

Region-Specific Appendix:

Aotearoa New Zealand (NZ)

Version 1.1

RandOmised Arthroplasty infection worlDwide Multidomain Adaptive Platform trial

Summary

This region-specific appendix describes and explains issues related to the ROADMAP trial specific to sites within Aotearoa New Zealand. This includes information relating to Aotearoa New Zealand-specific funding, ethics and governance, drug/domain availability within the region, and proposed sites to be included in the trial.

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1. ABBREVIATIONS

ACTT	Aotearoa Clinical Trials
AUS RTSC	Australian Regional Trial Steering Committee
CMG	Counties Manukau Health
CRF	Case report form
CTRA	Clinical Trials Research Agreement
DSA	Domain-Specific Appendix
DSWG	Domain-Specific Working Group
DSMC	Data Safety and Monitoring Committee
GTSC	Global Trial Steering Committee
MoU	Memorandum of Understanding
NHI	National Health Index
NHMRC	National Health and Medical Research Council
NZ	Aotearoa New Zealand
PI	Principal Investigator
PJI	Prosthetic Joint Infection
RAR	Response Adaptive Randomization
RCT	Randomized Controlled Trial
ROADMAP	RandOmised Arthroplasty infection worlDwide Multidomain Adaptive Platform trial
RSA	Region-Specific Appendix
RTSC	Regional Trial Steering Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SSI	Significant Safety Issue
SOP	Standard operating procedure
SUSAR	Suspected Unexpected Serious Adverse Reactions
TMG	Trial Management Group
UoN	University of Newcastle

2. PROTOCOL APPENDIX STRUCTURE

The structure of this protocol is different to that used for conventional trials because this trial is highly adaptive, and the description of these adaptations is better understood and specified using a 'modular' protocol design. While all adaptations are pre-specified, the structure of the protocol is designed to allow the trial to evolve over time, for example, by the introduction of new domains or interventions or both, and commencement of the trial in new geographical regions.

The protocol has multiple modules, in brief, comprising a Core Protocol (overview and design features of the study), multiple Domain-Specific Appendices (DSA; detailing all interventions currently being studied in each domain) and multiple Region-Specific Appendices (RSA; detailing regional management and governance).

The Core Protocol contains all information that is generic to the trial, irrespective of the regional location in which the trial is conducted and the domains or interventions that are being tested. The Core Protocol may be amended but it is anticipated that such amendments will be infrequent.

The Core Protocol does not contain information about the intervention(s), within each domain, because one of the trial adaptations is that domains and interventions will change over time. Information about interventions, within each domain, are covered in a DSA. These appendices are anticipated to change over time, with removal and addition of options within an existing domain, at one level, and removal and addition of entire domains, at another level. Each modification to a DSA will be subject to a separate ethics application for approval.

The Core Protocol also does not contain information specific to a particular region in which the trial is conducted, as the locations that participate in the trial are also anticipated to increase over time. Information that is specific to each region that conducts the trial is contained within an RSA. This includes information related to local management, governance, and ethical and regulatory aspects. It is planned that, within each region, only that region's RSA, and any subsequent modifications, will be submitted for ethical review in that region.

3. REGION-SPECIFIC APPENDIX VERSION

The version of the NZ Region-Specific Appendix is in this document's footer and on the cover page.

3.1. Version history

Document history:

Version Number	Date	Summary of changes
1.1	6 March 2025	Initial HDEC application

4. NZ RTSC GOVERNANCE

4.1. RTSC members

Chair: Dr Thomas Hills

Members: Dr Simon Young

Dr John Mutu-Grigg

Mr William Peters (Consumer Representative)

Dr Alexandra Mowday

Investigators from ROADMAP sites across the motu will be invited to join the RTSC as the ROADMAP trial evolves.

4.2. Contact Details

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5. NZ REGIONAL TRIAL STEERING COMMITTEE AUTHORIZATION

The NZ Regional Trial Steering Committee (NZ RTSC) have read the appendix and authorize it as the official NZ Region-Specific Appendix for the study entitled ROADMAP. Signed on behalf of the committee,

Chair:
Dr Thomas Hills

Date:

6. BACKGROUND AND RATIONALE

6.1. Region definition

The NZ region encompasses all of Aotearoa New Zealand.

