Study Protocol Title: *Early Versus Delayed Weight-Bearing After Operatively Managed Trimalleolar Ankle Fractures (EASY-Ankle): A Pilot Randomized Controlled Single-Center Trial*

Protocol for a Pilot Study on Early Versus Delayed Weight-Bearing After Operatively Managed Trimalleolar Ankle Fractures (EASY-Ankle)

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Sponsor:	Ottawa Hospital Research Institute (OHRI)
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Version Date [Day, Month, Year]	*01/05/2026*

Study Protocol Title: *Early Versus Delayed Weight-Bearing After Operatively Managed Trimalleolar Ankle Fractures (EASY-Ankle): A Pilot Randomized Controlled Single-Center Trial*

Statement of Compliance

The Principal Investigator (PI) will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Research Ethics Board (REB) of Record, except where necessary to eliminate an immediate hazard(s) to the study participants. All personnel involved in the conduct of this study will have completed the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, PHIPA, and Protocol Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the REB of Record for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is enrolled. Any amendment to the protocol or consent materials will require review and approval by the REB of Record before the changes are implemented to the study. All changes to the consent form will be REB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

Principal Investigator:

Name: Dr. Bradley Meulenkamp

Signed: _____ Date: _____

<DD Month YYYY>

Site Address

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List of Abbreviations

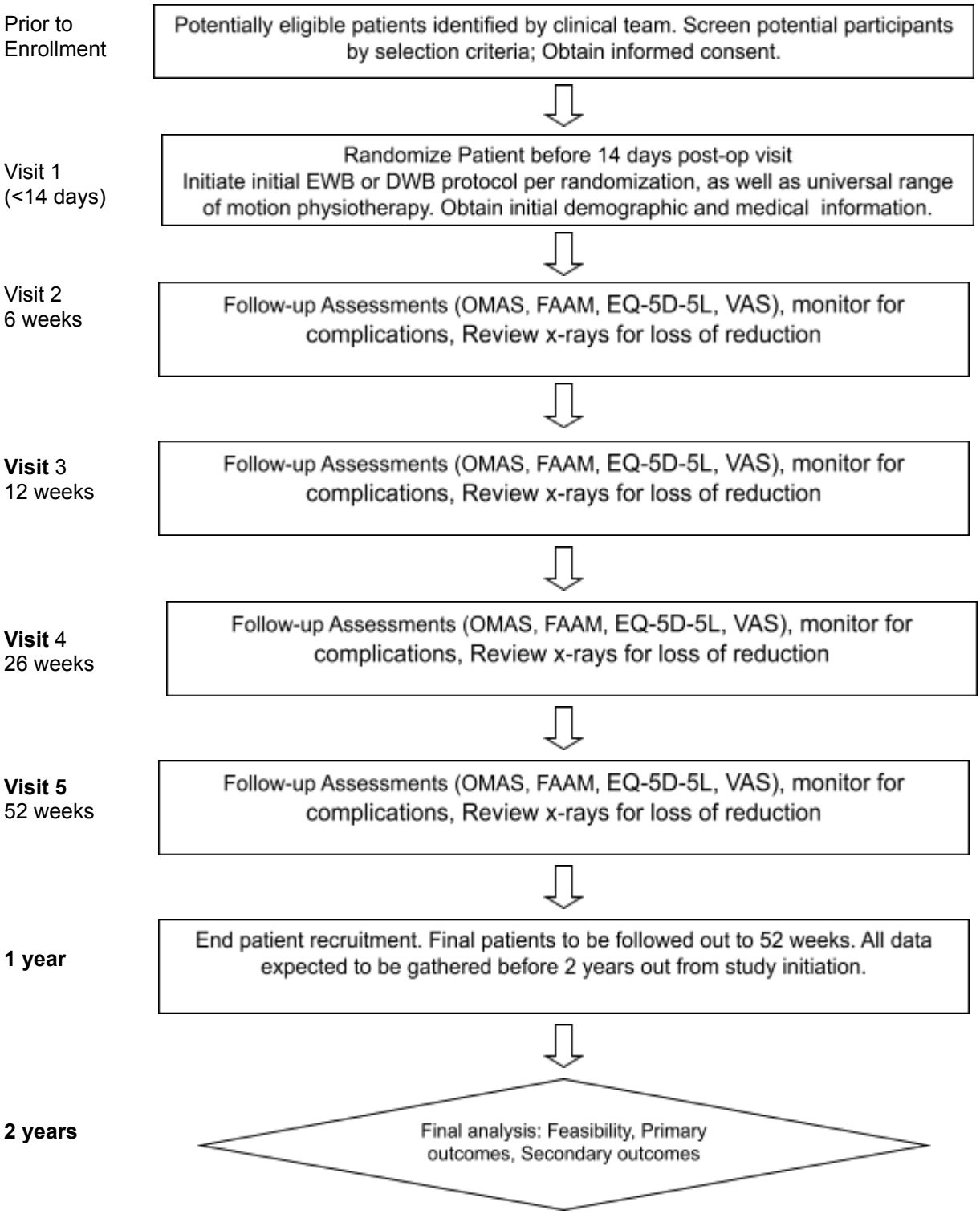
AE	Adverse Event/Adverse Experience
CRF	Case Report Form
CRS	OHRI - Clinical Research Support
CTO	Clinical Trials Ontario
DCS	Data Capture System
OHRI	Ottawa Hospital Research Institute
PHI	Personal Health Information
PHIPA	Personal Health Information Protection Act
REB	Research Ethics Board
TCPS2	Tri Council Policy Statement
TOH	The Ottawa Hospital
UOHI	University of Ottawa Heart Institute
EWB	Early Weight-Bearing
DWB	Delayed Weight-Bearing
ORIF	Open Reduction and Internal Fixation
NWB	Non-Weight Bearing
OMAS	Olerud and Molander Ankle Score
FAAM	Foot and Ankle Ability Measure
EQ-5D-5L	EuroQol 5 Dimensions 5L
VAS	Visual Analog Scale
DVT	Deep Vein Thrombosis
PE	Pulmonary Embolus
RCT	Randomized Controlled Trial

