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KEY WORDS

Outcome, Quality, Safety, Surgery, Nursing, Medical, Protocol

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ABSTRACT

Introduction

Incorporating patient reported outcome measures (PROMs) into usual care in hospitals can improve safety and quality. Gaps exist in electronic PROM (ePROM) implementation recommendations, including for elective surgery. The aims are to: (i) understand barriers and enablers to ePROM implementation in hospitals and develop ePROM implementation recommendations (AusPROM); (ii) test the feasibility and acceptability of the QoR-15 PROM for elective surgery patients applying the AusPROM; and (iii) establish if the QoR-15 PROM has concurrent validity with the EQ-5D-5L.

Methods and analysis

Phase I will identify barriers and facilitators for the implementation of the AusPROM using a Delphi technique. Phase II will determine QoR-15 acceptability for elective surgery patients across 4 pilot hospitals, using the AusPROM recommendations. For Phase II, patients will complete brief surveys, incorporating the QoR-15, in the week prior to surgery, in the week following surgery and 4 weeks post-surgery. The primary endpoint will be 4 weeks post-surgery. Phase III will be the national implementation of the AusPROM (30 hospitals) and the concurrent validity of the QoR-15 and generic EQ-5D-5L. This protocol adopts the SPIRIT-PRO guidelines.

Ethics and dissemination

The results will be disseminated via public forums, conferences and peer-reviewed journals. Ethics approval: La Trobe University (HEC20479).

Registration details

ANZCTR: 381169

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STRENGTHS AND LIMITATIONS

- The findings will highlight value of patient (acceptability domains) and health professional (Delphi technique) co-design to inform PROM implementation recommendations.
- A limitation is that the findings apply directly to hospital settings and might not generalise to community care.

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BACKGROUND

Patient Reported Outcome Measures (PROMs) provide a measure of patient views of the outcomes of surgical, medical, allied health, nursing or other therapeutic interventions[1-6]. Across the globe there is a push to take into account patient views of the outcomes of their episode of care, [2, 7-11] alongside the patient experience[12] and clinician measures of therapy outcomes[5]. There is growing evidence supporting the integration of PROMS into usual care to improve safety[13], quality[14], shared decision making[15] and processes of care[16, 17]. PROMs are argued to improve communication between doctors and patients[18]. They also enable health professionals to better understand patient perspectives and can empower patients to have stronger involvement in decisions about their own care[19].

The clinical use, evaluation and publication of PROM related studies has escalated across clinical areas in the last 5 years, especially cancer[20], mental health[11] and surgery[10]. There are now guidelines for completing systematic reviews of PROM literature[21] and guidelines for assessing the risk of bias within PROM systematic reviews[22]. Many studies focus on condition-specific PROMs, such as the HOOS and KOOS for osteoarthritis[6], cancer[23], diabetes[2] and mental health[11]. Others focus on healthcare settings such as public health [24], primary care[25] and aged care[1]. Yet others are directed towards interventions, such as joint replacement surgeries[26]. It is recommended that PROM data collection is electronic (ePROM), is integrated into existing clinical workflow and takes minimal time to complete[15]. In addition, strategies need to be introduced to overcome barriers to PROM implementation, by optimising infra-structure, platform development and usability, patient registration

processes, data linkages, reporting models, and stakeholder engagement[26]. With the increase use of PROMs in clinical care and clinical trials[27], feasibility testing is required to establish acceptability[12] . There are disease specific PROMs as well as generic PROMs that can used across healthcare sites and conditions[27, 28]. Although generic PROMs might not always be as sensitive as disease or condition specific PROMs, they are arguably easier to collect at scale due to the relevance across such a wide range of patient groups[27].

Despite applicability across healthcare settings, there is a paucity of literature, and subsequent gap in current knowledge on PROM feasibility and acceptability testing[12], implementation[24] and impact. This is particularly the case for elective surgery. A wide variety of PROMS are being used across different hospital[1, 4, 25], and there is a need for a valid PROM that is feasible to administer, and acceptable to elective surgery patients undergoing day surgery or overnight surgery. While the Quality of Recovery 15 item short-form (QoR-15)[29] has been validated for post-surgical patients, a need exists to establish if the QoR-15 is acceptable to patients and feasible to administer across a wide range of elective surgery patients on a national scale. In addition, there is a need to close gaps which exist in PROM implementation recommendations at a national level in Australia and internationally.

The aims of this mixed-methods clinical trial are to: (i) understand barriers and enablers for ePROM implementation across hospitals nation-wide; and to develop Australian ePROM implementation recommendations (entitled “AusPROM”); (ii) test the feasibility and acceptability of the QoR-15 PROM for elective surgery day and overnight patients, applying the AusPROM; and (iii) establish if the QoR-15 PROM has concurrent validity with the generic EQ-5D-5L multi-attribute quality of life measure.

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METHODS AND ANALYSIS

Study Design and Procedures

The over-arching objective is to direct future quality improvement activities to improve patient related outcomes, to advance clinical care and to improve patient – health care professional communication. The protocol adopts the Guidelines for Inclusion of Patient Reported Outcomes in Clinical Trials Protocols; SPIRIT-PRO[30] (see *Supplementary File*). The study findings will be disseminated via the La Trobe University Academic and Research Collaborative in Healthcare (ARCH) and presented at public forums, relevant local and international conferences, peer-reviewed journals and clinical guidelines. Ethics approval has been obtained from La Trobe University Human Research Ethics Committee (HEC20479).

A mixed-methods design shall be used, with three phases. To develop the final set of "AusPROM" Implementation Recommendations data from Phase I, II and III will be combined in an iterative process with Phase I extending alongside Phase II and III. Data from Phase I will influence Phase II and III, and likewise, data from Phase II and III will influence the latter stages of Phase I (Figure 1). Phase I will identify barriers and facilitators to nation-wide implementation of an ePROM to elective surgery patients using the Delphi technique with health professional staff, which shall also generate the AusPROM Recommendations. As Phase I is an iterative process, it will allow the findings to be integrated periodically throughout Phase II and III. Phase II will use a feasibility design[31] to determine QoR-15 PROM acceptability from the perspective of elective surgery patients from 4 pilot hospitals from 30 Healthscope hospitals, selected as a sample of convenience. Phase III is the national implementation (30 hospitals).

To provide structure to the implementation process the research team will use the PROM-cycle framework[32]. In addition, the national implementation will be shaped according to recommendations developed during the first two focus group iterations of Phase I and the patient acceptability from Phase II. Phase III will also examine the concurrent validity of the QoR-15 and generic EQ-5D-5L multi-attribute quality of life measure, with data collection at the 4 pilot hospitals.

Insert around here: Figure 1: The overlapping phases of the study to develop the final set of "AusPROM" Implementation Recommendations

The QoR-15 PROM is a 15 item short-form and it was based on the 40 item QoR-40 [29]. The QoR-15 has 15 items each rated on a 11-point scale from 0-10, with a maximum score of 150. It takes 2.4 minutes to complete and has reported good validity, reliability and responsiveness [4, 29]. There is evidence that the QoR-15 can be used from pre-surgery up to 24 hours to 7 days post-surgery, as a measure of change over time. [33, 34] The minimal clinical important difference of the QoR-15 is 8.0 [33].