6.2. Regional trial sponsor

Aotearoa Clinical Trials is the trial sponsor for the Aotearoa New Zealand region.

6.3. Role of the regional trial sponsor

The regional trial sponsor is responsible for initiation, management, provision of insurance and indemnity and financing the clinical trial for the sites within the region. The Clinical Trials Research Agreements (CTRAs) will be between the regional trial sponsor and each participating site.

6.4. Insurance

The sponsor/investigator has insurance in accordance with the relevant legal requirements in Aotearoa New Zealand.

6.5. Region-specific background

The ROADMAP trial is a combination of the original concepts from the completed PIANO observational study (1), PIANOFORTE pilot trial initiated within Australia and Aotearoa New Zealand (2), and clinician priority and equipoise surveys. The ROADMAP study has built on existing relationships, resources, knowledge and capacity within the PIANO collaborations, with many local Principal Investigators at proposed study sites involved in working groups for ROADMAP from the early stages of development including the protocol and the domain specific appendices. The aim of ROADMAP is to expand globally to include new countries that express interest. The intention of the ROADMAP trial is to include as many countries as possible and assist the Investigators of each country in applying for their own funding to support their trial related activities.

6.5.1. Aotearoa New Zealand-specific ethics and regulatory issues

In Aotearoa New Zealand, human research is conducted under an ethics oversight framework determined by the National Ethics Advisory Committee (NEAC) on Health and Disability Support Services (Kāhui Matatika o te Motu), which was established under Section 16 of the Aotearoa New Zealand Public Health and Disability Act 2000. The NEAC issues guidelines that set out the ethical standards that must be met by researchers (the Ethical Standards for Health and Disability Research and Quality Improvement guidelines, revised December 2019), in accordance with Aotearoa New Zealand law including (but not limited to) the Protection of Personal and Property Rights Act 1988; the New Zealand Bill of Rights Act 1990; the Privacy Act 2020; the Health and Disability Commissioner Act 1994; the Accident Compensation Act 2001; the Human Tissue Act 2008 and The Treaty of Waitangi Act 1975. The NZ Project Manager, with oversight from the Principal Investigator, will be responsible for the submission and ongoing ethical requirements for all sites within this region.

Each hospital within Aotearoa New Zealand has its own internal research governance review and approval process. This internal research review and approval process does not duplicate the national review of ethics or scientific merit of the study but ensures that the impact of the study on local resources is acceptable, that the appropriate departments support the research, and that the research aligns with the organization's research ethos. The local approval process also ensures that the proposed research complies with appropriate ethical, regulatory, and professional standards. The hospital will decide whether the site is authorised to participate in the research once this local review and approval process has been completed.

6.5.2 Relative/Whānau/Friend consent

Some relevant differences in consent processes exist between jurisdictions in Aotearoa New Zealand and overseas. For example, surrogate consent processes are acceptable in some Australian jurisdictions, and under certain circumstances, with varying approaches to obtaining and documenting consent to participate permitted.

In Aotearoa New Zealand, all participants must provide consent to participate in the ROADMAP platform. The option for enrolment through a relative/whānau/friend agreement process is not approved for use in Aotearoa New Zealand.

6.5.3 Aotearoa New Zealand-specific funding

ROADMAP in NZ was successfully awarded funding though a Health Research Council (HRC) project grant (24/395). This grant will support research activity within Aotearoa New Zealand. Each Aotearoa New Zealand site will receive a per-participant-payment for a nominal amount for each participant enrolled onto the ROADMAP platform trial. The details of the per-participant-payments will be included in the CTRA (see section 9.2.2). Further funding for new sites and sub-studies will be sought as required.

7. OBJECTIVES

The NZ RTSC will provide oversight of the trial in the context of Aotearoa New Zealand and is responsible for the following aspects of study management within the region.