1 PROTOCOL SUMMARY

1.1 *Synopsis*

Title	Protocol for a Pilot Study on Early Versus Delayed Weight-Bearing After Operatively Managed Trimalleolar Ankle Fractures
Short Title	EASY-Ankle
Study Description	This is a pragmatic, single center, randomized non-inferiority pilot clinical trial comparing Early Weight-Bearing (EWB) versus Delayed Weight-Bearing (DWB) protocols after open reduction and internal fixation (ORIF) of unstable trimalleolar ankle fractures. The study aims to assess the feasibility and preliminary safety/non-inferiority in terms of functional outcome. Participants are randomized 1:1, undergo a two-week non-weight-bearing period, followed by their assigned intervention, and complete assessments over 52 weeks.
Objectives	Primary Aim: To assess the feasibility of patient recruitment, participant adherence, and completeness of data collection for a subsequent definitive trial, and to quantify preliminary variations in ankle function (OMAS) at three months. Secondary Aims: To quantify preliminary differences in ankle function (OMAS), health-related quality of life (EQ-5D-5L, VAS), complications, and radiological outcomes (loss of reduction) at 6, 12, 26, and 52 weeks.
Study Design	Pragmatic, single center randomized non-inferiority pilot clinical trial.
Participant Population, Selection Criteria	Patients 18 years and older who have undergone operative fixation for an unstable trimalleolar ankle fracture within 14 days of injury, with satisfactory anatomical reduction and rigid internal fixation. Exclusions include lack of protective sensation, inability to adhere to trial procedures, bilateral treated ankle fractures, hindfoot nail treatment, morbid obesity (BMI >40), diabetes, or neuroarthropathy.
Study Sites	Single center (TOH)
Participant Duration	A maximum of 12 months (52 weeks) post-operation. The intervention period is approximately six weeks.
Number of participants	Recruitment will progress over 12 months with no fixed sample size, continuing based on pre-determined feasibility criteria (e.g., sufficient consent rate and compliance to instructions).
Study Phases (Screening, Observation Period, Follow-Up)	Screening/Consent, Randomization, Two-week Non-Weight-Bearing Period, Intervention/Observation Period (to 52 weeks), Follow-up.
Efficacy Evaluations	Olerud and Molander Ankle Score (OMAS), Foot and Ankle Ability Measure (FAAM), EuroQol 5 Dimensions 5L (EQ-5D-5L), and Visual Analog Scale (VAS) scores.
Safety Evaluations	Monitoring for complications, including fracture displacement (loss of reduction), non-union, malunion, infection, symptomatic deep vein thrombosis (DVT), pulmonary embolus (PE), and unplanned re-operation.
Statistical Analysis	Primarily descriptive analysis for feasibility outcomes. Preliminary linear regression model to estimate the mean difference in OMAS at three months (non-inferiority margin of -8 points) to inform future sample size calculations.
Data and Safety Monitoring Plan	Principal Investigator is responsible for data quality management and ongoing assessment of the study conduct. A Trial Steering Committee (TSC) will formally evaluate the trial's viability against pre-agreed progression criteria.

