Parallel session – Innovative Research Methods (22 March 14:00 – 15:15)

O18 BREAKING THE GOLD STANDARD: QUALITATIVE METHODS FOR TRIALS OF COMPLEX HEALTH INTERVENTIONS

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Background Randomised controlled trials (RCT) are widely considered to be the ‘gold standard’ for evaluating health interventions. Qualitative methods are often perceived as an ‘add-on’ to robust quantitative intervention evaluations. The current status of qualitative methods within trials undermines the enormous insights qualitative approaches contribute to our understanding of the impact interventions have on human health.

Objectives This presentation examines the ‘state of the art’ of qualitative methods currently used within trials of complex health interventions.

Methods In early 2018, we completed a rapid review of innovative qualitative methods mentioned in the RCT protocols of complex health interventions for a commentary to a special issue of Qualitative Health Research. ‘Innovative’ was used to refer to qualitative methods beyond atheoretical interviews or focus groups with trial participants. We generated a list of 189 qualitative research methods from a search of 27 qualitative methodology journals using the terms ‘innovat* new novel emerg*’, and then used this list as key terms to search protocols published since 2012 and registered with the ISRCTN trial database.

Results Our search showed that while 1452 of the registered trial protocols mentioned some form of qualitative research, only 34 of these discussed more innovative qualitative methods. Qualitative methods were most often employed during trial process evaluations or as formative research in the pre-trial phase. Protocols rarely went into depth about the details of the methods used or explained how their analysis would contribute to the trial results.

Conclusions These gaps significantly undermine the potential of qualitative methods to improve understandings of the successes and failures of interventions in different contexts. We will discuss these gaps and their implications for health intervention evaluation in detail, and also point to some areas of good practice arising from the special issue that we hope will push the field forward.