also be blinded to the intervention when analysing the primary and secondary outcomes.

Figure 5. Orientation of equipment

Procedure for unblinding if needed {17b}

Unblinding will not be required in this trial. The drop sheet will maintain blinding even when the intervention is released, and the return of arterial blood flow is checked by the sonographer.

Data collection and management

Plans for assessment and collection of outcomes {18a}

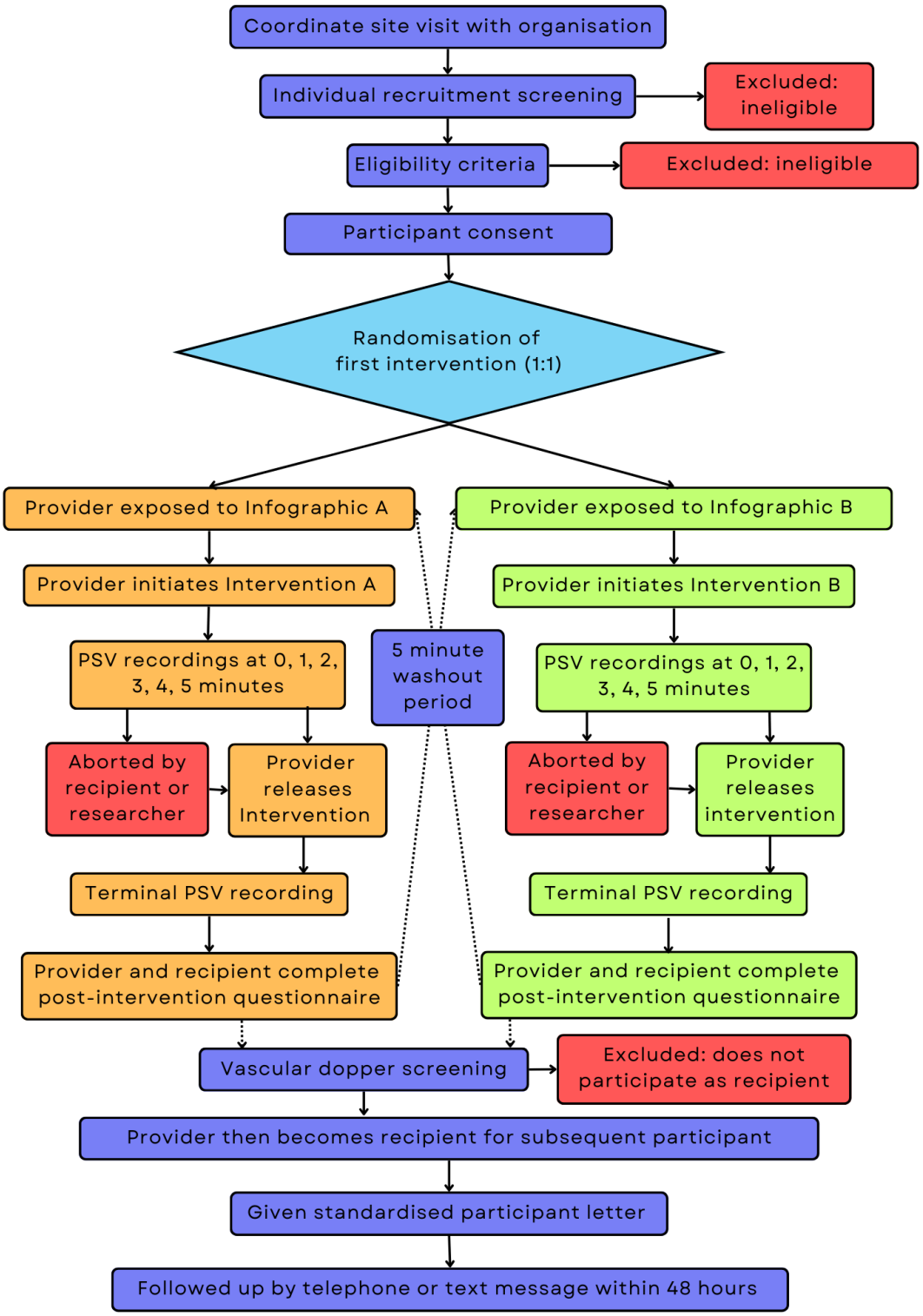

Figure 6. Schematic diagram of data collection

Participant role progression

Participants will progress from being a provider to being a recipient before exiting the testing area (Table 3). The exception to this is the participant who acts as the initial recipient (Participant 1) as they are no longer naive to the interventions. As the provider, participants will provide both techniques with a five-minute wash out period in between in. Participants may be required to be a recipient more than once, depending on the group requirements, but will only act as a provider once.