1.2 *Schematic of Study Design*



1.3 *Schedule of Activities*

A full schedule of activity of the study visits and assessments are outlined in the table below:

Assessment Type	Operative day	2 Weeks PO	6 Weeks PO	12 Weeks PO	26 Weeks PO	52 Weeks PO
Inclusion/Exclusion Criteria*	X	x				
Informed Consent*	X	x				
Randomization*	X	x				
Surgical Procedure	X					
Radiographs	X	x	X	X	X	X
Questionnaires			X	X	X	X

*The Inclusion/Exclusion criteria verification, as well as the Informed consent process and randomization could occur anytime between the Operative day and 2 weeks PO.

1.4 *Key Roles*

- Principal Investigator: Dr. Bradley Meulenkamp, MD MSc FRCSC Orthopedic Surgery
    - Responsible for the overall conduct and oversight of the study, data quality management, ongoing assessment of study conduct, and assuring compliance with the protocol and regulatory requirements.
- Co-Principal Investigator: Dr. Karl-André Lalonde, MD MEd FRCSC Orthopedic Surgery
    - Responsible for the overall conduct and oversight of the study, data quality management, ongoing assessment of study conduct, and assuring compliance with the protocol and regulatory requirements.
- Co-Investigator: Dr. Cameron Elgie, MD FRCSC Orthopedic Surgery Fellow
    - Involved in the day-to-day conduct of the study, including screening, enrollment, intervention delivery, and data collection.
- Clinical Research Coordinator: Responsible for the day-to-day coordination and administrative management of the study, including participant screening support, informed consent logistics, visit scheduling, questionnaire administration, maintenance of study binders and essential documents, data entry and query resolution in REDCap, protocol deviation and adverse event documentation, preparation for monitoring activities, communication with investigators and institutional departments, and ensuring study procedures are conducted in accordance with the protocol, GCP, REB requirements, and applicable institutional policies.

2 Introduction, Background Information and Scientific Rationale

2.1 *Background Information and Relevant Literature*

Trimalleolar ankle fractures represent severe, unstable injuries that necessitate open reduction and internal fixation (ORIF) to achieve anatomical reduction, facilitate proper healing and prevent post traumatic OA.[1] The conventional postoperative management protocol is a period of non-weight bearing (NWB) with immobilization in a cast or orthosis, typically for approximately six weeks.[2] This traditional approach is underpinned by theoretical concerns regarding potential secondary fracture

displacement, implant failure, or wound complications if early weight-bearing (EWB) or mobilization is initiated.[3,4]

A substantial and growing body of high-level evidence, including systematic reviews and randomized controlled trials, now supports the implementation of EWB and mobilization protocols for surgically treated ankle fractures in general[3,5–11]. These protocols have been shown to improve short-term functional outcomes, increase range of motion (ROM), and expedite the return to work and daily activities without increasing the incidence of major complications such as fixation failure or loss of reduction.[3,5–11]

A significant knowledge gap persists regarding the specific subgroup of trimalleolar fractures. Despite a general trend toward early weight-bearing (EWB), these complex and often perceived as unstable injuries have frequently been excluded from existing EWB trials.[7] Even when included, trimalleolar fractures have not been critically examined in subgroup analyses[4,6] Biomechanical data suggests that trimalleolar fractures are no less stable under weight-bearing loads.1[2] This lack of focused data contributes to ongoing clinical uncertainty and highlights the need for dedicated investigation.

2.2 *Rationale*

A pilot study is needed to specifically evaluate the safety and feasibility of an EWB protocol following ORIF of unstable trimalleolar ankle fractures. The findings will provide essential preliminary data to inform the design of a future, definitive randomized controlled trial for this distinct patient population.

2.3 *Potential Risks & Benefits*

2.3.1 Potential Risks

- Very Likely (21% -100%): Post-operative discomfort, pain, and swelling.
- Less Likely (5 – 20%): Problems with ankle healing, such as wound complications or minor complications that may delay healing.
- Rarely (1 – 4% - Most Serious Risks):
    - *o* Loss of reduction/fracture displacement (the bone shifting), which may require another surgery.
    - *o* Bone failing to heal (non-union or malunion), a serious, long-term complication that may require re-operation.
    - *o* Severe infection, which may require hospitalization and prolonged antibiotic treatment.
    - *o* Blood clot in your leg (Deep Vein Thrombosis or DVT) or lungs (Pulmonary Embolism or PE), which are life-threatening risks.
    - *o* Unplanned re-operation.

