Pilot and feasibility studies are an essential part of trial preparation. Trials carried out in a health care setting typically involve complex interventions that require considerable planning if they are to be implemented successfully. Complex interventions are conventionally made up of several interacting components and present special problems related to their sensitivity to the local context and the logistics of applying experimental methods in a health care setting. The UK Medical Research Council’s guidance document on complex interventions emphasises the importance of thorough groundwork in designing and evaluating complex interventions and stresses the importance of contextualising and conceptualising the problem at the development stage.

Recent papers have shown that there was, and still is a dearth of pilot studies in the literature that state they are specifically in preparation for a randomised controlled trial, and that give a clear list of key objectives relating to the pilot phase. Feasibility and pilot studies are conducted to assess the feasibility and integrity of the study protocol, but the differences between the two are not clear-cut. This talk will provide an overview of the objectives of feasibility and pilot studies, considering issues of study design and analysis, and provide some useful examples and references. The development of CONSORT extension guidelines for reporting pilot trials will be briefly mentioned as well as a new recently launched BIOMED central journal arising from this work.