- Manage and oversee all the sites within the region
- Advise on case report forms (CRFs) as required
- Engage with the ROADMAP domain specific working groups regarding availability, feasibility, and suitability of potential therapeutic agents within NZ
- Facilitate engagement with peer groups about the project, including the ROADMAP domain specific working groups and subcommittees
- Engage with potential collaborations for sharing of resources
- Assist the data linkage and data registry groups with Aotearoa New Zealand-specific processes
- Identify potential new sites within NZ and put this forward to the Global Trial Steering Committee (GTSC)
- Identification of, and liaising with, PIs from sites that are under-performing
- Coordination with Australia regarding the study monitor for the region

- Consider NZ specific issues for proposed sub-studies or analyses
- Advise the ROADMAP GTSC regarding allocation of funds within NZ as well as opportunities for further funding
- Advise the NZ TMG regarding ethics and governance issues specific to NZ

The NZ RTSC will delegate responsibilities of the day-to-day management of the ROADMAP trial within the region to the NZ Trial Management Group (TMG) as stipulated in Section 9.5.

8. TRIAL DESIGN

The ROADMAP trial has two components, a platform, and a registry. The platform is a randomised evaluation of surgical and antibiotic treatments in patients who consent to participate in the randomised trial. There is also a linked observational prosthetic joint infection registry. This RSA will inform all domains conducted as part of ROADMAP. Treatment allocation will be randomised, as described in the Core Protocol and DSAs.

8.1. Population

ROADMAP enrols patients admitted to a participating hospital with confirmed Prosthetic joint infection (PJI) who meet the Core Protocol eligibility criteria.

8.2. Eligibility criteria

Patients are eligible for the ROADMAP platform if they meet the platform-level inclusion and none of the platform-level exclusion criteria and if they consent to participate in the trial. There are no additional inclusion or exclusion criteria that apply specifically to patients within Aotearoa New Zealand. All patients who meet the platform-level inclusion and none of the platform-level exclusion criteria but are not participating in the platform will be eligible for the registry.

9. TRIAL CONDUCT

9.1. Region-specific data collection

9.1.1. Clinical Data Collection (de-identified data)

Data for classification of ethnicity will be collected for Aotearoa New Zealand participants. Data collection will be consistent with the Core Protocol section 8.11. Aotearoa New Zealand sites will enter

the de-identified data into an online secure password-protected web-based trial database (Spinnaker software), that is managed and operated by Spiral Web Solutions Ltd (Aotearoa New Zealand). Both ROADMAP Platform and ROADMAP Registry participants will have their clinical data collected in the Spinnaker database.

9.1.2. Data Collection for Data Linkage (identifiable data)

For identifiable data required for data linkage, each NZ site will have access to a purpose-built, password-protected, secure REDCap database, stored and administered locally on a NZ server. In Aotearoa New Zealand the only identifiable data collected for data linkage will be National Health Index (NHI) number and date of birth. Researchers will only be able to access their own site data for the purposes of recording or amending data.

The sponsor will provide a central data manager coordinator (in the case of Aotearoa New Zealand, this will be the ROADMAP NZ project manager) and access to and oversight of data from each site will only be possible for the person in this position.

9.1.3. Microbiology

All participating NZ hospital laboratories will be asked to send the isolated causative organisms from each ROADMAP platform patient (but not for registry patients) in batches to the Middlemore Hospital Laboratory in Auckland, Aotearoa New Zealand. Middlemore will then ship bacterial isolates in batches to Hunter Medical Research Institute in Newcastle, New South Wales, Australia for long-term storage and analysis. Shipment frequency will be determined by the rate of recruitment, and consequently the number of isolates collected at each site. Further detail about storage and shipment of isolates will be specified in a Microbiology appendix (operational document).

The stored bacterial isolate has been cultured in the laboratory, does not contain any human tissue, and is not considered to be a human biospecimen according to the National Ethics Advisory Committee (NEAC).

9.1.4. Patient Safety Escalation Pathway

ROADMAP trial staff are required to complete an EQ-5D-5L health questionnaire at the 12-month follow-up appointment as described in the study protocol. Guidance on the pathway for NZ Trial Staff to follow if study participants are identified as being anxious/depressed or requiring additional support upon completion of this questionnaire is described in a regional-specific SOP (Section 13.1, sub-appendix).