2.3.2 Potential Benefits

- The experimental intervention may or may not be of direct medical benefit to the participant.
- There is potential for a functional and quality of life improvement related to the experimental (EWB) group.
- The information learned from this study is expected to help other people recovering from these fractures in the future, by optimizing post-operative recovery and guiding future larger trials.

3 Objectives and Purpose

3.1 *Primary Objective*

1. To assess the feasibility of patient recruitment, participant adherence to the intervention protocols, and the completeness of data collection procedures for a subsequent definitive trial focused on early versus delayed weight-bearing in operatively treated trimalleolar ankle fractures.
2. To quantify and make preliminary conclusions on variations in ankle function between early and delayed weight-bearing groups, using the Olerud and Molander Ankle Score (OMAS) at three months post-randomization, in patients with trimalleolar ankle fractures.

3.2 *Secondary Objectives*

1. Quantify and draw preliminary conclusions on differences in ankle function using OMAS.
2. Quantify and draw preliminary conclusions on differences in health-related quality of life between treatment groups using EuroQol 5 Dimensions 5L (EQ-5D-5L) and visual analog scale (VAS) scores.
3. Investigate preliminary differences in the risk of complications (e.g., fracture displacement, non-union, malunion, infection, symptomatic deep vein thrombosis [DVT], pulmonary embolus [PE], and unplanned re-operation) between treatment groups.
4. Assess preliminary radiological outcomes, including intra-operative mal-reduction and postoperative loss of reduction.

4 Study Design and Endpoints

4.1 *Description of Study Design*

The EASY-Ankle study is a pragmatic, single center, randomized non-inferiority pilot clinical trial designed to compare two post-operative weight-bearing protocols in patients aged 18 and older who have undergone Open Reduction and Internal Fixation (ORIF) for an unstable trimalleolar ankle fracture. Participants are randomized 1:1 into either an Early Weight-Bearing (EWB) group, starting weight-bearing at two weeks post-surgery, or a Delayed Weight-Bearing (DWB) group, delaying it until six weeks post-surgery. The rationale for this pilot design is to evaluate the safety and feasibility of EWB for this complex injury, which has often been excluded from previous trials, and to gather preliminary data on recruitment, adherence, and OMAS variability to inform a future definitive Randomized Controlled Trial (RCT). Recruitment is planned for 12 months with a maximum participant follow-up of 52 weeks (12 months). Data collection focuses on clinical outcomes (OMAS, FAAM, EQ-5D-5L, VAS), safety/complications (e.g., loss of reduction, DVT, PE), and socio-demographic data.

4.2 *Duration of Study Participation*

It is expected that study participation will last a maximum of 12 months. Participants will be followed for 52 weeks (1 year) post-operation for a total of four protocol-mandated follow-up visits

4.3 *Total Number of Participants and Sites*

We will be recruiting patients over a period of 12 months at a single center. There is no fixed sample size for this pilot. The study will continue to progress based on pre-determined feasibility criteria (e.g., recruitment rates, patient compliance) to determine if a future definitive trial is viable.

5 Study Enrollment and Withdrawal

5.1 *Participant Inclusion Criteria*

Patients will be eligible for inclusion into the trial if:

- They are 18 years and older.
- They have undergone operative fixation for an unstable trimalleolar ankle fracture with or without syndesmotic injury requiring fixation, where satisfactory anatomical reduction and rigid internal fixation have been achieved according to established AO principles, including fixation of the posterior malleolus where indicated.
- Surgery was performed within 14 days of the injury.
- They are able and willing to give informed consent.

5.2 *Participant Exclusion Criteria*

Patients will be excluded from this trial if any of the following apply:

- They have a lack of protective sensation (e.g., peripheral neuropathy).
- They are unable to adhere to trial procedures.
- They have bilateral operatively treated ankle fractures.
- They received a hindfoot nail to treat the index fracture.
- Patients with morbid obesity (body mass index >40), diabetes, or neuroarthropathy.

5.3 *Strategies for Recruitment and Retention*

Recruitment: The recruitment strategy for this pilot study will be pragmatic, utilizing the existing clinical team to identify potential participants. As trimalleolar ankle fractures are relatively common injuries presenting to the orthopedic service, the clinical team is well-positioned to screen for and approach eligible patients as they are identified during routine clinical care.

