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Patient-Reported Experience Measures in Vascular Surgery Enhancement (PREMIERE) study: protocol for a mixed-methods study to develop and validate a vascular surgery-specific patient-reported experience measure

Maram Darwish ,[1,2] Robert Palmer,[3] James Coulson,[4,5] David C Bosanquet,[3] Kathleen Withers[5,6]

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For numbered affiliations see end of article.

Correspondence to
Mrs Kathleen Withers;
withersk@cardiff.ac.uk

ABSTRACT

Introduction Patient-reported experience measures (PREMs) capture patients' healthcare journey experiences. No validated PREMs are specific to vascular surgery patients. This study aims to develop and validate a vascular surgery-specific PREM to assess patient experience and satisfaction.

Methods and analysis Patient Reported Experience Measures In Vascular Surgery Enhancement Study is a two-phase multisite sequential mixed-methods study. The qualitative phase will develop a draft PREM; the quantitative phase will validate it. The study will be conducted across three major vascular units in Wales. Up to 40 patients and healthcare professionals will participate in the qualitative phase. Approximately 150–200 patients will be recruited for the quantitative validation. Inclusion criteria are: (1) age ≥18; (2) recent vascular procedure; (3) inpatient vascular care; (4) not cognitively impaired; (5) consent to participate and (6) English or Welsh proficiency. Primary outcomes will be construct validity and reliability. Secondary outcomes will include patient engagement, healthcare provider perspectives and health system impacts. Thematic analysis will be conducted using NVivo. Psychometric validation will include item analysis, internal consistency testing and factor analysis.

Ethics and dissemination The study was approved by the London—Camberwell St Giles Research Ethics Committee, coordinated by the Health Research Authority and Health and Care Research Wales (REC reference: 24/PR/0522).

Trial registration number NCT06363175.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A multisite validation process ensures diverse patient inclusion and generalisability.
⇒ Translating the patient-reported experience measure into Welsh enhances inclusivity and accessibility.
⇒ Strong patient involvement, from study development through to analysis and dissemination, will enhance the validity and reach of findings.
⇒ The study's applicability may be limited to the UK potentially restricting its relevance to non-UK populations.
⇒ The defined inclusion/exclusion criteria may lead to under-representation of some individuals.

INTRODUCTION

Patient reported experience measures (PREMs) have emerged as instruments designed to capture patients' experiences of their healthcare journey. This may include staff communication, ease and availability of access to information, and coordination of care, physical and mental well-being support, openness of the team and involvement in treatment decisions, and overall satisfaction of the clinical setting.[1 2] In the field of vascular surgery, the effectiveness of surgical care is often evaluated by surgeons, the decision-making process for treatment modalities, the availability of resources (ie, tools, equipment, technologies and support systems) and the precise execution of the surgery.[3] However, there is a growing recognition of the importance of considering patients' perspectives on their surgical journey experience when assessing treatment outcomes.[4]

In the UK, surgical care quality focuses on three domains: patient safety, clinical outcomes and patient experience.[5] High-quality care involves including patients' views and quantifying their experiences. Improving the perioperative experience has been shown to positively impact clinical outcomes.[6]

PREMs have been used in oncology, mental health and primary care to capture patients' perspectives and identify areas

for improvement.[7–9] Few PREMs focus on surgical patients,[10–12] and none are specifically designed for vascular surgery patients. Existing surgical PREMs often use 'satisfaction' and 'experience' interchangeably, affecting the generalisability and accuracy of conclusions. Limited information exists on validated PREMs for vascular patients or their feedback on surgical experiences. Research shows patients prioritise empathy, shared decision-making and holistic care, whereas clinicians focus on clinical outcomes and efficiency.[13 14] These divergent views can lead to misunderstandings, impacting patient satisfaction and engagement.

Our aim is to develop and validate a high-quality PREM for vascular patients, providing them a voice and aiding healthcare providers in capturing these insights. Implementing PREMs in vascular surgery can highlight areas for improvement,[15] enhance communication,[3] increase patient engagement and improve patient safety.[16] Addressing these aspects will improve patient adherence to treatment plans and overall satisfaction, positively impacting patient outcomes.[17–19] This study protocol outlines the methodology and steps involved in developing and validating the PREM.