Phase I The primary outcome of Phase I is the development of the set of national implementation recommendations (AusPROM), with the primary endpoint being conclusion of the national implementation (following the conclusion of Phase III). It is expected that staff and patient education will be developed and delivered based on these recommendations. Even though the AusPROM recommendations will initially be developed for the Australian context, a number of the recommendations will have international applicability. A goal is to simplify administration by not requiring direct care staff to implement the tool. Therefore,

there will be two perspectives: (i) from staff implementing it centrally at corporate office; (ii) direct care staff in the hospitals who are encouraging patients to complete the ePROM as well as utilise findings from the ePROM survey. Several studies talk about the impost (cost/time) of data collection[35-37] and our objective is to circumvent that by ensuring that system-wide processes are in place so that the tool can be implemented with minimal staff support.

The Delphi technique can be used to examine complex problems through an iterative process guided by expert opinions, known as a group knowledge acquisition model[38]. The Delphi technique in this study was aligned to the Classical Delphi where the focus is on facts and the objective is the elicit opinion and gain consensus via a series of focus groups[38-41]. The Delphi technique will involve nursing staff from each of the four pilot hospitals, as well as doctors who have involvement in the implementation. They will be asked to participate in each of the three iterative focus groups. Focus groups will occur prior to the commencement of Phase I, as well as prior to, and at the conclusion of, Phase III. The focus groups will be directed toward two issues of priority: (i) barriers and enablers for the national implementation of ePROMs and (ii) recommendations for the implementation and integration of an ePROM into usual care.

Staff inclusion criteria include being aged 18+, employed at Healthscope hospitals and working at one of the included hospitals, and a registered nurse or doctor. There are no specific exclusion criteria. Written informed consent is required for participation.

An email will be sent from the site Director of Nursing to the potential staff participants across the four pilot hospitals, inviting the staff member to participate. They will be invited to contact the research team if they would like to participate in the study. Staff will be identified

via the site Director of Nursing and the Chief Medical Officer or General Manager. It will be explained that participation includes three 1-hour focus groups spread out over a 10-month period. It is expected that there will be at least 10 staff participants in the Delphi study. Previous studies have shown that a Delphi study sample size ranging from 6 to 50 had minimal impact on 6 of 9 different consensus indices[42], indicating that the planned sample of size of up to 10 participants will be adequate for this Delphi study.

Phase II will use a feasibility design to complete survey pre-testing at 1 pilot hospital, as well as determine the response rate and QoR-15 ePROM acceptability from an elective surgery patient perspective across 4 pilot hospitals. The pre-testing (n=100) will investigate feasibility from a technical perspective (the rest of this phase relates to feasibility from the patient perspective). Technical feasibility testing includes the pulling of survey distribution list reports from hospital administration data, distributing the survey and testing the assumed patient email and /or mobile number capture rate for survey distribution. Patients will complete brief surveys across three timepoints, incorporating the QoR-15 and two acceptability questions, in the week prior to surgery (noting small QoR-15 modifications were required pre-surgery), in the week following surgery and 4 weeks post-surgery. Time to complete the survey is estimated at 5 minutes based on previous studies[29]. The primary outcome of Phase I is feasibility relating to the response rate and the primary endpoint will be 4 weeks post-surgery. The secondary outcome is the degree of ePROM survey acceptability.

Quantitative data includes the survey response rate and completion rate for patients who receive an invitation to participate, as well as acceptability of the ePROM survey on a 0-10 Likert scale (10 = highly acceptable and 0 = not acceptable). In addition, response scores for

the QoR-15 will be reported over the three time points as a change score and as a percentage of participants who return to pre-surgical status at 4-week post-surgery.

Qualitative data includes patient responses from an open-ended question regarding ePROM survey acceptability. Responses will be themed via a content analysis using the theoretical framework of acceptability (TFA)[43]. The TFA includes aspects of patient attitude, burden (including length of survey and the timing of the three surveys), ethicality, understanding of the intervention, opportunity costs, perceived effectiveness and self-efficacy for survey completion[43]. There will also be a content analysis where the frequency of themes is reported for each of the TFA domains.

Patients aged 18+ will be recruited via email and / or text messages following hospital pre-admission for elective surgery at one of the included hospitals. It is noted that in Australia email and text are appropriate strategies for PROM data collection as 86% of households have internet access[44], 91% with household internet use mobile or smart phones[44] and 94% of people who use the internet do so to access emails[45]. The current patient email capture-rate is around 80% for the health service and patients will be excluded if they do not provide either a valid email address or mobile phone number. Patients will also be excluded if they do not have adequate English (survey is only presented in English), if they tick the "opt out" box on the hospital admission paperwork for participation in patient surveys, if they are pregnant, or in the case of death no further surveys will be sent. The survey invitation will include a link to the participant information sheet and there will be a tick box for consent to participate at the start of the survey. Data will be deidentified and presented in an aggregate format. For incomplete surveys, a reminder email and text will be sent up to 1 week later, to improve

adherence rates. We shall include the data from all patients, whether they complete 1, 2 or the complete set of 3 surveys.

For Phase II, four hospitals have been recruited to participate in data collection. To be representative of the national health service involved in the study, the four hospitals have a mix of day and overnight services, they will include small and large hospitals, and are located across three states of Australia. They were selected as samples of convenience of facilities with more than 200 beds across multiple states in Australia and staff willing to participate. It is estimated that over a three-month period around 2,000 patients will receive the ePROM survey. As current patient survey response rates are around 40% for the health service, it is estimated that around 800 patients will complete the pre-surgery survey over three months of data collection, with only 500 patients completing all three surveys due to the five week time horizon between surveys combined with the three month data collection period. As Phase II is a feasibility study a formal power calculation for the sample size has not been undertaken[46]. Instead, the sample size was based on numbers needed to adequately determine the response rate at 4 weeks post-surgery (primary outcome).

Phase III focuses on the national ePROM implementation (30 hospitals), informed by the early Phase I Delphi study informing the AusPROM recommendations, and the concurrent validity analysis of the QoR-15 and generic EQ-5D-5L multi-attribute quality of life measure (four hospitals). The primary outcome for Phase III is the national survey response rate (30 hospitals), with success achieved if the response rate for the pilot sites (4 hospitals) is equalled or exceeded. Patient recruitment and inclusion / exclusion criteria is the same as Phase II.

As the objective of this study is to successfully integrate a ePROM across a national health service to direct future quality improvement activity and ultimately advance clinical care and patient-doctor communication, a whole of health service approach is required. The implementation phase therefore has a sample size based on national hospital representation and it is estimated that over a three-month period around 15,000 patients will receive the ePROM survey.

Data Analysis Plan

Phase I: To report the barriers and enablers for implementation of an ePROM the results of the three Delphi focus groups will be themed according to the National Institute of Clinical Studies barriers and enablers framework[47]. This framework includes six levels of potential barriers and enablers including the innovation itself (integrating the ePROM survey into usual care), the professionals / staff, the patient, the social context, the organisation context and the economic and political context. To report the recommendations for the integration of an ePROM into usual care, consensus statements will be drafted in the initial focus group, and re-drafted and refined in the subsequent focus groups.

Phase II and III: Survey response rate and completion rate will be reported as a number and percentage of the total. Response scores for the QoR-15 will be reported over the three time points as a change score and as a percentage of participants who return to pre-surgical status at 4-weeks post-surgery. This will include (a) a comparison between all surveys at baseline, within 1 week post-surgery and at 4 weeks post-surgery; and (b) only include patients who have completed all three surveys (captured through a unique survey identified which will link multiple surveys completed by the same patient). Missing data shall be in reference to a patient missing one or more of the three surveys. There will be no imputation of missing data.