Retention: Participant retention is expected to be high because the mandated study follow-up schedule (6, 12, 26, and 52 weeks post-operation) mirrors the standard-of-care timeline for post-operative fracture treatment. By aligning the study visits with routine clinical follow-ups, the burden on the participant is minimized, which is a key factor in maximizing compliance and retention over the 12-month study duration. Additionally, efforts will be made to reduce financial burden by reimbursing participants for parking costs incurred during study visits.

5.4 *Participant Withdrawal or Termination*

5.4.1 Reasons for Withdrawal or Termination

Participant Choice (Withdrawal): Participants can choose to end their participation in this research at any time without having to provide a reason. They may also withdraw their permission to use information that was collected about them for this study.

Study Doctor Termination: The study doctor may stop a participant's participation in the study early, and without their consent, for reasons such as:

- The participant is unable to tolerate the study intervention.
- The participant is unable to complete all required study procedures.
- New information shows that the study intervention is no longer in the participant's best interest.
- The study doctor no longer feels this is the best option for the participant.
- The participant develops a post-operative complication that necessitates changing their weight-bearing status.

5.4.2 Handling of Participant Withdrawals or Termination

Individuals may choose to end their participation at any time and can do so by notifying the study team. If they choose to withdraw entirely, data from those participants will be discarded. While withdrawing permission to use collected data also signifies withdrawal from the study, the consent process explicitly allows participants to withdraw from active intervention but permit the ongoing collection of study data up to the final follow-up period. This ensures the maximum possible data retention. If a participant's involvement is terminated early by the study doctor due to complications or intolerance of the intervention, the reasons will be discussed with the individual, and their care will revert to the treating surgeons preference outside of the research protocol.

If all attempts to contact the participant are unsuccessful after 180 days following a missed appointment, the participant will be formally documented and classified as Lost to Follow-up. The Investigator will, however, attempt to obtain permission from the participant (if contact is re-established) to record major complication data up to the protocol-described end of the participant follow-up period, even if they decline further active study participation.

6 Study Assessments and Procedures

The enrollment process will involve two key phases that occur between the operative day and 2 weeks post-operation (PO). Patients are identified by a member of the clinical team based on review of medical records and routine X-rays to confirm inclusion criteria (e.g., age ≥18, trimalleolar fracture, surgery within 14 days) and rule out exclusion criteria (e.g., morbid obesity, diabetes). The primary procedures for confirming eligibility, such as the review of medical records (fracture details, surgical reports) and routine post-operative X-rays, are considered part of standard or usual patient care outside of the research study. As such, these procedures do not require any additional consenting beyond the main Informed Consent for participation in the trial itself. The clinical team next receives verbal consent from the patient to be approached by a member of the research team.

After eligibility is confirmed by the research team, the participant is provided with the Informed Consent Form (ICF) and given the opportunity to discuss the study with the research team. The participant must be given adequate time to review the consent form and have all their questions answered. Consent must be obtained via a signed Informed Consent Form (ICF), confirming that participation in the study is entirely voluntary and that the decision to participate or withdraw will not affect the usual medical care received outside of the study.

Following consent, a final review of the medical records, including surgical details and follow-up X-rays (if available at this stage), confirms full compliance with all selection criteria. The participant must also confirm their ability and willingness to adhere to the trial procedures.

Once consent is obtained and eligibility is confirmed, the participant is randomly assigned (1:1 ratio) to either the Early Weight-Bearing (EWB) or Delayed Weight-Bearing (DWB) intervention group.

The verification of inclusion/exclusion criteria, the informed consent process, and the randomization must all be completed anytime between the Operative day and 2 weeks Post-Operation (PO). The two-week period immediately following surgery is the non-weight-bearing period for all participants before the randomized intervention begins.

7 Study Procedures / Evaluations

7.1 *Intervention Assignment:*

Participants will be randomly assigned (1:1 ratio) to one of two interventional groups following their trimalleolar ankle fracture surgery.

- Pre-Randomization: All participants will be non-weight-bearing (NWB) for the first two weeks post-op to allow for swelling reduction and wound healing.
- Early Weight-Bearing (EWB) Group: Participants will be instructed to start weight-bearing as tolerated on their affected leg starting two (2) weeks following their surgery, using walking aids as needed.
- Delayed Weight-Bearing (DWB) Group: Participants will be instructed to avoid any weight-bearing on their operated leg for a duration of six (6) weeks following their surgery, continuing to use walking aids during that time. After the six-week period, patients can begin weight-bearing as tolerated.