Baseline Data Collection

All participants will have baseline data collected prior to randomisation, as listed in Table 2. When acting as a recipient, a baseline measurement of the SFA PSV will be taken by a qualified sonographer using a high frequency linear transducer. This measurement will be taken at the distal SFA, with the location marked on each participant to ensure reliability for subsequent readings and assist efficiency of timing.

Participant data
Age
Biological sex
Gender
Native language/s
First aid training
Occupation
Level of education
Arm dominance
Coastal activities
Height
Weight
BMI
Thigh circumference
Grip strength

Table 2.

Trial Data Collection

After the provider is exposed to the first infographic (T0), they then apply the technique and indicate when this is completed (T1). At this point the sonographer immediately records the PSV, repeating this at 1 (T2), 2 (T3), 3 (T4), 4 (T5), 5 minutes (T6). Three measurements are taken for each timepoint with the median value used. A researcher will record times from a digital stopwatch and indicate minutely timepoints for the sonographer to take measurements. Once all PSV values are recorded and the intervention is released, the sonographer checks that normal blood flow has returned, and the above steps are repeated for the second intervention. Following this, the recipient leaves the testing area, the provider transitions to become the recipient and a new participant enters the testing area to as the provider. This cycle is repeated until the end of the data collection session (Table 2).

Data will be recorded onto a paper-based clinical research form (CRF) by a member of the research team. Following the data collection session, all CRF data will be entered into an Excel spreadsheet.

Episode	1	2	3	4	5
Provider	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6
Recipient	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5

Table 3. Transition of participants as provider or recipient per session

	STUDY PERIOD									
	Enrolment	Allocation	Post-allocation							Close-out
TIMEPOINT	$-t_1$	0	t_1 = Infographic	t_2 = 0min	t_3 = 1min	t_4 = 3min	t_5 = 4min	t_6 = 5min	t_7 = session completion	t_8 = 24-48hrs
ENROLMENT:										
Eligibility screen	X									
Formal eligibility	x									
Informed consent	X									
Lower limb evaluation	X									
Randomisation		X								
INTERVENTIONS: (applied continually in a ranomised sequence with 5min washout period between)										
Inguinal Fist Compression				X	x	x	x	X		
Commercial Windlass Tourniquet				X	x	x	x	X		
ASSESSMENTS:										
Participant characteristics	X									
Time to apply intervention			X	X						

Blood flow (Peak Systolic Velocity)				X	X	X	X	X	X	
Provider – intervention application difficulty									X	
Provider – ability to sustain intervention									X	
Provider – preference for intervention									X	
Recipient – maximal level of discomfort									X	
Recipient – preference for intervention									X	
Adverse outcomes									X	X

Table 4. Participant timeline table.

Plans to promote participant retention and complete follow-up {18b}

Key outcome measures will be collected once the interventions have been applied. Any data collected from recipients or providers who withdraw from the trial will be retained and used for analysis. Any adverse events will be recorded at the end of the data collection session, with follow-up contact made within 48 hours to document any further adverse events and as a safety feature.

Data management {19}

All data will be treated in accordance with Bond University's Research Data Management and Sharing Policy [23]. Data will be initially recorded on CRFs which will then be scanned with original physical copies destroyed. The remaining digital data will be stored Microsoft SharePoint for the mandatory data retention period of 5 years.

Confidentiality {27}

No individual data will be reported in this trial.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

This study does not involve the collection of biological specimens.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Continuous data will be summarised as mean (standard deviation), or median (interquartile range) and categorical data will be summarised as frequency (percentage). Differences between interventions in continuous outcomes, including the primary outcome of percentage reduction in PSV, will be analysed using paired t-tests, or the Wilcoxon signed rank test if normality assumptions are violated. The primary outcome will be tested for superiority of the IFC intervention. The null hypothesis of no difference in PSV reduction between interventions will be rejected if the p-value for this outcome is less than 0.05. Additional testing for period or carryover effects will be performed using Analysis of Variance. The effect of provider and recipient factors on the primary outcome will be assessed using a mixed-effects model, with the parameter of interest included as a fixed effect. Significance testing for categorical outcomes will be performed using Fisher's Exact Test. All data will be analysed using Stata v14.2 or later.

Interim analyses {21b}

There is no requirement to perform an interim analysis or have stopping guidelines for this trial.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Subgroup analyses will be performed on the baseline data outlined in Table 2, provided there is adequate data.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

The primary analysis will be conducted on an intention-to-treat basis. Thus, outcomes collected for each episode at 5 minutes post application of the intervention will be compared according to the randomly allocated order of intervention, regardless of the actual performance of this intervention by the provider. For the primary analysis, recipients who did not have primary outcome data recorded at the 5 minute time point (e.g. due to inability to tolerate the intervention) will have the missing outcome data imputed as the last recorded observation for that recipient, under the principle of including data from all randomised participants in an Intention-to-Treat analysis. A sensitivity analysis will be conducted using the Per-Protocol population, constituting only recipients with primary outcome data available at the 5-minute time point.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

Deidentified data associated with the trial will be available upon reasonable request.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

This trial will be coordinated by clinicians working at major trauma centres in Australia (Gold Coast University Hospital and The Canberra Hospital) and academics from the Water Based Research Unit at Bond University, Robina, Australia. The Trial Steering Committee will be composed of academics, emergency physicians and a trauma surgeon, who will provide oversight and will regularly meet during trial recruitment.