We shall also perform an analysis whereby we stratify the PROM results for different hospitals, different surgical groups and according to age. This will enable us to compare our results with global reports on surgical PROM outcomes for different groups.

Phase II: Acceptability of the ePROM survey on a 0-10 Likert will be presented as a mean with interquartile ranges. Responses from an open-ended question regarding ePROM survey acceptability will be themed via a content analysis using the theoretical framework of acceptability (TFA)[43]. There will also be a content analysis where the frequency of themes is reported for each of the TFA domains.

Phase III shall establish if the condition specific QoR-15 PROM has concurrent validity with the generic EQ-5D-5L multi-attribute quality of life measure, and data from the four pilot sites during the Phase II patient ePROM survey. We will assess the concurrent validity between the tests, on the basis of Spearman's correlation coefficients, as the data is not expected to be normally distributed. A correlation coefficient of less than 0.3 will be considered weak, between 0.3 and 0.5 will be considered moderate, and above 0.5 will be considered strong. It is noted that this analysis of the additional quality of life questions are pending on the acceptability of the Phase II ePROM survey (which did not include quality of life). Missing data will be managed by excluding participants case wise. Statistical significance is defined as $p<0.05$ and analyses will be completed on IBM SPSS Version 25[48].

Patient and Public Involvement

We designed this protocol ensuring patient involvement in the choice of PROM, study design, data collection forms and implementation plan. Consumers (patients, health

professionals, healthcare managers) will be involved in all parts of the project dissemination of study findings. Consumer representatives contributed to this document.

DISCUSSION & CONCLUSIONS

Development of the AusPROM recommendations will provide a new and novel contribution to the literature, locally and globally. It is anticipated that the findings will highlight the value of patient (acceptability domains) and health professional (Delphi technique) co-design to inform the implementation recommendations for patient focused outcome measures. The results of this PROM study will also illuminate the feasibility and value of using the QoR-15 to understand how patients rate their elective surgery outcomes. In addition, the findings have the potential to benefit elective surgery patients, clinicians, hospitals, researchers and policy makers. Once embedded into usual care, data from this e-PROM could help to improve patient experiences and outcomes for elective surgery. Information gained in the barriers and enablers phase of the study shall inform the development of e-PROM related educational materials for patients and clinicians. The education material shall aim to ensure that patients are better prepared for post-discharge management of their condition and better able to cope with the recovery process. Potential health service benefits could include benchmarking different hospitals to see if e-PROM results are higher or lower at a particular site, or for specific surgical procedures or disciplines, allowing strategies to respond to positive or negative deviance. For policy makers, this study has the potential to provide input into economic funding directions, as funding moves towards paying for outcomes, rather than only paying for activity.

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Author contributions

All authors contributed to the preparation, drafting and editing of this protocol manuscript. MEM, NB, VA and JW designed the protocol. MEM and NB wrote the first draft, and all other authors critically appraised and revised the manuscript. All authors read and approved the final version.

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Data Access and Availability

The named authors on this protocol will have access to the final trial dataset. Individual patient level data will not be available for sharing at the conclusion of this study. Study results will be disseminated via

Competing interest statement

i. The funding source will have no influence over the study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

ii. Professor Natasha Brusco (Alpha Crucis Group) was funded by Healthscope as a consultant for this study.

iii. Professor Meg Morris receives salary funding from Healthscope and La Trobe University

iv. Associate Professor Victoria Anderson, Mr Jeffrey Woods, Anita Hodge and Damien Lloyd are employees at Healthscope.

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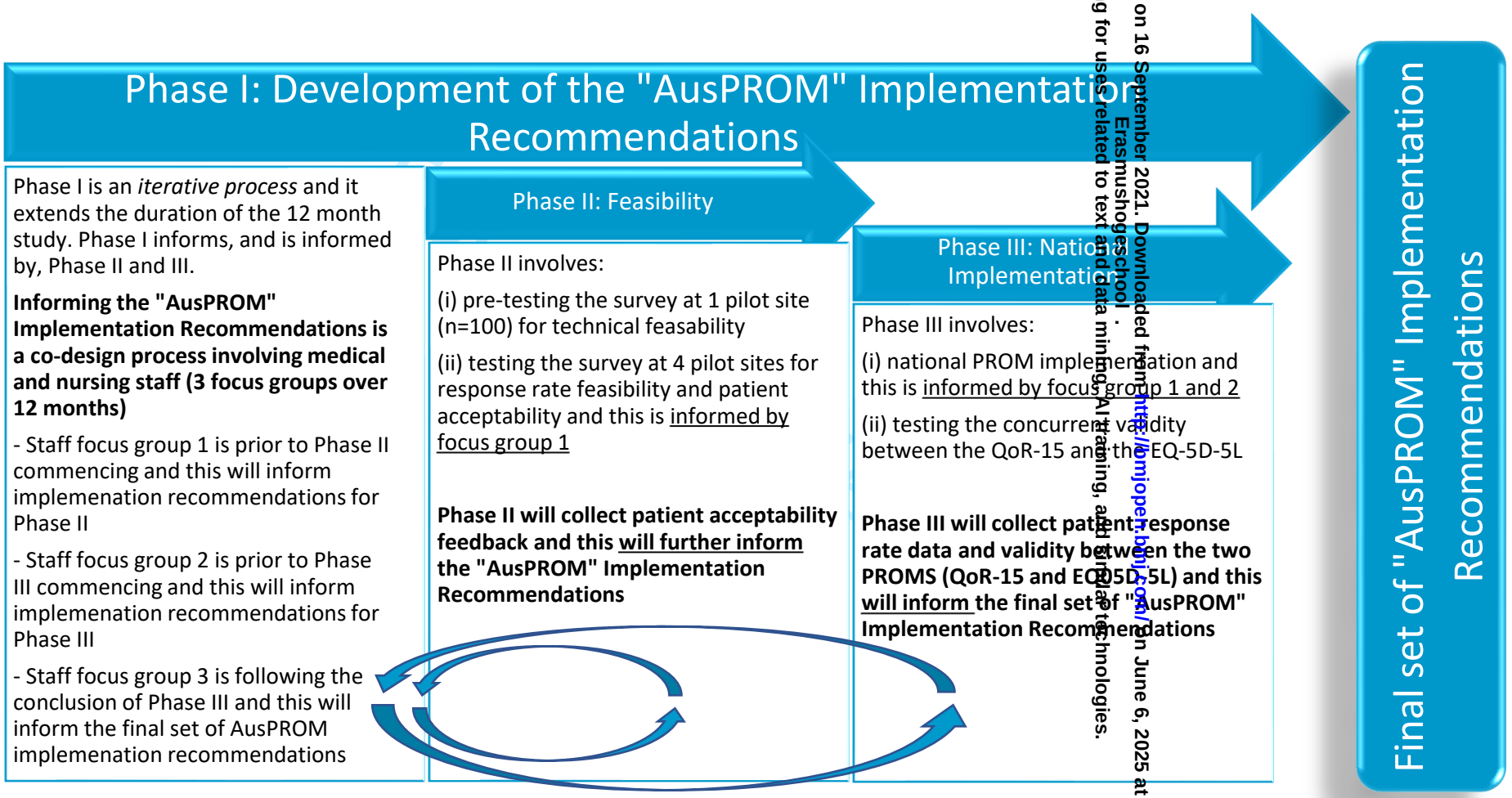

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

A protocol for the development of national patient reported outcome measure implementation recommendations for elective surgery patients in Australia: the AusPROM Recommendations