7.2 *Rehabilitation:*

All participants will begin standardized ankle exercises (active and passive range-of-motion) two weeks post-surgery, as instructed by the clinic physiotherapist, regardless of their weight-bearing group. These exercises are to be performed daily with the immobilization cast/orthosis removed.

7.3 *Data Collection (Experimental and Non-Experimental):*

- Demographic and Medical Information: Collection of age, sex, occupation, height, weight, medical history, medications, allergies, and pre- and post-surgical data (fracture type, date/time of injury, surgery details, complications).
- Monitoring for Complications: Review and monitoring of any side effects or complications (e.g., loss of reduction, non-union, infection, DVT, PE, unplanned re-operation).
- Radiological Outcomes: Review of routinely collected X-rays (radiographs) at follow-up visits (Operative day, 2, 6, 12, 26, and 52 Weeks PO) to assess for loss of reduction (talar subluxation >2mm, excessive talar tilt >2°, or a tibiofibular clear space ≥5mm).

7.4 *Questionnaire Administration*

Ankle function and health-related quality of life will be assessed through the following questionnaires, completed at the 6, 12, 26, and 52 weeks post-operation follow-up visits (approximately 20 minutes total to complete):

- Olerud and Molander Ankle Score (OMAS): To assess ankle function, pain, and ability to perform daily activities (walk, jump, run, use stairs).
- Foot and Ankle Ability Measure (FAAM): To assess ankle function in everyday and more demanding activities.
- EuroQol 5 Dimensions 5L (EQ-5D-5L) and Visual Analog Scale (VAS): To assess health-related quality of life (mobility, self-care, daily activities, pain/discomfort, and anxiety/depression) and degree of pain.

7.5 *Control of Bias and Confounding*

The study employs a randomized design (1:1 ratio). Participant or intervention provider blinding is not possible due to the nature of weight-bearing instructions. To reduce bias, all objective and subjective

outcome assessments will be conducted by personnel blinded to the treatment allocation to the best of our abilities.

8 Statistical Considerations

8.1 *Study Hypotheses*

We hypothesize that Early Weight Bearing (EWB) will be non-inferior to Delayed Weight Bearing (DWB) in terms of functional outcome.

Specifically, this non-inferiority is quantified using the Olerud and Molander Ankle Score (OMAS) at three months post-randomization, with the protocol specifying a non-inferiority margin of -8 points for the OMAS.

8.2 *Sample Size Determination*

This is an independent pilot study designed to assess operational feasibility and gather preliminary data for the definitive non-inferiority Randomized Controlled Trial (RCT) sample size calculation. This phase is not statistically powered to detect efficacy differences. We will recruit to this pilot study over the course of 12 months. A Trial Steering Committee (TSC) will use a “traffic light” to formally evaluate the trials viability against pre-agreed progression criteria, which address key areas of uncertainty or risk.[18]

Progression from the pilot to the main trial will be governed by progression criteria categorized into three decision types: Continue (Green), indicating all targets have been met and the main trial should proceed; Amend (Amber), indicating remediable issues requiring a 'rescue plan' before proceeding with caution; or Stop (Red), indicating intractable issues that prevent progression. These criteria focus on three common operational challenges: trial recruitment, protocol adherence, and outcome data completeness. Trial Recruitment Feasibility will be assessed using rates per center per unit time, requiring an Eligibility Rate Target ≥60% of screened patients and a Consent Rate Target ≥30% of eligible patients. Failure to meet these mandates a thorough exploration of screening logs to identify the root cause (e.g., insufficient approach, low eligibility, or low consent). Protocol Adherence is critical to maintaining statistical power, particularly in the delayed weight-bearing (DWB) group where non-compliance is a known challenge. Targets include a Cross-Over Rate Target ≤5% and an Intervention Compliance Target ≥90% with key procedures (e.g., beginning range-of-motion exercises at two weeks postoperatively). Adherence will be monitored via self-reporting, with non-compliance in the DWB group specifically noted to inform strategies for the definitive trial. Finally, Outcome Data Completeness will assess likely participant retention, requiring an Attrition/Loss to Follow-up Target ≤15% and a Valid Primary Outcome Data Target ≥80% for the OMAS data. The assessment must explore the degree of missing data within key outcomes, and the resulting OMAS variability data will be utilized to conduct the final sample size calculation for the definitive randomized trial.

8.3 *Statistical Methods*

For this pilot study, all analyses will be primarily descriptive to assess feasibility and generate preliminary estimates.