9.2. Region-specific regulatory aspects

9.2.1. Regulatory environment

Medsafe is the Aotearoa New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in Aotearoa New Zealand. Medsafe administers the application and approval process for clinical trials under an authority delegated from the Director-General of Health. Medsafe receives and processes applications, liaises with the relevant Health Research Council (HRC) committee and the applicant, and issues approval letters. The HRC maintains standing committees to consider clinical trial applications and make recommendations to the Director-General. The Standing Committee on Therapeutic Trials (SCOTT) considers applications for pharmaceutical-type medicines and must approve use of medicines within trials in Aotearoa New Zealand if that medicine is not already approved by Medsafe for that indication in Aotearoa New Zealand. Section 30 of the Medicines Act authorises the Director-General of Health to approve a clinical trial on the recommendation of the HRC.

9.2.2. Legal environment

Aotearoa Clinical Trials (ACTT) will enter into a sponsor agreement with the University of Newcastle. All participating Aotearoa New Zealand hospitals will enter into a clinical trials research agreement (CTRA) with Aotearoa Clinical Trials as the study sponsor. The CTRA will be developed using the NZACRes CTRA template for Collaborative or Cooperative Research Group studies. The NZ ACRES template is accepted across all Aotearoa New Zealand sites. All CTRAs for this region will be prepared by ACTT and submitted to the research governance office at each site for review, acceptance, and execution.

9.2.3. ROADMAP trial safety reporting requirements

The NZ region regulatory requirements for reporting adverse events in clinical trials is stipulated in the "Standard Operating Procedures for Health and Disability Ethics Committees" and "Guideline on the Regulation of Therapeutic Products in New Zealand". The regional trial sponsor (ACTT) via the NZ TMG will be responsible for collating the information and reporting of any Sudden Unexpected Serious Adverse Reactions (SUSARs) or Significant Safety Issues (SSIs) to Medsafe and reviewing HDEC as per HDEC requirements. For Medsafe, the reporting timeline for SUSARs from time of awareness is as follows:

- fatal or life threatening within 7 calendar days

- all others will be held accessibly, to be made available on request.

Reporting timeline for SSI from time of awareness is stipulated in Table 1.

Table 1. Sponsor Reporting of Significant Safety Issues.

Action	Timeline
Urgent safety measure (USMs)	Immediately and within 7 calendar days
Temporary halt of a trial	Within 7 calendar days
Early termination of a trial	Within 15 calendar days

The Core Protocol outlines the safety reporting requirements for the ROADMAP trial (Section 10). It is the responsibility of the Principal Investigator (PI) from the study site within the NZ region to ensure they follow the Core Protocol adverse event reporting and any local governance requirements when they identify a serious adverse reaction (SAR) that is deemed to be unexpected (Suspected Unexpected Serious Adverse Reaction; SUSAR) and any Significant Safety Issues (SSI).

All SUSARs/SSIs must be reported to the NZ sponsor (ACTT) via the NZ TMG within 24 hours of site personnel becoming aware of the event. The PI must complete the details in the Safety Reporting CRF as outlined in the Core Protocol.

The NZ sponsor (ACTT) will report to the overall sponsor (University of Newcastle).

The global sponsor (UoN), via the NZ TMG, will report all SSIs and SUSARs that meet the urgent safety measure (*a measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety*[4]) to all sites via the site PIs (for local governance safety reporting requirements) and the reviewing ethics committee, and Medsafe within 72 hours of becoming aware of the event. SSIs that are not considered to be an urgent safety measurement will be reported within 15 days of becoming aware of the issue.

SARs do not require *expedited* reporting to the NZ trial management group or NZ sponsor. All SARs will be reviewed periodically by the DSMC and will be reported to the reviewing ethics committee in the annual report.

Any local governance safety reporting requirements is the responsibility of the PI at that site.

ROADMAP must comply with the Good Clinical Practice framework. ROADMAP is registered with ClinicalTrials.gov (NCT06771050).

9.3. Region-specific availability of and access to trial interventions

All interventions will be offered to each participating site within Aotearoa New Zealand. Although it is preferred that all sites participate in all domains available, each individual site PI will have the capacity

to choose which interventions the site will participate in based on site clinical equipoise and what is feasible for their hospital.

9.3.1. Surgical treatment domain

The surgical domain will be available to all sites in NZ where there is clinical equipoise, and it is expected that any components used in revision operations will be supplied and funded by participating sites, as they would be outside the context of a trial. Both revision surgery and DAIR (debridement and implant retention) are routinely used operative interventions in this context (late acute PJI).