OBJECTIVES

Primary objective

1. Create and validate a PREM that captures patients experiences in vascular surgery: preoperative, surgical procedure, postoperative care, follow-up and overall satisfaction.

Secondary objectives

1. Gather clinicians' views on implementation and identify gaps between their perceptions and patient experiences.
2. Assess the feasibility and acceptability of the PREM questionnaire in routine practice, including administration ease, completion rates and feedback from patients and healthcare providers.

METHODS AND ANALYSIS

Study design

Patient Reported Experience Measures In Vascular Surgery Enhancement Study (PREMIERE) will follow a multisite sequential mixed-methods design. This study is a collaborative effort between the Southeast Wales Vascular Network, the Welsh Value in Health Centre, the Centre for Healthcare Evaluation, Device Assessment and Research (CEDAR) and Cardiff University. The study was prospectively registered at ClinicalTrials.gov (NCT06363175).

Population and setting

The study will include healthcare professionals (HCPs) and patients from the National Health Service (NHS) in the UK as part of the study population. The local vascular team at each participating unit will approach potential participants. Patients will be identified through vascular wards or routine outpatient clinic care. Those who are receiving in-patient vascular care, defined as vascular surgery specific care that is provided to patients who are admitted to the hospital under the care of the vascular surgery team for more than 24 hours, or those who have recently been discharged within a 3-month period.[20] This would include individuals with conditions such as peripheral artery disease, carotid artery disease, aortic disease and venous disorders. Recruitment efforts will focus on patients preoperatively in the in-patient setting, or shortly after service use (within 3 months) to reduce recall bias.[20] We will target the major centralised vascular units, which refer to specialised multidisciplinary teams consisting of vascular surgeons, interventional radiologists, vascular nurses, vascular technologists and other HCPs who collaborate to provide comprehensive care for patients with vascular disorders within a healthcare facility that focuses on the diagnosis, treatment and management of vascular conditions and diseases,[21] to capture a wide range of patient demographics. Specific inclusion/exclusion criteria are provided below.

Outcome measures

Primary outcome measures:

1. Construct validity of the PREM tool: the extent to which the PREM measures the vascular patients' experience of vascular care. This will be evaluated through factor analysis, convergent and discriminant validity tests, and theoretical alignment with established constructs.
2. Reliability of the PREM tool: assessed through employing statistical measures including Cronbach's alpha and split-half reliability to assess the degree of internal consistency and stability of the PREM.

Secondary outcome measures:

1. Patient engagement: tracking patient engagement with the PREM tool throughout the study period, including completion rates and feedback.
2. Healthcare provider perspectives: healthcare providers' perspectives on the PREM tool at key time points during the study (after implementation, at follow-up assessments).

Study procedures

PREMIERE is a multisite sequential mixed-methods cohort study, incorporating qualitative and quantitative approaches in two phases. The qualitative phase will focus on developing a draft PREM for vascular surgery patients, while the quantitative phase will aim to validate the draft PREM to create a 'final PREM' (summarised in figure 1).

Qualitative phase (draft PREM development)

The qualitative phase will involve three steps:

1. A focus group with HCPs to collect preliminary insights, identify key themes, explore any potential biases and inform selection of patient groups for further data gathering.
2. Semistructured qualitative interviews with vascular surgery patients to identify key dimensions and factors