- **Feasibility Outcomes:** Recruitment rates, participant adherence (self-reported), and completeness of outcome data will be reported using descriptive statistics (e.g., means, standard deviations, frequencies, percentages).
- **Preliminary OMAS Analysis:** Scores at three months will be summarized descriptively. A linear regression model will estimate the preliminary mean difference between EWB and DWB

groups, which will inform future power calculations for a pre-specified non-inferiority margin of -8 points for OMAS.
- **Preliminary Secondary Outcomes:** Secondary clinical outcomes will be similarly summarized descriptively. Preliminary effect sizes and confidence intervals will be presented for continuous and binary outcomes.
- **Compliance:** An intention-to-treat (ITT) analysis will be performed, with a descriptive report of compliance rates for both groups based on participant self-report.

9 Source Documents and Access to Source Data / Documents

Access to study records will be limited to REB-approved members of the study team. The PI will permit study-related monitoring, audits, and inspections by the REB and/or OHRI compliance and quality assurance groups of all study related documents (e.g. source documents, data collection instruments, study data etc.). The PI will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

Participation as a PI in this study implies acceptance of potential inspection by REB and / or applicable OHRI compliance and quality assurance offices.

10 Study Oversight

The Principal Investigator (PI) is responsible for overall study oversight, including data quality management and ongoing assessment of study conduct, in compliance with the protocol and regulatory requirements. Monitoring is structured on a risk-based approach, prioritizing the protection of participants and the integrity of critical data, which includes key functional outcomes (OMAS) and a robust safety assessment around complications. The study's specific safety evaluations include monitoring for and reporting of fracture displacement (loss of reduction), non-union, malunion, infection, symptomatic deep vein thrombosis (DVT), pulmonary embolus (PE), and unplanned re-operation. The overall viability of the trial will be formally evaluated by a Trial Steering Committee (TSC) against pre-agreed progression criteria, covering recruitment, adherence, and outcome data completeness. The TSC will also be responsible for monitoring procedures using a peer-to-peer model by members of the TSC. This will include Source Document Verification (SDV) on Informed Consent Forms (ICFs), eligibility criteria, and all reported Unanticipated Problems/Serious Adverse Events (SAEs). This focused SDV on complications will confirm that all protocol-related safety endpoints are meticulously tracked and reported for all applicable participants. Subsequent monitoring will be conducted monthly, and a report detailing observations, corrective actions, and follow-up requirements will be generated after each event for review and sign-off by the Principal Investigator (PI).

11 Ethics / Protection of Human Participants

11.1 *Ethical Standard*

All study procedures will be conducted in accordance with TCPS2 and the Declaration of Helsinki ethical standards

11.2 *Informed Consent Process and Documentation*

Informed consent is a comprehensive process that is initiated prior to the individual's agreement to participate and continues throughout their study involvement. Extensive discussion of the study's procedures, risks, and potential benefits will be provided to the potential participant by a member of the research team or study staff, who will act as the Principal Investigator's (PI) delegate. Consent forms will be REB-approved, and the potential participant will be asked to carefully read and review the document in a private setting at the study site to ensure their privacy. The PI/delegate will explain

the research study in terms suited to the participant's comprehension and answer any questions that may arise, ensuring the participant fully understands the purposes, procedures, and potential risks of the study, as well as their rights as a research participant. Potential participants will be provided sufficient time to think about the study and its implications, and they should have the opportunity to discuss it with their surrogates, if they so choose, prior to agreeing to participate. The potential participant will sign the informed consent document before any procedures are conducted specifically for the study. Participants are protected by the explicit emphasis that the quality of their medical care will not be adversely affected if they decline to participate. Written, signed informed consent will be documented on the ICF. A copy of the signed informed consent document will be given to the participant for their records and one will be stored in the participant's research record. The consent process, including the name of the individual obtaining consent, will be thoroughly documented in the participant's research record. Any alteration to the standard consent process (e.g., use of a translator, consent document presented orally, etc.) and the justification for such alteration will likewise be documented.

11.3 *Consent / Assent and Other Informational Documents Provided to Participants*

Written documentation of informed consent is required prior to starting the intervention. The study's primary consent material is the Informed Consent Form (ICF), which includes a Summary of Informed Consent Form at the beginning. This form describes in detail the study intervention/observations, study procedures, and risks, and is given to the participant. The participant's signature on the ICF serves as written documentation of their informed consent.