9.3.2. Antibiotic choice domain

The antibiotic choice domain will be available to all sites in NZ where there is clinical equipoise, and it is expected that rifampicin (if the patient is allocated to receive it) will be supplied by the participating hospital pharmacy as it would be outside the context of a trial. Rifampicin will be prescribed by the treating clinical team, PI, or their delegate for the ROADMAP trial as per usual hospital practice. The "backbone antibiotics" are one or more routinely used antibiotics directed against the causative pathogen(s); these will be chosen by the clinical team in consultation with guidance from the protocol and the site PI. As for rifampicin, it is expected that the backbone antibiotics will be supplied by the participating hospital pharmacy and will be prescribed by the treating clinical team, PI, or their delegate for the ROADMAP trial as per usual hospital practice. All backbone antibiotics recommended in the protocol are registered for use in NZ and have established safety profiles.

9.3.3. Antibiotic duration domain

The Antibiotic Duration Domain will be available to all sites in NZ, and assesses a treatment strategy, not individual therapeutic agents. The actual antibiotic(s) used (as opposed to their duration) will be chosen by the treating team, in consultation with guidance from the protocol and the site PI, and will be provided by the hospital or community pharmacy, as it would be outside the context of a trial.

9.3.4. Registry

The study population for the registry includes all patients admitted to a ROADMAP participating hospital with PJI. The registry specifies no interventions and only collects data on health status, clinical care, and outcomes consistent with that of the ROADMAP trial such as death, quality of care indicators and a limited number of comorbidities.

9.4. Trial start-up and initiation

The PI from each site within the region must attend a Site Initiation Visit (SIV) facilitated by the NZ TMG. Remote site initiation visits may be used (e.g., via Zoom). Following attendance at the SIV the PI can submit the required approval documents to the NZ TMG for compliance checks and if satisfied, the NZ TMG will provide the PI with authorisation to activate recruitment (known as a "green light").

Upon activation, the PI will gain access to the ROADMAP Spinnaker and REDCap databases. All protocol documents will be available via the ROADMAP website and the ROADMAP Spinnaker database. Each site will be required to maintain a trial Site File, as per ICH-GCP. Preferentially this will be an electronic site file, but sites may elect to use a paper site file if desired. The TMG will provide sites with a template folder structure for the electronic site file.

The NZ TMG will provide a trial coordinator/project manager to oversee and support PIs from the region. PIs will be given the contact details of the NZ trial coordinator.

9.5. Region-specific trial management

The NZ RTSC will provide oversight of the trial in the context of NZ, and report to the Global Trial Steering Committee (GTSC). The NZ TMG will have responsibility for the day-to-day management of the ROADMAP trial within Aotearoa New Zealand, which includes but is not limited to the following responsibilities:

- Manage the lead HDEC submission, amendments, and safety/annual reporting
- Maintain Sponsor Trial Master File
- Amend study documentation for the ROADMAP trial including CRFs, protocol, domains, appendices, and consenting materials to make them specific to NZ
- Facilitate the CTRA execution within each site
- Prepare agenda, progress reports including financial statement and write minutes for the NZ RTSC
- Oversee data entry and completeness from regional sites for ROADMAP database and ROADMAP data registry.
- Support PI at each site via phone and email as required
- Collate and report any SUSARs or SSIs that meet the reporting criteria for the Medicines Adverse Reactions Committee (MARC; a subsidiary of Medsafe, reporting to the Ministry of Health)

- Manage isolate transfers from sites to central study laboratory
- Coordination with the region's study monitor and monitoring processes
- Prepare newsletters, study progress for PIs from each site
- Facilitate sharing of resources with collaborators
- Facilitate the data linkage process for the region
- Assist the NZ RTSC with any preparation required for any proposed sub-studies
- Maintain the ROADMAP NZ trial budget
- Advise the NZ RTSC on any opportunities for further funding
- Facilitate the online initiation sessions for all site PIs within the region

9.6. Region quality assurance and trial monitoring process

Please refer to section 8.13 of the Core Protocol.

9.6.1. Quality assurance

The central data coordinator will review site data entry in the database for completeness and timeliness for the sites they are assigned. Quality assurance checks for arriving isolates at the ROADMAP central laboratory will be checked against the ROADMAP database entries. Quality assurance checks for participant identifiers entered into the REDCap database will be checked against the ROADMAP Spinnaker database entries.