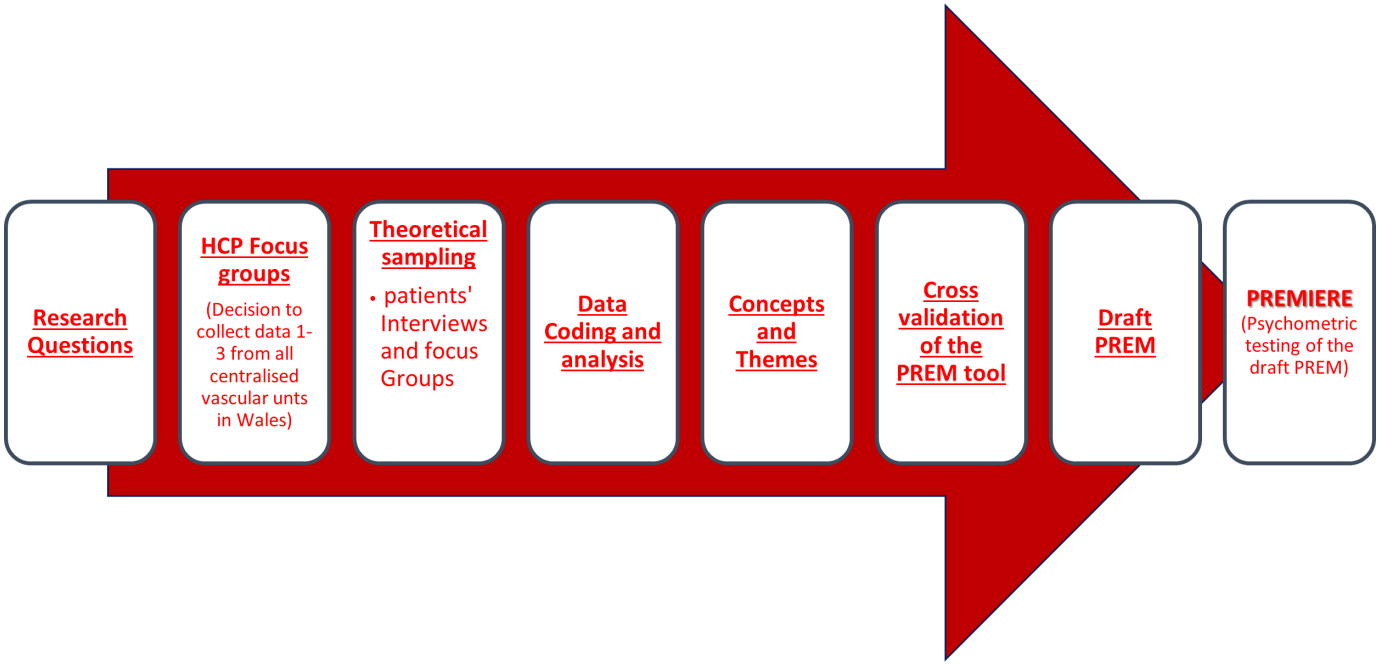

Figure 1 Overview of the PREMIERE study design. HCP, healthcare professional; PREM, patient-reported experience measure; PREMIERE, Patient Reported Experience Measures In Vascular Surgery Enhancement Study.

that contribute to the patient experience in vascular surgery.

3. Cross-validation of the PREM through focus groups with patients (face validity and content validity) to explore patients' opinions further and determine factors that would affect the experience of the vascular surgery patients and get input on the clarity and comprehensiveness of the items chosen, and the wording of the questions.

HCPs focus group

To gather insights from healthcare providers, we will conduct a focus group with 6–8 HCPs. Two research team members will oversee the session: one leading the discussion and the other facilitating. The session will last up to 90 min for a thorough exploration of topics. Conducted via NHS-approved Microsoft Teams,[22] sessions will be recorded and transcribed by Microsoft Teams' built-in feature[23] and checked for accuracy. All recordings and transcripts will be anonymised.

Patients' interviews

Vascular patients' perspectives will be explored through semistructured interviews until data saturation is reached,[24] with an anticipated sample size of 20–30 participants. Using proportional random sampling, we aim for maximum variation. Interviews, lasting 30–60 min, will be audio recorded and transcribed by Microsoft Teams with participant consent. Guided by the study's theoretical framework, an iterative approach will shape the interview guide.[25] All recordings and transcripts will be anonymised and checked for accuracy.

For Welsh-speaking patients, we will seek support from the CEDAR translation team, employing thematic rather than word-for-word translation as recommended in the literature.[26]

Cross-validation

Following data analysis from HCPs' focus groups and patients' interviews, a preliminary version of the PREM will be created based on identified themes. The research team will then conduct cross-validation to refine items, identify gaps and test wording. This involves focus group discussions with a sample of the initially interviewed patients. If insufficient participants from the initial cohort agree to join, purposefully selected vascular patients meeting the same criteria will be included. Eligible participants will be identified based on their interviews to maximise diversity. A total of 12–24 participants from all participating units will take part in the focus groups. Conducted via Microsoft Teams, focus groups will last 1–2 hours and be led by one of the research team, with support from another as a focus-group coordinator. Open-ended questions will guide discussions on question wording, item relevance and usability. Discussions will be transcribed using intelligent verbatim transcription. Inductive thematic analysis will develop preliminary coding structures to organise the data thematically. Based on qualitative data analysis results, a new draft of the questionnaire will be submitted to a set of at least 30 vascular patients, who meet the inclusion criteria below. The face and content validity of the instrument and the content validity index will be calculated.