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*
The SPIRIT-PRO Elaboration and Extension questions have been added to this version of the SPIRIT checklist

Section/item	Item No	Description	Reporting of the item
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Reported in the manuscript
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Reported in the manuscript
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	Version 1 of the protocol submitted January 2021
Funding	4	Sources and types of financial, material, and other support	Reported in the manuscript
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Reported in the manuscript
	SPIRIT-5a-PRO Elaboration	Specify the individual(s) responsible for the PRO content of the trial protocol.	All authors are responsible for the PROM content of the protocol
	5b	Name and contact information for the trial sponsor	Trial sponsor is Healthscope
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Reported in the manuscript
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A

Section/item	Item No	Description	Reporting of the item
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Reported in the manuscript
	SPIRIT-6a-PRO Elaboration	Describe the PRO specific research question and rationale for PRO assessment, and summarize PRO findings in relevant studies.	Reported in the manuscript
	6b	Explanation for choice of comparators	Reported in the manuscript
Objectives	7	Specific objectives or hypotheses	Reported in the manuscript
	SPIRIT-7-PRO Elaboration	State specific PRO objectives or hypotheses (including relevant PRO concepts/domains).	Reported in the manuscript
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Reported in the manuscript
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Reported in the manuscript
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Reported in the manuscript
	SPIRIT-10-PRO Extension	Specify any PRO-specific eligibility criteria (e.g. language/reading requirements or prerandomization completion of PRO). If PROs will not be collected in the entire study sample, provide a rationale and describe the method for obtaining the PRO subsample	Reported in the manuscript
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	This is an observational study of usual care with a PROM introduced to capture the patient perception of usual care
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A

Section/item	Item No	Description	Reporting of the item
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Reported in the manuscript
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Reported in the manuscript
	SPIRIT-12-PRO Extension	Specify the PRO concepts/domains used to evaluate the intervention (e.g. overall HRQOL, specific domain, specific symptom) and, for each one, the analysis metric (e.g. change from baseline, final value, time to event) and the principal time point or period of interest.	Reported in the manuscript
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Reported in the manuscript
	SPIRIT-13-PRO Extension	Include a schedule of PRO assessments, providing a rationale for the time points, and justifying if the initial assessment is not pre randomization. Specify: time windows; whether PRO collection is prior to clinical assessments; and if using multiple questionnaires, whether order of administration will be standardized.	Reported in the manuscript
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Reported in the manuscript
Sample size	SPIRIT-14-PRO Elaboration	Where a PRO is the primary endpoint, state the required sample size (and how it was determined) and recruitment target (accounting for expected loss to follow-up). If sample size is not established based on PRO endpoint, then discuss the power of the principal PRO analyses.	Reported in the manuscript

Section/item	Item No	Description	Reporting of the item
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Reported in the manuscript
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A – observational survey design
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A – observational survey design
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A – observational survey design
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A – observational survey design
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A – observational survey design
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Reported in the manuscript

Section/item	Item No	Description	Reporting of the item
	SPIRIT-18a(i)- PRO Extension	Justify the PRO instrument to be used, and describe domains, number of items, recall period, instrument scaling/scoring (e.g. range and direction of scores indicating a good/poor outcome). Evidence of PRO instrument measurement properties, interpretation guidelines, and patient acceptability/burden should be provided or cited if available, ideally in the population of interest. State whether the measure will be used in accordance with any user manual and specify and justify deviations if planned.	Reported in the manuscript
	SPIRIT-18a(ii)- PRO Extension	Include a data collection plan outlining the permitted mode(s) of administration (e.g. paper, telephone, electronic, other) and setting (e.g. clinic, home, other).	Reported in the manuscript
	SPIRIT-18a(iii)- PRO Extension	Specify whether more than one language version will be used, and state whether translated versions have been developed using currently recommended methods.	Reported in the manuscript
	SPIRIT-18a(iv)- PRO Extension	Where the trial context requires someone other than the trial participant to answer on their behalf (a proxy reported outcome), state and justify this. Provide/cite evidence of the validity of proxy assessment if available.	N/A
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Reported in the manuscript
	SPIRIT-18b(i)- PRO Extension	Specify PRO data collection and management strategies for minimising avoidable missing data.	Reported in the manuscript
	SPIRIT-18b(ii)- PRO Elaboration	Describe the process of PRO assessment for participants who discontinue or deviate from their assigned intervention protocol	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Reported in the manuscript
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Reported in the manuscript

Section/item	Item No	Description	Reporting of the item
	SPIRIT-20a-PRO Elaboration	State PRO analysis methods including any plans for addressing multiplicity/type 1 (α) error.	Reported in the manuscript
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Reported in the manuscript
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Reported in the manuscript
	SPIRIT-20c-PRO Elaboration	State how missing data will be described and outline the methods for handling missing items or entire assessments (e.g. approach to imputation and sensitivity analyses).	Reported in the manuscript
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	A DMD is not required in this study as this is an observational study of usual care with a PROM introduced to capture the patient perception of usual care.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
	SPIRIT-22-PRO Extension	State whether or not PRO data will be monitored during the study to inform the clinical care of individual trial participants and, if so, how this will be managed in a standardized way. Describe how this process will be explained to participants, e.g. in the participant information sheet and consent form.	PROM data will not be monitored during the study, only at the conclusion of the study.
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	The trial conduct will not be audited
Ethics and dissemination			

Section/item	Item No	Description	Reporting of the item
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics approval has been obtained from La Trobe University Human Research Ethics Committee (HEC20479)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Important protocol modifications will be communicated via the ANZCTR
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Reported in the manuscript
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Reported in the manuscript
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Reported in the manuscript
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Reported in the manuscript
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Reported in the manuscript
	31b	Authorship eligibility guidelines and any intended use of professional writers	Reported in the manuscript under Author Statement. There is no intent to use professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Plans to share participant-level dataset is reported in the manuscript. The full protocol is shared via the ANZCTR. Statistical code will not be shared.

Section/item	Item No	Description	Reporting of the item
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Available upon reasonable request
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A
Questionnaires	PRO Elaboration		Available upon reasonable request

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Protocol for implementation of the "AusPROM" recommendations for elective surgery patients: A mixed-methods cohort study

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5 July 2021 (revision 1)

Protocol for implementation of the "AusPROM" Recommendations for elective surgery patients: A mixed-methods cohort study.

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KEY WORDS

Arthroplasty, Outcome, Quality, Surgery, PROM, Consumer, Implementation, Hospital

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ABSTRACT

Introduction

Incorporating patient reported outcome measures (PROMs) into usual care in hospitals can improve safety and quality. Gaps exist in electronic PROM (ePROM) implementation recommendations, including for elective surgery. The aims are to: (i) understand barriers and enablers to ePROM implementation in hospitals and develop ePROM implementation recommendations (AusPROM); (ii) test the feasibility and acceptability of the QoR-15 PROM for elective surgery patients applying the AusPROM; and (iii) establish if the QoR-15 PROM has concurrent validity with the EQ-5D-5L.

Methods and analysis

Phase I will identify staff barriers and facilitators for the implementation of the AusPROM recommendations using a Delphi technique. Phase II will determine QoR-15 acceptability for elective surgery patients across 4 pilot hospitals, using the AusPROM recommendations. For Phase II, in addition to a consumer focus group, patients will complete brief acceptability surveys, incorporating the QoR-15, in the week prior to surgery, in the week following surgery and 4 weeks post-surgery. The primary endpoint will be 4 weeks post-surgery. Phase III will be the national implementation of the AusPROM (29 hospitals) and the concurrent validity of the QoR-15 and generic EQ-5D-5L. This protocol adopts the SPIRIT-PRO guidelines.