Composition of the data monitoring committee, its role and reporting structure {21a}

The Research Governance Officer at Bond University will monitor the conduct of the research trial, ensuring that the trial is conducted according to protocol and that data are collected appropriately.

Adverse event reporting and harms {22}

Participants will be assessed for adverse events resulting from their involvement in the trial at the end of data collection episodes and within 48 hours of completion. All adverse events and any other unintended effects of the trial interventions will be recorded and the principal investigator will report any serious events to the institutional Human Research Ethic Committee (HREC) within 72 hours of notice.

Participants that have abnormalities detected on screening assessment will be provided with a letter for their General Practitioner informing them of the finding and advising further assessment and management.

Frequency and plans for auditing trial conduct {23}

Annual progress reports will be submitted to the Research Governance Officer (RGO) and the HREC committee whilst the project is active, and a final report will be submitted on trial completion. This will include the trial status, adverse events, complaints, and any protocol deviations.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any research protocol amendments will be submitted to the institutional HREC for approval before implementation. If approved, changes to the protocol will be disseminated to the research group.

Dissemination plans {31a}

The findings from this research are intended to be disseminated through local resuscitation meetings, international conferences, peer-reviewed publications and websites.

Discussion

Based on a recent pilot study with a similar protocol, there is the potential that IFC will achieve a greater reduction in femoral blood flow than CWT when applied by untrained bystanders after brief infographic exposure. Complete occlusion of the femoral artery with IFC may also be achieved more frequently and be faster and easier to apply than CWT. Reducing blood loss is a cornerstone of trauma care and has been shown to improve patient outcomes [4]. Thus, implementing an intervention that can be easily taught and

does not require equipment has the potential to reduce the disease burden of traumas such as shark attacks.If IFC is found to be superior to CWT, the findings will play a significant role in shaping future guidelines for first aid management of massive arterial haemorrhage from lower limb trauma in the civilian, industrial and military spaces.

Trial status

The current protocol is version 1.0 dated XX XXX 2024, being the final version approved by the HREC and prior to the first participant recruited to the trial. Participant recruitment is anticipated to commence mid 2024 and be completed within 12-18 months.

Abbreviations

CRF - Clinical Research Form

IFC - Inguinal Fist Compression

CWT – Commercially Manufactured Windlass Tourniquet

PSV – Peak Systolic Velocity

SFA – Superficial Femoral Artery

SLSA - Surf Life Saving Australia

APP – Arterial Pressure Point

APPT – Arterial Pressure Point Technique

ILCOR – International Liaison Committee on Resuscitation

HREC - Human Research Ethic Committee

RGO - Research Governance Officer

SHARC – Stopping Haemorrhage by Applicaiton of Rope Tourniquet

GRS – Griffith Randomisation Service

Acknowledgements

Campbell, Dr Donald OAM, FACEM, MBBS

Authors' contributions {31b}

Conceptualisation – this project is based upon original research by NT and DL. The iinitial pilot for this study protocol was led by JF with input from the remaining authors.
Trial design – contribution from all authors
Protocol development - KB with oversight from JF/PS and input from remaining research team
Funding application - lead by KB and PS with input from remaining research team
Statistical analysis – PJ

All authors read and approved the final manuscript.

Funding {4}

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Availability of data and materials {29}

Data will be available from the principal investigator upon reasonable request.

Ethics approval and consent to participate {24}

Ethics approval was obtained from XX, XXXXX, 2023 (HREC number). Written informed consent will be obtained from all participants.

Consent for publication {32}

Model participant information and consent form can be provided upon reasonable request.

Competing interests {28}

The authors have no competing interests to declare.

Authors' information (optional)

Dr Bruce is an emergency physician and early career researcher with pre-hospital experience.

Dr Furness is an Assistant Professor of Physiotherapy and the subject convenor of evidence-based practice research subjects.

Dr Snelling is an emergency physician, sonologist and established career researcher who has designed and successfully run multiple randomised controlled trials.

Dr Jones is an emergency physician and early career researcher with statistical expertise.

Dr Patel is an experienced acute care and trauma surgeon at a tertiary trauma centre. He has a deep interest in trauma research, having been involved in prior collaborative research.

Mr Philip Abery and Mr Kevin Kemp-Smith are both academics at Bond University who will support the trial through their research experience.

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