Quantitative phase (PREM validation)

In the quantitative phase, the draft PREM will be administered to a sample of vascular patients (N=150–200) across the UK for validation, assessing the psychometric

properties of the developed PREM questionnaire (construct validity and reliability). Anticipated participation includes 5–15 vascular units across the UK. Patients will have the option to complete the draft PREM on paper forms or via an electronic, user-friendly platform. This dual approach ensures accessibility and accommodates diverse patient preferences. Completed forms will be collected and returned to the research team for psychometric property assessment.

To ensure the PREM reflects the varied experiences and needs of vascular patients across demographics and disease characteristics, patients will be sampled using a proportional random sampling technique to achieve diversity and representation. A broad range of patients with different types of vascular conditions will be included to capture a wide spectrum of experiences and perspectives. Efforts will be made to ensure equal representation of male and female participants to account for potential gender-related nuances in experience reporting. Age diversity will also be prioritised to cover the range of age-related perspectives on vascular care. Additionally, emphasis will be placed on ensuring diversity in ethnic backgrounds, comorbidities, disease severity and vascular treatment history to provide a comprehensive understanding of how various patient populations experience vascular care and how these factors impact their reported experiences.

Drawing from prior experiences in developing PREMs, a contingency plan for addressing PREM validation issues has been drafted, including both preventive and remedial measures. Proactive measures in our study encompass: (1) pilot testing with a diverse sample to identify potential issues related to item wording, response options or item relevance before proceeding with full-scale psychometric evaluation; (2) soliciting input from experts in psychometrics in CEDAR and HCPs to ensure the relevance and appropriateness of the PREM items and measurement model prior to validation testing; (3) conducting content validity assessments through vascular patients focus group session to verify that the PREM items accurately capture the intended constructs and are relevant to the target population; (4) establishing clear scoring rules for the PREM to ensure consistent interpretation of responses and minimise ambiguity in scoring procedures that could lead to invalid results and (5) implementing continuous monitoring of data quality, participant engagement and response patterns during the validation phase to detect potential issues early on and address them proactively.

In the event that the PREM is deemed invalid following psychometric testing, a systematic and data-driven approach will be employed to address validation challenges and enhance the robustness of the PREM. Further details are given in the statistical analysis section below.

Translation of the PREM questionnaire from English to Welsh

To comply with The Welsh Language (Wales) Measure 2011[27] and accommodate the linguistic needs of our Welsh-speaking participants, the research team will translate the final validated PREM tool into Welsh. The translation of the PREM will be undertaken with the support of the CEDAR translation and validation team using methods recommended by the International Society for Pharmacoeconomics and Outcomes Research.[28] This process ensures the maintenance of semantic, content and conceptual equivalence throughout the translation.[29–31]

Eligibility criteria: patients

To be eligible to participate in this study, a patient must meet all the following inclusion criteria:

1. Have within the last 3 months undergone a vascular procedure or intervention under the care of a vascular surgery team in the inpatient setting as defined by The Vascular Society of Great Britain and Ireland.[32] This includes:
   a. Aneurysm procedures.
   b. Carotid procedures.
   c. Peripheral arterial disease procedures.
   d. Other procedures including thoracic outlet procedures, sympathectomy and venous procedures.
2. Adults aged 18 years or older.
3. Not cognitively impaired (as determined by medical reports and/or self-reporting).
4. Willing and able to provide written consent for participation.
5. Able to speak, read and write English or Welsh.

Exclusion criteria are:

1. Patients who lack capacity or suffer from cognitive impairment.
2. Patients who are unable to speak, read and write English or Welsh.

Patients meeting the eligibility criteria will be approached for inclusion. Selection or participation in this study will not influence any clinical treatment. Verbal and written information will be given by the study team, and written materials will include an information letter and an informed consent form.

Eligibility criteria: HCPs

Inclusion criteria:

1. HCPs involved in the care of vascular surgery patients (ie, vascular surgeons, nurses, anaesthetists, physiotherapists, occupational therapists).
2. At least 3 years of experience in vascular surgery service.
3. Willing to provide consent and participate in the project.