9.6.2. Monitoring

Aotearoa Clinical Trials will provide a study monitor for the ROADMAP trial sites within the NZ region. The study monitor will be provided with a detailed monitoring plan.

9.7. Blinding

9.7.1. Blinding

Unless otherwise specified, interventions will be open label. The global ROADMAP Data Management Plan the blinded/unblinded aggregate data that will inform the outcomes of the trial, and who may have access to unblended aggregate data. For further information, please refer to the global ROADMAP Data Management Plan.

9.7.2. Unblinding

Not relevant.

10. ETHICAL CONSIDERATIONS

The trial protocol and associated appendices, as well as other trial documentation, will be submitted to the Health and Disability Ethics Committee (HDEC) in Aotearoa New Zealand. Sites will not be able to recruit participants until ethics and governance approval has been obtained.

Informed consent will be obtained in accordance with section 8.4 of the Core Protocol and the study's HDEC approval.

11.GOVERNANCE ISSUES

The University of Newcastle (UoN) is the primary sponsor of the trial. Aotearoa Clinical Trials (ACTT) is the Aotearoa New Zealand sponsor. ACTT is responsible for obtaining ethical approval for the trial, ensuring adequate trial insurance is obtained, entering into clinical trial research agreements with sites, and complying with all Sponsor responsibilities as outlined in the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines.

Site-specific governance approval for each Aotearoa New Zealand site will be obtained before recruitment begins.

12.REFERENCES

1. Davis JS, Metcalf S, Clark B, Robinson JO, Huggan P, Luey C, et al. Predictors of Treatment Success After Periprosthetic Joint Infection: 24-Month Follow up From a Multicenter Prospective Observational Cohort Study of 653 Patients. Open Forum Infect Dis. 2022;9(3):ofac048.
2. Manning L, Metcalf S, Dymock M, Robinson O, Clark B, Nelson R, et al. Short- versus standard-course intravenous antibiotics for peri-prosthetic joint infections managed with debridement and implant retention: a randomised pilot trial using a desirability of outcome ranking (DOOR) endpoint. International Journal of Antimicrobial Agents. 2022;60(1):106598.

13.SUB-APPENDIX

13.1. Patient Safety Escalation Pathway SOP

1. Purpose

This SOP describes the pathway for ROADMAP Trial Staff to follow when study participants are identified as being anxious/depressed or requiring additional support upon completion of the EQ-5D-5L health questionnaire at the 12-month follow-up appointment.

2. Definitions

Trial Staff – the person or persons with delegated authority to the trial, trained to conduct the assessments for a study in a consistent manner.

Site Principal Investigator (PI) – responsible for the overall conduct of the study (ICG GCP E6) and protection of participants' rights, safety, and well-being.

Duty of care - a legally imposed obligation or duty (derived from common law) to "take care". This means a duty to ensure they take care that any actions carried out in relation to the patient (participant in research) do no harm, and they do not omit anything that could have prevented harm to the patient (participant).

3. Materials and Equipment

A copy of the EQ-5D-5L health questionnaire required for the 12-month follow-up appointment.

4. Procedure

4.1. General principles

- Trial Staff must practice in congruence with relevant New Zealand laws and within the professional guidelines and scope of practice of their profession (if applicable).
- The Code of Health and Disability Consumers' Rights and GCP guidelines protect participants' privacy, rights, and autonomy. Participants identified during follow-up visits as having high scores for anxiety or depression have the right to refuse assistance or referral for further help.
- Trial Staff must use their professional judgement to determine whether the situation is an emergency or the participants' wishes should be overridden to prevent harm to themselves or others.
- If Trial Staff are registered health professionals, they have a duty of care to ensure their actions (or omissions) do not harm someone else, which includes third persons such as family members or others.

