Protocol section	Description	Why should I consider including this?	Included? (Y/N)
Administrative Information	Identify roles and responsibilities of PRO personnel	Inclusion of staff with PRO expertise in protocol development and coordination of data collection should improve data quality.	
Introduction	Provide PRO specific background information	So that people understand the burden of disease/treatment in the context of existing evidence and study population.	
	Provide a PRO-specific rationale	So that everyone understands why PROs are being assessed in the study. The rationale will also help inform the selection of instruments/domains and timing of assessments.	
	Provide PRO-specific hypotheses	These will be tested in the trial.	
	Provide PRO-specific objectives	Pre-specified hypotheses and objectives will helpfully inform the study team, promote high quality data collection and help minimise unplanned analyses.	
Methods: Participants, interventions and outcomes	Detail PRO sample/setting	This is particularly important if the PRO sample differs from the main study population.	
	Specify PRO-specific eligibility criteria	Details of any PRO specific eligibility criteria (such as language requirements) will help study staff and aid interpretation of generalisability of PRO results.	
	Specify PRO endpoint	It is good practice to define whether the PRO is a primary secondary or exploratory endpoint and to pre-specify the domain(s)/timepoint for the principal analyses to avoid issues related to multiple statistical testing.	
	Specify timing of PRO-assessments	Standardising the timing (usually prior to clinical assessment) and defining a clinically relevant assessment schedule and time-windows will help improve data quality.	
	Justify timing of PRO assessments	Timepoints should be justified in relation the study hypotheses, recall period and disease progression.	
	The PRO-sample size should be discussed and justified.	This should be considered in the context of the study rationale/hypothesis.	
Methods: assignment of interventions	Discuss PROs in the context of blinding.	In a blinded study it may be useful to detail PRO administration techniques that help minimise unblinding.	
Methods: Data collection, management and analysis	Describe the PROM	Information of the questionnaires being used in the study should be provided in the protocol. This may include information on the number of items/domains, instrument scaling/scoring, reliability, content and construct validity, responsiveness, sensitivity, respondent burden, cultural adaptation/validity, recall period and validation plan if appropriate.	
	Justify the choice of PROM in relation the study hypotheses	This information may be helpful for those reviewing the protocol (e.g. funders/RECs) and study staff.	
	Justify the choice of PROM in relation to measurement properties.	The validity, reliability and responsiveness of the tool should be clearly referenced (unless under development).	
	Justify the choice of PROM in relation to patient acceptability and burden.	Information on patient acceptability/burden including time to complete will be useful for study staff and trial participants.	
	Detail PRO data collection plan	This is crucial information for study staff. This should include information on how (mode) and where the measure will be administered and whether different languages are available and whether proxies are permissible.	
	Detail guidelines/training for research personnel.	Such guidance will help promote data quality and could include information on who is responsible for PRO data/cover for leave absence, how to discuss the PRO with patients and plans to maximise compliance.	
	Specify plans to minimise avoidable missing data	This may include checking forms for missing data, plans to contact patients with missing data and documenting reasons for missing data. For further information on minimising missing data please click (link to RMB review).	
	Describe PRO-specific quality assurance	This will help promote data quality and may include: guidance for data entry coding decisions regarding missing or ambiguous response or specifying procedures for a central PRO data monitoring system aimed at identifying and rectifying potential	

		data collection problems.	
	Provide a PRO Statistical Analysis Plan	Pre-specification of analyses is good practice and will help ensure that the PRO data will be used in a meaningful way to improve future patient care.	
	Describe plans to address multiplicity of PRO data	Because PROs are often assessed at multiple timepoints and be analysed by overall scores or subdomains there is opportunity for multiple statistical testing. Pre-specifying principal or order of analyses can help minimise this problem.	
	Define PRO clinical significance	Pre-specification of a clinically important difference will help interpretation of the study results.	
	Define statistical methods to deal with missing PRO data	There are a number statistical methods that can be used to deal with missing data (ref Fayer/Fairclough). The planned approach should be described.	
Monitoring	Define PRO data monitoring	The role of the data monitoring committee in relation to PROs should be defined.	
	Include plans for the identification and monitoring of PRO-Alerts	Our recent survey of UK research personnel demonstrated inconsistent management of PRO Alerts. An a priori plan for consistent/standardised management of PRO alerts that is clearly communicated to all appropriate trial staff should be included in the protocol. For details of the options available please click.	
Ethics and dissemination	Provide PRO-specific patient information/consent information	It is essential that the study team and patients understand why the PRO data is being collected and how it will be used. Patients and staff should be provided with information including: reasons for evaluating the PRO, what it will involve, risks and benefits, frequency and timing/timeframe, the need to answer all questions, the importance of completing questions without being influenced by the opinions of others and, if appropriate, identify if consent to QOL assessment is required for entry into the trial	
	Describe PRO-specific confidentiality procedures	The protocol and patient information should specify who will access the PRO data and whether it will be used to influence the clinical management of the patient.	
	Outline PRO dissemination policy	Plans for feedback to study participants and the publication policy for the PRO data may help maximise the impact of the study results.	
Appendices	Provide a copy of PRO-specific patient information/consent form	Helpful for reviewers and research personnel.	
	Provide a PRO assessment checklist or flowchart	Helpful for reviewers and research personnel.	
	Provide a copy of the PROM (and translated versions if applicable).	Helpful for reviewers and research personnel.	
	Provide PROM completion instructions.	Helpful for research personnel.	

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