Statistical analysis and sample size calculation

Sample size calculation

For the development phase, a sample size of around 20–30 participants is typically considered sufficient to achieve data saturation in qualitative research.[33] However, we will follow the principle of data saturation, which means that data collection will be continued until no new themes or insights emerge from the interviews or focus groups.

In the validation phase, a sample size of 150–200 participants will be targeted to ensure robust statistical power for the psychometric analyses. This sample size estimation is based on the recommended guidelines for structural equation modelling and factor analysis,[34] which suggest a minimum of 5–10 participants per item in the instrument. With the PREM consisting of 15–20 items, based on our literature review on available PREMs in other surgical domains,[35] a sample size of 150–200 will provide a sufficient participant-to-item ratio for confirmatory factor analysis (CFA) and other psychometric tests, allowing for reliable estimation of model fit indices, factor loadings and covariance patterns. This sample size will also facilitate subgroup analyses based on demographic and clinical characteristics, ensuring adequate representation of the patient population undergoing vascular surgery. The final sample size will be determined after the cross-validation and item reduction.

Statistical analysis

The qualitative data collected from focus groups with HCPs and patients' interviews will be analysed using a structured approach. The audio-recorded data will be transcribed and organised before undergoing a rigorous coding process to identify recurring themes and patterns. The qualitative analysis software NVivo (V.10)[36] will be used for coding based on emergent themes, concepts and categories. Comparative analysis will be conducted to explore differences between HCPs' and patients' perspectives, while thematic analysis will identify overarching themes. Constant comparison techniques will be employed to examine relationships within and across data sets. The analysis will be targeted to uncover insights that inform healthcare practices and patient-centred interventions in the context of vascular surgery.

In the validation phase of our study, we will follow the Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) checklist[37] in assessing the psychometric properties and scoring system of the PREM. The COSMIN checklist includes criteria for internal consistency, reliability, measurement error, validity (content, structural, criterion, cross-cultural), hypotheses testing, responsiveness, interpretability, item response theory (IRT) requirements and generalisability of the results. The reliability of the PREM will be evaluated using Cronbach's alpha. A coefficient cut-off point >0.7 will be used to indicate high internal consistency. Construct validity will be assessed through CFA, to demonstrate model fit and strong factor loadings (cut-off points: Comparative Fit Index >0.90, Tucker-Lewis Index >0.90, root mean square error of approximation <0.08). Eigenvalues, scree plot and factor loadings will be examined to determine the number of factors to retain. Items with factor loadings ≥0.40 will be considered to have good factor loading. Convergent and discriminant validity will be confirmed through correlations with established measures. Hypothesised correlations will be tested using Pearson's correlation coefficient. To avoid missing data, we will only use complete cases (ie, PREMs where all questions have been answered) for all construct validity and internal consistency testing. Pairwise deletion will be used for test–retest analysis.

Contingency plan for addressing PREM validation issues

In the event that the PREM is deemed invalid following psychometric testing, regression analysis and IRT will be used to explore the relationships between items and refine the measurement model. Data analyses will be conducted to evaluate the construct validity and reliability of the revised PREM following adjustments based on psychometric findings. Descriptive statistics, histograms and counts and item-total correlations will be used to characterise the distribution of participant responses and assess the item-level performance of the PREM before and after validation adjustments. Intraclass correlation coefficients will be calculated to evaluate the consistency of ratings from different raters or assessors involved in the validation process for the PREM.

Patient and public involvement

The Patients' Experience Team at Cardiff and Vale University Health Board has reviewed our patient-facing materials and provided valuable patient feedback on participant information sheets and interview guides. Additionally, our research team includes DC, a vascular patient who has undergone multiple vascular operations. DC brings extensive experience in raising awareness about vascular disease through public forums, including the Limbless Association Charity and BBC Radio Wales. Also, our research is dedicated to amplifying patients' voices and will engage participants across Wales. A diverse group of patients will be actively involved in all stages of the PREM development, from initial planning through to dissemination.

ETHICS AND DISSEMINATION

Ethics

The study will be conducted in compliance with the principles of the Declaration of Helsinki (2013),[38] the principles of Good Clinical Practice and in accordance with the Research Governance Framework for Health and Social Care (England).[39] The study was approved by the London—Camberwell St Giles Research Ethics Committee, coordinated by the Health Research Authority (HRA) and Health and Care Research Wales (REC reference: 24/PR/0522, Clinical Trial Registration: NCT06363175, registered on 11 April 2024).