Ethics and dissemination

The results will be disseminated via public forums, conferences and peer-reviewed journals. Ethics approval: La Trobe University (HEC20479).

Registration details

ANZCTR: 381169

STRENGTHS AND LIMITATIONS

- The findings will highlight value of patient (acceptability domains) and health professional (Delphi technique) co-design to inform PROM implementation recommendations in hospitals.
- Barriers and facilitators to implementation of e-PROMS will be identified.
- A limitation is that the findings apply directly to hospital settings and might not generalise to community care.

5 July 2021 (revision 1)

MANUSCRIPT

BACKGROUND

Patient reported outcome measures (PROMs) provide a measure of patient views of the outcomes of surgical, medical, allied health, nursing or other therapeutic interventions[1-6]. Across the globe there is a push to take into account patient views of the outcomes of their episode of care, [2, 7-11] alongside the patient experience[12] and clinician measures of therapy outcomes[5]. There is growing evidence supporting the integration of PROMS into usual care to improve safety[13], quality[14], shared decision making[15] and processes of care[16, 17]. PROMs are argued to improve communication between doctors and patients[18]. They also enable health professionals to better understand patient perspectives and can empower patients to have stronger involvement in decisions about their own care[19].

The clinical use, evaluation and publication of PROM related studies has escalated across clinical areas in the last 5 years, especially cancer[20], mental health[11] and surgery[10]. There are now guidelines for completing systematic reviews of PROM literature[21] and guidelines for assessing the risk of bias within PROM systematic reviews[22]. Many studies focus on condition-specific PROMs, such as the HOOS and KOOS for osteoarthritis[6], cancer[23], diabetes[2] and mental health[11]. Others focus on healthcare settings such as public health [24], primary care[25] and aged care[1]. Yet others are directed towards interventions, such as joint replacement surgeries[26]. It is recommended that PROM data collection is electronic (ePROM), integrated into existing clinical workflow and takes minimal time to complete[15]. In addition, strategies need to be introduced to overcome barriers to PROM implementation, by optimising infra-structure, platform development and usability, patient registration processes,

data linkages, reporting models, and stakeholder engagement[26]. With the increase use of PROMs in clinical care and clinical trials[27], feasibility testing is required to establish acceptability[12] . There are disease specific PROMs as well as generic PROMs that can used across healthcare sites and conditions[27, 28]. Although generic PROMs might not always be as sensitive as disease or condition specific PROMs, they are arguably easier to collect at scale due to the relevance across such a wide range of patient groups[27].

Despite applicability across healthcare settings, there is a paucity of literature, and subsequent gap in current knowledge on PROM feasibility and acceptability testing[12], implementation[24] and impact. This is particularly the case for elective surgery. A wide variety of PROMS are being used across different hospital[1, 4, 25], and there is a need for a valid PROM that is feasible to administer, and acceptable to elective surgery patients undergoing day surgery or overnight surgery. While the Quality of Recovery 15 item short-form (QoR-15)[29] has been validated for post-surgical patients, a need exists to establish if the QoR-15 is acceptable to patients and feasible to administer across a wide range of elective surgery patients on a national scale. In addition, there is a need to close gaps which exist in PROM implementation recommendations at a national level in Australia and internationally.

The aims of this mixed-methods clinical study are to: (i) understand barriers and enablers for ePROM implementation across hospitals nation-wide; and to develop Australian ePROM implementation recommendations (entitled “AusPROM”); (ii) test the feasibility and acceptability of the QoR-15 PROM for elective surgery day and overnight patients, applying the AusPROM implementation strategy; and (iii) establish if the QoR-15 PROM has concurrent validity with the generic EQ-5D-5L multi-attribute quality of life measure.

METHODS AND ANALYSIS

Study Design and Procedures

The over-arching objective is to direct future quality improvement activities to improve patient related outcomes, to advance clinical care and to improve communication between patients and health care professionals. The protocol adopts the Guidelines for Inclusion of Patient Reported Outcomes in Clinical Trials Protocols; SPIRIT-PRO[30] (see *Supplementary File*).

A mixed-methods design shall be used, with three phases. To develop the final set of "AusPROM" implementation recommendations, data from Phase I, II and III will be combined in an iterative process with Phase I extending alongside Phase II and III. Data from Phase I will influence Phase II and III, and likewise, data from Phase II and III will influence the latter stages of Phase I (Figure 1). Phase I will identify staff barriers and facilitators to nation-wide implementation of an ePROM to elective surgery patients using the Delphi technique with health professionals and other hospital staff. During this phase we shall also generate the AusPROM Recommendations. Because Phase I is an iterative process, it will allow the findings to be integrated periodically throughout Phase II and III. Phase II will use a feasibility design[31] to determine QoR-15 PROM acceptability from the perspective of elective surgery patients from 4 pilot hospitals from 29 Healthscope hospitals, selected as a sample of convenience. Phase III is the national implementation (29 hospitals). Consumer feedback and co-design in embedded throughout the Phases. This includes a consumer co-designing and co-authoring the project from its concept; patients completing brief acceptability surveys alongside the QoR-15 throughout Phase II, in the week prior to surgery,

in the week following surgery and 4 weeks post-surgery; as well as a consumer focus group at the end of Phase II.

To provide structure to the implementation process the research team will use the PROM-cycle framework[32]. In addition, the national implementation will be shaped according to recommendations developed during the first two focus group iterations of Phase I and the patient acceptability from Phase II. Phase III will also examine the concurrent validity of the QoR-15 and generic EQ-5D-5L multi-attribute quality of life measure, with data collection at the 4 pilot hospitals.

Insert around here: Figure 1: The overlapping phases of the study to develop the final set of "AusPROM" Implementation Recommendations

The QoR-15 PROM is a 15 item short-form and it was based on the 40 item QoR-40 [29]. The QoR-15 has 15 items each rated on an 11-point scale from 0-10, with a maximum score of 150. It takes 2.4 minutes to complete and has reported good validity, reliability and responsiveness [4, 29]. There is evidence that the QoR-15 can be used from pre-surgery up to 24 hours to 7 days post-surgery, as a measure of change over time. [33, 34] The minimal clinical important difference of the QoR-15 is 8.0.[33]

Phase I The primary outcome of Phase I is the development of the set of national implementation recommendations (AusPROM recommendations), with the primary endpoint being conclusion of the national implementation following the conclusion of Phase III. It is expected that staff and patient education will be developed and delivered based on these recommendations. Even though the AusPROM recommendations will initially be developed

for the Australian context, a number of the recommendations will have international applicability. A key goal is to simplify administration, whilst acknowledging that compliance be assisted by hospital staff (e.g., front desk staff, medical assistants, nurses, allied health professionals, medical practitioners, surgeons) encouraging patients to fill out the PROMs. Therefore, there will be two perspectives: (i) from staff implementing it centrally at corporate office; (ii) staff in the hospitals who are encouraging patients to complete the ePROM as well as utilise findings from the ePROM survey. This will include health professionals as well as some non-clinical hospital staff from the front desk and administration teams. Several prior studies discuss the impost (cost/time) of data collection[35-37] and our objective is to circumvent that by ensuring that system-wide processes are in place so that the tool can be implemented efficiently.

