Conduct feasibility study to explore what works

Develop study protocol

Conduct pilot trial

(A) has pilot confirmed design & methods are feasible & appropriate except for minor details?

YES

Carry forward data from pilot

Conduct full, refined trial

Trial Management Group refines design in detail

(B1) has pilot confirmed design & methods are feasible & appropriate in principle but need refining in detail?

YES

Trial Management Group reviews design in depth; data from pilot not carried forward

NO

(B2) do full trial procedures encompass those used in pilot trial?

YES

Carry forward data from pilot

Analysis

Results and conclusions

NO

Pilot data not carried forward

(C) has pilot identified the need for change that the pilot did not set out to assess?

YES

NO