Dissemination

On completion, the study will be reported following The Strengthening the Reporting of Observational Studies in Epidemiology Statement.[40] We plan to publish the results as scholarly articles in international peer-reviewed journals. Our objective is to disseminate our protocol and findings through open access or open science channels

to ensure wide availability. Additionally, all results will be presented at international scientific meetings to inform the global vascular community.

Status and timeline of the study

The study is expected to start in the third quarter of 2024. The PREM development phase is expected to last 6 months, and the validation phase is expected to last a further 6 months. It is anticipated that the study will be completed in the second quarter of 2025, with data analysis and dissemination intended to be completed by the end of 2025.

DISCUSSION

There is a growing body of research highlighting the effectiveness of specialty-specific PREMs over generic hospital PREMs.[41–43] Studies have demonstrated that specialty-specific PREMs tailored to specific patient populations yield more accurate and meaningful data regarding patient experiences within the specific specialty.[41–43] These studies have shown that using specialty-specific PREMs allows for a more comprehensive understanding of patients' needs, recovery experiences and the unique challenges associated with different healthcare contexts. Furthermore, the implementation of specialty-specific PREMs has been linked to improved patient–provider communication, enhanced quality of care and targeted interventions that address the specific needs of the patient population.[43–45]

Vascular surgery is a complex and often stressful surgical journey that can have a profound impact on patients' lives. Therefore, understanding patients' experiences and incorporating their feedback is crucial for delivering high-quality surgical care.[46] The non-linear nature of vascular surgery patient journeys[47] involving different treatment modalities and long-term management presents unique aspects that cannot be captured by generic PREMs. Vascular surgery patients encompass a unique demographic profile, often comprising older individuals with a higher prevalence of comorbidities which can significantly impact their overall health and treatment experiences.[48] Also, vascular conditions tend to affect individuals from diverse socioeconomic backgrounds, with varying access to healthcare, potentially influencing their experiences and outcomes in distinctive ways.[49] The complex interplay of these factors underscores the need to develop a PREM tailored to the specific needs and challenges of this diverse and often vulnerable patient population.

The adoption of a vascular-specific PREM has the potential to directly influence surgeons and other healthcare practitioners. By integrating a vascular-specific PREM into their daily practice, surgeons acquire an in-depth understanding of their patients' experience, including specific outcomes, obstacles and recovery accounts reported by their patients.[50 51] This personalised feedback can serve as a catalyst for surgeons to align their clinical approaches with patient-centred care. The insights derived from a vascular-specific PREM can empower surgeons to spearhead initiatives for enhancing care quality specific to the needs of their patient population, leading to improved patient experience and enhanced clinical results.

Limitations

The study's scope is limited to the UK. As a result, the applicability of the developed PREM to non-UK populations may be constrained. Nevertheless, the insights gained from this study could serve as a valuable foundation for future cross-national validation efforts. Individuals not meeting the defined inclusion/exclusion criteria may not be adequately represented. Cultural variations and healthcare systems differences should be recognised as potential factors influencing the study's outcomes, necessitating further research to promote broader adoption and validation of the developed PREM.

Author affiliations
[1]Department of Vascular Surgery, Cardiff and Vale University Health Board, Cardiff, UK
[2]Health Education East Midlands, Nottingham, UK
[3]Cardiff and Vale University Health Board, Cardiff, UK
[4]University Hospital of Wales, Cardiff, UK
[5]Cardiff University, Cardiff, UK
[6]The Welsh Value in Health Centre, Cwm Taf University Health Board, Abercynon, UK

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Contributors MD conceived the research idea, developed the study protocol and drafted the manuscript. RP designed the statistical analysis plan, provided data management strategies and contributed to manuscript preparation. JC assisted in developing the study protocol, participated in the literature review and contributed to manuscript writing. DCB provided critical revisions to the study protocol, contributed to the design of the study framework and assisted in drafting sections of the manuscript. KW supported protocol development, contributed to the methodology and provided critical manuscript revision. All authors reviewed and approved the final version of the manuscript. MD is the guarantor for this manuscript and accepts full responsibility for the finished work, the conduct of the study and the decision to publish.

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Competing interests None declared.

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ORCID iD
Maram Darwish http://orcid.org/0000-0001-7040-3903

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