APPENDIX C: IMPLEMENTABILITY CHECKLIST

PLANNING PHASE

1. Has trial planning involved end-users?

a. Who are the intended end-users of the results of this trial?
b. Which end-users could have a role in implementation?
c. Can end-users help define how the range of possible results of this trial would be applied to the range of possible changes in practice or policy and map these to potential impact on patient outcomes or healthcare system productivity or both?
d. Does the research question have relevance to end-users?
e. Are the trial end-points patient-centred outcomes and, if not, are the outcomes accepted as clinically meaningful in the discipline?
f. Are the trial end-points that are under consideration known to be sufficient to influence end-users to change practice or policy?
g. Is the trial powered to detect the minimum clinically significant difference that would be important to end-users?
h. Does the choice of comparator reflect current and likely ongoing practice and so provide a meaningful comparison for end-users? If trade-offs are required have all alternatives or multiple comparator groups been considered?
i. Does the population recruited to the trial reflect the population in which the interventions would be implemented?
j. Can the trial entry criteria be interpreted easily and quickly by clinicians who would need to identify similar patients to change practice or policy?

2. Has the clinical context of the trial been defined sufficiently?

a. Has a systematic review been conducted and demonstrated that there is unmet need for evidence regarding effectiveness of the candidate intervention?
b. Is current standard care, including variation in standard care, described?
c. If the intervention is already in clinical practice, is there evidence of harm or burden sufficient to justify a trial of withdrawal of a component of standard care?

3. Is regulatory approval likely to be needed to contribute to implementation?

4. Have trial designs that randomise populations, rather than individuals, been considered?

5. For complex interventions has feasibility of delivery of the intervention in a trial been established?

6. Does the trial team have sufficient expertise to ensure that issues related to implementability have been considered during trial planning?

7. Is the trial best conducted within a trial network?

8. Has there been consideration of including a section within the trial protocol that discusses potential issues that relate to implementation

a. Pre-specification of the implication of different trial results to implementation
b. Consideration of barriers and enablers to potential implementation
c. Consideration of trial design issues that contribute to implementability
d. Planned pathways for dissemination and evidence synthesis
e. Whether parallel observational work is planned to measure implementation

DESIGN AND CONDUCT PHASE

1. Population to which trial results apply

a. Are trial sites representative of sites that would undertake implementation?
b. Is the target population as generalisable as possible?
c. If there are concerns about differential treatment effect within the target population can this be better managed with stratification?
d. Can trial entry criteria be applied easily and quickly in clinical practice or into policy?

2. Delivery of intervention is optimised for implementation

a. Is the intervention being delivered in the same way and by the same type of staff who would implement into practice?
b. Are trial activities related to adherence, compliance, and monitoring similar to clinical practice?
c. For complex interventions, are the methods used to train staff during the trial suitable for training routine clinical staff?

3. Choice of comparator and background care

a. Does the choice of comparator allow meaningful comparison that will facilitate implementation?
b. Are any restrictions regarding concomitant care capable of being implemented into practice or policy?

4. Plan of analysis and sub-group analyses

a. Is the trial planned to be analysed on an intention-to-treat basis?
b. Are planned sub-group analyses based on variables known at the time a decision to implement would be made during a clinical encounter?

5. Nesting the trial within a registry

a. Is it possible for the registry to provide information about characteristics and outcomes of patients who would have been eligible for the trial but were not enrolled?

6. Process evaluation and fidelity

a. For complex interventions, is a process evaluation being incorporated into the trial so that this information can guide potential implementation

7. Health economics

a. Where there is differential cost of interventions has a health economic analysis been planned and incorporated into the study design?

REPORTING PHASE

1. Is there a commitment that the results of the trial will be reported, irrespective of results or completion of the trial?

2. Is there a commitment to report using CONSORT or the appropriate modification of CONSORT for alternative trial designs?

3. Does the trial report sufficient information to allow implementation of the intervention into practice or policy? For example, does reporting meet the requirements of the TiDIER check-list?

4. What is the trial's data sharing policy?

5. Has accessibility of trial results been considered?

6. Have all conflicts or duality of interest been identified and reported?