The Delphi technique can be used to examine complex problems through an iterative process guided by expert opinions, known as a group knowledge acquisition model[38]. The Delphi technique in this study was aligned to the Classical Delphi where the focus is on facts and the objective is the elicit opinion and gain consensus via a series of focus groups[38-41]. The Delphi technique will involve nursing staff from each of the four pilot hospitals, as well as doctors who have involvement in the implementation. They will be asked to participate in each of the three iterative focus groups. Focus groups will occur prior to the commencement of Phase I, as well as prior to, and at the conclusion of, Phase III. The focus groups will be directed toward two issues of priority: (i) barriers and enablers for the national implementation of ePROMs and (ii) recommendations for the implementation and integration of an ePROM into usual care.

Staff inclusion criteria include being aged 18+, employed at Healthscope hospitals and working at one of the included hospitals, and a registered nurse, doctor, allied health professional or administration staff member. There are no specific exclusion criteria. Written informed consent is required for participation.

An email will be sent from the site Director of Nursing to the potential staff participants across the four pilot hospitals, inviting the staff member to participate. They will be invited to contact the research team if they would like to participate in the study. Staff will be identified via the site Director of Nursing and the Chief Medical Officer or General Manager. It will be explained that participation includes three 1-hour focus groups spread out over a 10-month period. It is expected that there will be at least 10 staff participants in the Delphi study. Previous studies have shown that a Delphi study sample size ranging from 6 to 50 had minimal impact on 6 of 9 different consensus indices[42], indicating that the planned sample of size of up to 10 participants will be adequate for this Delphi study.

Phase II will use a feasibility design to complete survey pre-testing at 1 pilot hospital, as well as determine the response rate and QoR-15 ePROM acceptability from an elective surgery patient perspective across 4 pilot hospitals. The pre-testing (n=100) will investigate feasibility from a technical perspective (the rest of this phase relates to feasibility from the patient perspective). Technical feasibility testing includes the pulling of survey distribution list reports from hospital administration data, distributing the survey and testing the assumed patient email and /or mobile number capture rate for survey distribution. Patients will complete brief surveys across three timepoints, incorporating the QoR-15 and two acceptability questions, in the week prior to surgery (noting small QoR-15 modifications were required pre-surgery), in the week following surgery and 4 weeks post-surgery. Time to

complete the survey is estimated at 5 minutes based on previous studies[29]. The primary outcome of Phase II is feasibility relating to the response rate and the primary endpoint will be 4 weeks post-surgery. The secondary outcome is the degree of patient ePROM survey acceptability. At the conclusion of Phase II consumers will be invited to participate in a focus group to discuss in detail the patient acceptability of the PROM survey as well as recommendations for implementation. It is acknowledged that optimal time-points for PROM data collection can sometimes vary according to the patients' condition. For example, elective knee replacement patients often don't confer their full benefit until many months after surgery whereas elective hernia repairs recover within weeks. The extra complexity involved with tailoring time points to different surgeries was beyond the scope of the current study, hence we standardised the time-points for PROMs data collection for elective surgeries. The optimal time points for data collection will be further investigated through the consumer and staff feedback on acceptability.

Quantitative data includes the survey response rate and completion rate for patients who receive an invitation to participate, as well as acceptability of the ePROM survey on a 0-10 Likert scale (10 = highly acceptable and 0 = not acceptable). In addition, response scores for the QoR-15 will be reported over the three time points as a change score and as a percentage of participants who return to pre-surgical status at 4-week post-surgery.

Qualitative data includes patient responses from an open-ended question regarding ePROM survey acceptability as well as the consumer focus group. Responses will be themed via a content analysis using the theoretical framework of acceptability (TFA)[43]. The TFA includes aspects of patient attitude, burden (including length of survey and the timing of the three surveys), ethicality, understanding of the intervention, opportunity costs, perceived

effectiveness and self-efficacy for survey completion[43]. There will also be a content analysis where the frequency of themes is reported for each of the TFA domains.

Patients aged 18+ will be recruited via email and / or text messages following hospital pre-admission for elective surgery at one of the included hospitals. It is noted that in Australia email and text are appropriate strategies for PROM data collection as 86% of households have internet access[44], 91% with household internet use mobile or smart phones[44] and 94% of people who use the internet do so to access emails[45]. The current patient email capture-rate is around 80% for the health service and patients will be excluded if they do not provide either a valid email address or mobile phone number. Patients will also be excluded if they do not have adequate English (survey is only presented in English), if they tick the "opt out" box on the hospital admission paperwork for participation in patient surveys, if they are pregnant, or if they are undergoing a hip, knee or shoulder replacement, and in the case of death no further surveys will be sent. Patients undergoing a hip, knee or shoulder replacement are excluded due to a parallel project in place at the health service targeting this patient population through another PROM process. The survey invitation will include a link to the participant information sheet and there will be a tick box for consent to participate at the start of the survey. Data will be deidentified and presented in an aggregate format. For incomplete surveys, a reminder email and text will be sent up to 1 week later, to improve adherence rates. We shall include the data from all patients, whether they complete 1, 2 or the complete set of 3 surveys.

For Phase II, four hospitals have been recruited to participate in data collection. To be representative of the national health service involved in the study, the four hospitals have a mix of day and overnight services, they will include small and large hospitals, and are located

across three states of Australia. They were selected as samples of convenience of facilities with more than 200 beds across multiple states in Australia and staff willing to participate. It is estimated that over a three-month period around 2,000 patients will receive the ePROM survey. As current patient survey response rates are around 40% for the health service, it is estimated that around 800 patients will complete the pre-surgery survey over three months of data collection, with only 500 patients completing all three surveys due to the five week time horizon between surveys combined with the three month data collection period. As Phase II is a feasibility study a formal power calculation for the sample size has not been undertaken[46]. Instead, the sample size was based on numbers needed to adequately determine the response rate at 4 weeks post-surgery (primary outcome).

Phase III focuses on the national ePROM implementation (29 hospitals), informed by the early Phase I Delphi study informing the AusPROM recommendations, and the concurrent validity analysis of the QoR-15 and generic EQ-5D-5L multi-attribute quality of life measure (four hospitals). The primary outcome for Phase III is the national survey response rate (29 hospitals), with success achieved if the response rate for the pilot sites (4 hospitals) is equalled or exceeded. Patient recruitment and inclusion / exclusion criteria is the same as Phase II.

As the objective of this study is to successfully integrate an ePROM across a national health service to direct future quality improvement activity and ultimately advance clinical care and patient-doctor communication, a whole of health service approach is required. The implementation phase therefore has a sample size based on national hospital representation and it is estimated that over a three-month period around 15,000 patients will receive the ePROM survey.

Data Analysis Plan

Phase I: To report the staff barriers and enablers for implementation of an ePROM the results of the three Delphi focus groups will be themed according to the National Institute of Clinical Studies barriers and enablers framework[47]. This framework includes six levels of potential barriers and enablers including the innovation itself (integrating the ePROM survey into usual care), the professionals / staff, the patient, the social context, the organisation context and the economic and political context. To report the recommendations for the integration of an ePROM into usual care, consensus statements will be drafted in the initial focus group, and re-drafted and refined in the subsequent focus groups.

Phase II and III: Survey response rate and completion rate will be reported as a number and percentage of the total. Response scores for the QoR-15 will be reported over the three time points as a change score and as a percentage of participants who return to pre-surgical status at 4-weeks post-surgery. This will include (a) a comparison between all surveys at baseline, within 1 week post-surgery and at 4 weeks post-surgery; and (b) only include patients who have completed all three surveys (captured through a unique survey identified which will link multiple surveys completed by the same patient). Missing data shall be in reference to a patient missing one or more of the three surveys. There will be no imputation of missing data. We shall also perform an analysis whereby we stratify the PROM results for different hospitals, different surgical groups and according to age. This will enable us to compare our results with global reports on surgical PROM outcomes for different groups.

