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| Item | | | | | Description |
| INTRODUCTION | | | | |  |
|  | | Background | | | Overview of the existing situation regarding the scientific question you wish to explore |
|  | | Rationale | | | Description of how you are planning to approach the investigation of the scientific question. |
|  | | Objectives | | | Description of what the aim of your approach is. |
| METHODS | | | | |  |
|  | | Study Design | | | Description of the study design (e.g., interrupted time-series, cross-sectional etc.). |
|  | | Participants | | |  |
|  | | | Inclusion/Exclusion Criteria | | Criteria for selection and rejection of participants. |
|  | | | Recruitment Procedures | | Where will you find them, and how you will recruit them. |
|  | | | Sample Size | | Number of patients to be recruited based on power calculations. |
|  | Study Procedures | | | | Description of what participants will be asked to do, what data will be collected and how, details of what equipment will be used etc. |
|  | Data Analysis and Outcomes | | | | Description of variables and primary and secondary outcomes. |
|  | Data management | | | | Description of the type of data, how long data will be retained, how data will be stored, where data will be held etc. |
|  | Data transfers | | | | Description of how and with whom data will be shared (what contracts). |
|  | Ethical and regulatory considerations | | | |  |
|  | | | | Research ethics approval | From which authority(ies) will an ethics approval be obtained. |
|  | | | | Informed consent | Procedures to obtain consent from participants. |
|  | | | | Confidentiality | How confidentiality (concerning data from participants) will be achieved. |
|  | | | | Declaration of interests | Description of funding (if any) and declaration of partners' conflicting interests (financial and other). |
|  | | | | Access to data | How and who will be granted access to data. |