- The Code of Health and Disability Consumers' Rights (Right 4) states that every consumer has the right to have services of an appropriate standard. Where this right is breached it can be assumed that the health professional has breached their duty of care.
- There is a potential in all trials for participants to already be distressed for reasons unrelated to the study, or for study related follow-up procedures to provoke distress for the participant.
- Prosthetic joint infection is associated with reduced quality of life.
- We aim to understand the impact of prosthetic joint infection on quality of life by using the EQ-5D-5L questionnaire at the 12-month follow-up telephone call
- The interventions evaluated in the ROADMAP study reflect treatments that are given as part of the spectrum of usual care given to patients with prosthetic joint infection.
- Patients in ROADMAP will receive follow-up from their usual clinicians (e.g., orthopaedic surgeon and general practitioner).
- If a ROADMAP participant is identified as being anxious or depressed, the ROADMAP Team will endeavour to help that person receive the support they need through their usual general practitioner or other available services/agencies.

4.2. Actions to take when concerns are identified

4.2.1. A participant scores moderately/severely/extremely anxious or depressed on the EQ-5D-5L questionnaire.

- Advise to see a GP or offer to contact GP on their behalf.
- Ask if family are available to help.
- Continue study questions if appropriate and participant is willing to do so.
- Document any issues and any advice given to the patient.
- Inform the PI/site within two days of the questionnaire.

4.2.2. A participant expresses concerns (not urgent) or asks for help.

- Advise to see a GP or offer to contact GP on their behalf.
- Ask if family are available to help.
- Suggest freely available helplines/support agencies (Appendix 1).
- Continue study questions if happy to do so especially as it might highlight other problems.
- Document the issues, what was discussed, and what suggestions were given.
- Inform the PI/site on the day of the questionnaire.

4.2.3. A participant is suicidal, threatening self-harm or harm to others (urgent help required).

- Stop the questionnaire.
- <u>If the participant is alone:</u>
    - Ask if there is someone to contact who can help.
    - Ask if they can contact their GP for help or offer to contact GP on their behalf.
    - Ask if they are currently receiving emotional support or mental health treatment and ask if they can contact make contact or offer to contact on their behalf.
- <u>If the participant is not alone:</u>
    - Ask if there is someone else with them who can help.
    - Offer to speak to them.
    - Ask if they are currently receiving emotional support or mental health treatment and ask if they can contact make contact or offer to contact on their behalf.
- <u>If the situation is considered severe:</u>
    - Ask if there is someone there to help or stay with them until help arrives (speak to that person).
    - Call an ambulance/crisis team/police.
- Document the issue thoroughly and what was done about it.
- Inform the PI as soon as possible. If unable to contact the site PI, inform the NZ lead investigator (Dr Thomas Hills).

4.3. After the appointment

5. Provide a written report to the site which includes any action taken or advice given by the assessor and referrals/actions required by the site staff.
6. For urgent matters it may be necessary to telephone the site PI immediately after the call.
7. Assessors should be mindful of their own need to debrief, either informally with colleagues or formally through an Employee Assistance Programme.

5. Contact details for emergency services and support agencies

This list is intended as a guide and should not be considered exhaustive. It is subject to change.

URGENT HELP (available 24 hours a day, 7 days a week)

AGENCY	CONTACT DETAILS

Police/Ambulance (in life-threatening situations)	111 from any phone
Mental Health Foundation Crisis	0800 800 717
Local DHB Mental Health Crisis Team (CATT Team)	https://mentalhealth.org.nz/help

NON-URGENT HELP AND SUPPORT AGENCIES

AGENCY	CONTACT DETAILS
Suicide Crisis Helpline	0508 828 865
Depression.org.nz (to talk to a trained counsellor)	0800 111 757
Anxiety New Zealand	0800 269 4389
Lifeline (for counselling and support)	0800 543 354
1737, Need to talk? (to talk to a trained counsellor)	Free call or text 1737
Shine domestic violence helpline	0508 744 633
Women's Refuge crisis line	0800 733 843
Healthline (for advice from registered nurses)	0800 611 116
Samaritans (for confidential support for loneliness or emotional distress)	0800 726 666
Mental Health Foundation	09 623 4812

Rural Support Trust	0800 787 254
The lowdown.co.nz (help and resources for anxiety and depression)	thelowdown.co.nz or text 5626 0800 111 757
Yellow Brick Road (for support for families with a family member experiencing mental health issues)	yellowbrickroad.org.nz
Age Concern (for support for older adults experiencing abuse/neglect)	0800 652 105