Phase II: Acceptability of the ePROM survey on a 0-10 Likert will be presented as a mean with interquartile ranges. Responses from the open-ended survey question and the consumer focus group, regarding ePROM survey acceptability, will be themed via a content analysis using the theoretical framework of acceptability (TFA)[43]. There will also be a content analysis where the frequency of themes is reported for each of the TFA domains.

Phase III shall establish if the condition specific QoR-15 PROM has concurrent validity with the generic EQ-5D-5L multi-attribute quality of life measure, and data from the four pilot sites during the Phase II patient ePROM survey. We will assess the concurrent validity between the tests, using Spearman's correlation coefficients, as the data is not expected to be normally distributed. A correlation coefficient of less than 0.3 will be considered weak, between 0.3 and 0.5 will be considered moderate, and above 0.5 will be considered strong. It is noted that this analysis of the additional quality of life questions are pending on the acceptability of the Phase II ePROM survey (which did not include quality of life). Missing data will be managed by excluding participants case wise. Statistical significance is defined as $p<0.05$ and analyses will be completed on IBM SPSS Version 25[48]. Of note, the minimally clinically important difference for the QoR-15 PROM has already been established by Myles et al (2016) as 4.6 to 8.0 (49). The manuscript by Myles et al. also shows the value of the "patient acceptable symptom state" (PASS)[49]. For the QoR-15 it is a score or 118 or better. PASS defines what minimal threshold (score) patients would accept for their own recovery.

Patient and Public Involvement

We designed this protocol ensuring patient involvement in the choice of PROM, study design, data collection forms and implementation plan. Consumers (patients, health

professionals, healthcare managers) will be involved in all parts of the project dissemination of study findings. Consumer representatives contributed to this document.

DISCUSSION & CONCLUSIONS

Development of the AusPROM recommendations will provide a novel contribution to the literature, locally and globally. Of note, the AusPROM is not yet another new PROM. Rather it is a set of recommendations for implementation of PROMS in hospital settings. It is anticipated that the findings will highlight the value of patient (acceptability domains) and health professional (Delphi technique) co-design to inform the implementation recommendations for patient focused outcome measures. The results of this PROM study will also illuminate the feasibility and value of using the QoR-15 to understand how patients rate their elective surgery outcomes. In addition, the findings have the potential to benefit elective surgery patients, clinicians, hospitals, researchers and policy makers.

Once embedded into usual care, data from this e-PROM could help to improve patient experiences and outcomes for elective surgery. Information gained in the barriers and enablers phase of the study shall inform the development of e-PROM related educational materials for patients and clinicians. The education material shall aim to ensure that patients are better prepared for post-discharge management of their condition and better able to cope with the recovery process. Potential health service benefits could include benchmarking different hospitals to see if e-PROM results are higher or lower at a particular site, or for specific surgical procedures or disciplines, allowing strategies to respond to positive or negative deviance. For policy makers, this study has the potential to provide input into economic funding directions, as funding moves towards paying for outcomes, rather than only paying for activity.

The results will be compared and contrasted with previous nation-wide PROM implementation projects. This will be important given the challenges encountered during the implementation of some measures, such as the UK NHS PROM[50] and some orthopaedic-related PROMs[51]. The current project will be different and arguably more effective due to strong consumer engagement at all stages of design and implementation, as well as drawing upon the learnings of hundreds of surgical outcome studies of the QoR-15 from across the globe[52, 53], including large randomised trials[54-56].

ETHICS AND DISSEMINATION

The study findings will be disseminated via the La Trobe University Academic and Research Collaborative in Healthcare (ARCH) and presented at public forums, relevant local and international conferences, and in peer-reviewed journals and clinical guidelines. Ethics approval has been obtained from La Trobe University (Australia) Human Research Ethics Committee (HEC20479).

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Author contributions

All authors contributed to the preparation, drafting and editing of this protocol manuscript. MEM, NB, VA, PM, AH, CJ, DL, VR, AC, VA and JW designed the protocol. MEM and NB wrote the first draft, and all other authors critically appraised and revised the manuscript. All authors read and approved the final version.

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Data Access and Availability

The named authors on this protocol will have access to the final trial dataset. Individual patient level data will not be available for sharing at the conclusion of this study. Summary data will be available on request to the authors.

Competing interest statement

i. The funding source will have no influence over the study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.
ii. Professor Natasha Brusco (Alpha Crucis Group) was funded by Healthscope as a consultant for this study.
iii. Professor Meg Morris has a joint appointment between La Trobe University and Healthscope.
iv. Associate Professor Victoria Anderson, Mr Jeffrey Woods, Anita Hodge and Damien Lloyd are employees at Healthscope.

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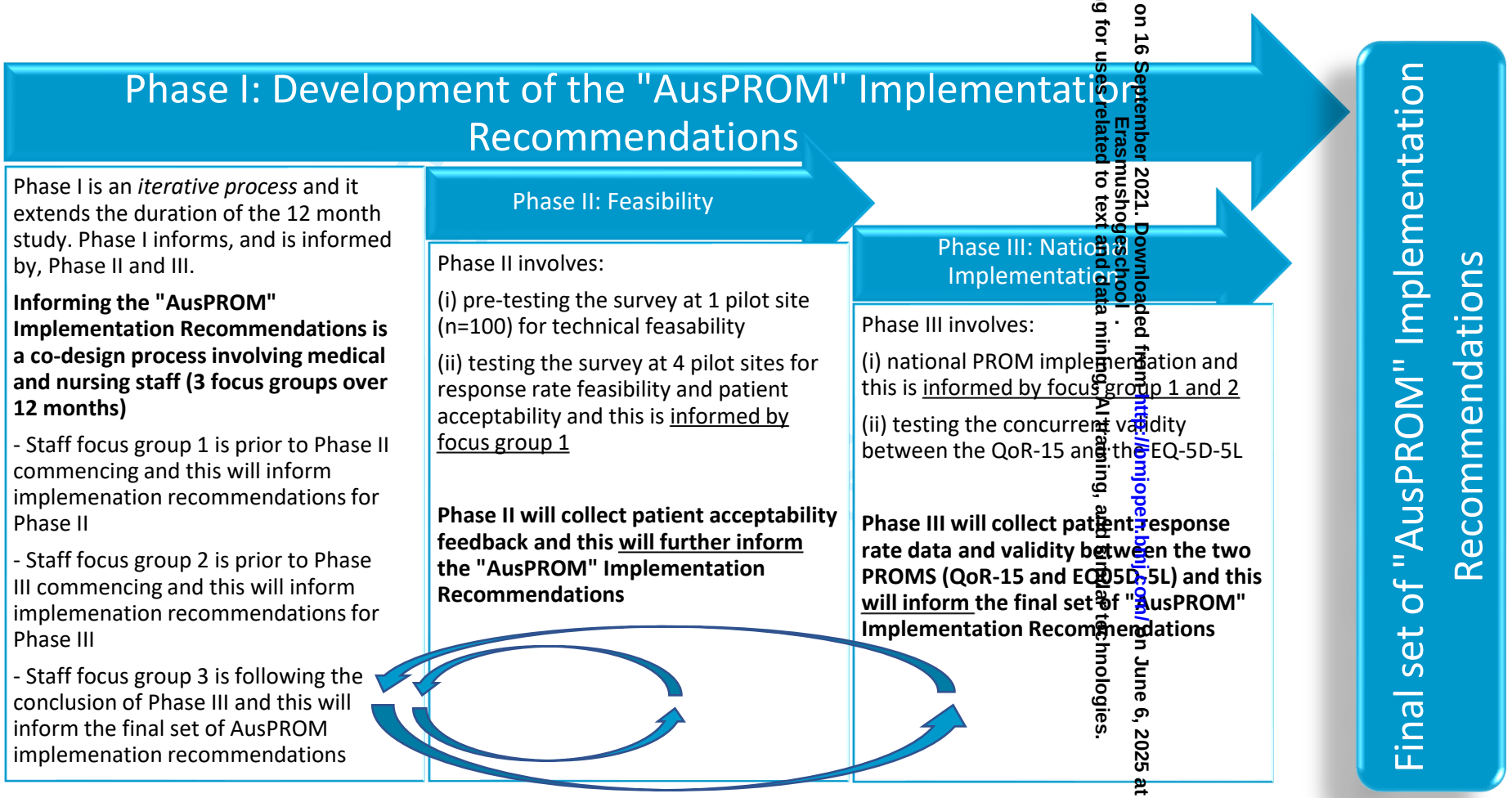