The following consent materials are submitted with this protocol:

1. EASY-Ankle (Early Weight Bearing Vs Delayed Weight bearing) Informed Consent Form (ICF) V2.0

12 Research Data Management

12.1 *Data Management Plan*

The Research Coordinator and PI and any other delegated, trained, study staff will have access to the study data. Collected data will include demographic and medical information (e.g., age, sex, occupation, height, weight, medical history, medications, allergies), surgical and fracture-related data, radiographic outcomes, questionnaire data (OMAS, FAAM, EQ-5D-5L, VAS) and study-related complications (e.g. loss of reduction, infection, DVT, PE, re-operation).

AEs/complications will be collected from the patient's medical record and will be recorded in an AE tracking log for oversight by the PI.

Patient MRN will be recorded on the study master list only. All study data will be entered into RedCap. Data will be housed on TOH servers. All study documentation will be stored in an encrypted file on TOH servers. Any paper documents will be kept in a locked filing cabinet in the locked Orthopaedic Research office.

12.2 *Data Collection and Management Responsibilities*

Data collection is the responsibility of the study staff at the site under the supervision of the site PI. The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

Copies of the electronic CRF (eCRF) will be provided for use as source documents and maintained for recording data for each participant enrolled in the study. Data reported in the eCRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official electronic study record.

Clinical data and clinical laboratory data will be entered into RedCap, a data capture system provided by the Data Management System team of the OHRI The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

Study data will be entered into RedCap a secure, web-based application designed to support data capture for research studies. The application and data are housed on servers provided by the OHRI. These servers are located within the OHRI secure data center.

12.3 *Data Sharing and Reuse*

De-identified study data may be shared with members of the research team, collaborators, and regulatory bodies (e.g., REB or OHRI oversight bodies) for the purposes of study monitoring, analysis, and publication. Data will be shared in coded or aggregate form, and no directly identifiable personal health information (PHI) will be disclosed.

Data sharing may occur for academic dissemination, including conference presentations and peer-reviewed publications.

All data sharing will comply with institutional policies, PHIPA regulations, and REB approvals. Any external data sharing beyond the study team will require appropriate data sharing agreements and ethical approval, where applicable.

The study team may use the collected data for future related research purposes, subject to REB approval.

12.4 *Study Records Retention*

All study records will be retained by the Principal Investigator for a minimum of 10 years in accordance with OHRI and institutional requirements. Records will be securely stored on encrypted TOH/OHRI servers, with any physical documents stored in locked filing cabinets within secure research offices. After the retention period, records will be securely destroyed in accordance with institutional policies and applicable regulations.

13 Protocol Deviations

All protocol deviations will be documented, reviewed, and reported in accordance with REB and institutional OHRI requirements. Deviations will be identified through routine monitoring of study conduct, data entry, and source documentation.

Deviations will be recorded in a protocol deviation log and reviewed by the Principal Investigator to assess their impact on participant safety, data integrity, and study outcomes.
Protocol deviations are not permitted unless necessary to eliminate an immediate hazard to a participant. Any such deviations will be reported to the REB as required and appropriately logged within the study documents.
Where applicable, corrective and preventive actions will be implemented to minimize recurrence of deviations. Any significant deviations may require REB notification and approval.

14 Knowledge Translation

At the conclusion of the study, participants will be provided with a lay summary of the key findings of the EASY-Ankle pilot trial. This summary will be written in plain language, avoiding technical jargon, and will be mailed or emailed to all participants who indicated they wished to receive the study results on their Informed Consent Form (ICF). The study team will endeavor to send this summary within six months of the final manuscript being published. Participants will also be informed that the full study results, including the final publication, will be available through the Principal Investigator's research office upon request.

A manuscript will be prepared and submitted to a peer-reviewed journal to inform the orthopedic community about the feasibility, preliminary safety, and efficacy of early weight-bearing in operatively managed trimalleolar ankle fractures, and to guide the development of a definitive trial protocol.

The study findings will be presented locally at academic rounds and research symposia to engage the immediate clinical and research community. Furthermore, the results will be disseminated through presentations at major national and international meetings, including the The American Orthopaedic Foot & Ankle Society (AOFAS) meeting and the Canadian Orthopaedic Association (COA) meeting.

While this pilot study focuses on short-to-medium term outcomes, it is recognized that a 12-month follow-up may not be sufficient to assess the long-term development of post-traumatic ankle arthritis.[5,6] Planning for a definitive trial will consider an extended follow-up period (e.g., 3-5 years) to adequately capture these important long-term outcomes.

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APPENDIX A: Critical to Quality (CtQ) Factors