Protocol for implementation of the "AusPROM" Recommendations for elective surgery patients: A mixed-methods cohort study.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*
The SPIRIT-PRO Elaboration and Extension questions have been added to this version of the SPIRIT checklist

Section/item	Item No	Description	Reporting of the item
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Reported in the manuscript
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Reported in the manuscript
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	Version 1 of the protocol submitted January 2021
Funding	4	Sources and types of financial, material, and other support	Reported in the manuscript
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Reported in the manuscript
	SPIRIT-5a-PRO Elaboration	Specify the individual(s) responsible for the PRO content of the trial protocol.	All authors are responsible for the PROM content of the protocol
	5b	Name and contact information for the trial sponsor	Trial sponsor is Healthscope
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Reported in the manuscript
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A

Section/item	Item No	Description	Reporting of the item
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Reported in the manuscript
	SPIRIT-6a-PRO Elaboration	Describe the PRO specific research question and rationale for PRO assessment, and summarize PRO findings in relevant studies.	Reported in the manuscript
	6b	Explanation for choice of comparators	Reported in the manuscript
Objectives	7	Specific objectives or hypotheses	Reported in the manuscript
	SPIRIT-7-PRO Elaboration	State specific PRO objectives or hypotheses (including relevant PRO concepts/domains).	Reported in the manuscript
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Reported in the manuscript
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Reported in the manuscript
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Reported in the manuscript
	SPIRIT-10-PRO Extension	Specify any PRO-specific eligibility criteria (e.g. language/reading requirements or prerandomization completion of PRO). If PROs will not be collected in the entire study sample, provide a rationale and describe the method for obtaining the PRO subsample	Reported in the manuscript
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	This is an observational study of usual care with a PROM introduced to capture the patient perception of usual care
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A

Section/item	Item No	Description	Reporting of the item
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Reported in the manuscript
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Reported in the manuscript
	SPIRIT-12-PRO Extension	Specify the PRO concepts/domains used to evaluate the intervention (e.g. overall HRQOL, specific domain, specific symptom) and, for each one, the analysis metric (e.g. change from baseline, final value, time to event) and the principal time point or period of interest.	Reported in the manuscript
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Reported in the manuscript
	SPIRIT-13-PRO Extension	Include a schedule of PRO assessments, providing a rationale for the time points, and justifying if the initial assessment is not pre randomization. Specify: time windows; whether PRO collection is prior to clinical assessments; and if using multiple questionnaires, whether order of administration will be standardized.	Reported in the manuscript
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Reported in the manuscript
Sample size	SPIRIT-14-PRO Elaboration	Where a PRO is the primary endpoint, state the required sample size (and how it was determined) and recruitment target (accounting for expected loss to follow-up). If sample size is not established based on PRO endpoint, then discuss the power of the principal PRO analyses.	Reported in the manuscript

Section/item	Item No	Description	Reporting of the item
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Reported in the manuscript
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A – observational survey design
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A – observational survey design
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A – observational survey design
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A – observational survey design
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A – observational survey design
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Reported in the manuscript

Section/item	Item No	Description	Reporting of the item
	SPIRIT-18a(i)- PRO Extension	Justify the PRO instrument to be used, and describe domains, number of items, recall period, instrument scaling/scoring (e.g. range and direction of scores indicating a good/poor outcome). Evidence of PRO instrument measurement properties, interpretation guidelines, and patient acceptability/burden should be provided or cited if available, ideally in the population of interest. State whether the measure will be used in accordance with any user manual and specify and justify deviations if planned.	Reported in the manuscript
	SPIRIT-18a(ii)- PRO Extension	Include a data collection plan outlining the permitted mode(s) of administration (e.g. paper, telephone, electronic, other) and setting (e.g. clinic, home, other).	Reported in the manuscript
	SPIRIT-18a(iii)- PRO Extension	Specify whether more than one language version will be used, and state whether translated versions have been developed using currently recommended methods.	Reported in the manuscript
	SPIRIT-18a(iv)- PRO Extension	Where the trial context requires someone other than the trial participant to answer on their behalf (a proxy reported outcome), state and justify this. Provide/cite evidence of the validity of proxy assessment if available.	N/A
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Reported in the manuscript
	SPIRIT-18b(i)- PRO Extension	Specify PRO data collection and management strategies for minimising avoidable missing data.	Reported in the manuscript
	SPIRIT-18b(ii)- PRO Elaboration	Describe the process of PRO assessment for participants who discontinue or deviate from their assigned intervention protocol	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Reported in the manuscript
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Reported in the manuscript

Section/item	Item No	Description	Reporting of the item
	SPIRIT-20a-PRO Elaboration	State PRO analysis methods including any plans for addressing multiplicity/type 1 (α) error.	Reported in the manuscript
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Reported in the manuscript
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Reported in the manuscript
	SPIRIT-20c-PRO Elaboration	State how missing data will be described and outline the methods for handling missing items or entire assessments (e.g. approach to imputation and sensitivity analyses).	Reported in the manuscript
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	A DMD is not required in this study as this is an observational study of usual care with a PROM introduced to capture the patient perception of usual care.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
	SPIRIT-22-PRO Extension	State whether or not PRO data will be monitored during the study to inform the clinical care of individual trial participants and, if so, how this will be managed in a standardized way. Describe how this process will be explained to participants, e.g. in the participant information sheet and consent form.	PROM data will not be monitored during the study, only at the conclusion of the study.
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	The trial conduct will not be audited
Ethics and dissemination			

Section/item	Item No	Description	Reporting of the item
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics approval has been obtained from La Trobe University Human Research Ethics Committee (HEC20479)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Important protocol modifications will be communicated via the ANZCTR
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Reported in the manuscript
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Reported in the manuscript
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Reported in the manuscript
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Reported in the manuscript
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Reported in the manuscript
	31b	Authorship eligibility guidelines and any intended use of professional writers	Reported in the manuscript under Author Statement. There is no intent to use professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Plans to share participant-level dataset is reported in the manuscript. The full protocol is shared via the ANZCTR. Statistical code will not be shared.

Section/item	Item No	Description	Reporting of the item
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Available upon reasonable request
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A
Questionnaires	PRO Elaboration		Available upon reasonable request

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.