

Final report: N87 Advancing the integration of mixed methods in clinical trials: a two day summit and expert panel on the integration of data from randomised controlled trials (RCTs) and qualitative research

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The ConDuCT II and North West Hubs and collaborators from the University of Exeter applied for £9,950 from the MRC Hubs for Trials Methodology Research (HTMR) Network. The full amount of funding was awarded from the University of Liverpool to the University of Bristol. Funds were transferred to the University of Exeter to host a two day summit and expert panel on the integration of data from RCTs and the qualitative research that is undertaken with them.

- **The original objectives were:**

- (1) Identify current strengths and weaknesses in the integration of quantitative and qualitative methods in clinical trials;
- (2) Establish the next steps required to provide the trials community with guidance on the integration of mixed methods in RCTs;
- (3) Set-up a network of individuals, groups and organisations willing to collaborate on a related application to the MRC Methodology Panel in June 2017.

- **The planned outputs and impacts were:**

- (1) A summit and expert panel to bring together methodological experts in clinical trials and mixed methods to produce an authoritative position paper on the current strengths and weaknesses in the integration of quantitative and qualitative methods in clinical trials. This paper will be disseminated to the trials community via the MRC HTMR network and Clinical Trials Units network.
- (2) An application to the MRC Methodology Research Programme in June 2017 for funds to produce guidance on integrated mixed methods in RCTs. Panel discussion on day two of the summit will form the basis of the application; experts who attend the summit will collaborate on the application via the network set up as part of this project.
- (3) Establish a network of collaborators

- **Progress to date:**

1. The summit (on day one) and expert panel (on day two) were held on 3 & 4 May 2017 in Exeter with 20 attendees from England, Scotland, Wales, Sweden, Australia and the United States. Attendees were international experts in RCTs, qualitative research and mixed methods and represented stakeholders working on the evaluation of medical devices, pharmaceutical, surgical and complex interventions in clinical and public health settings. Delegates attended the summit and expert panel.

2. The summit was focussed on current strengths and weaknesses in the integration of quantitative and qualitative trial data. A series of international and UK presentations informed discussion on existing techniques for integrated analysis, mixed method study designs that facilitate the integration of quantitative and qualitative data, and writing grant applications and reports for trials involving integrative analysis.
3. The expert panel considered the need for guidance on the analytic integration of quantitative and qualitative trial data and the next steps to produce guidance. Members also worked on draft content for a position paper to describe the current level and potential benefits of integration.
4. Evaluation forms submitted by delegates showed that the event exceeded the expectations of 82% of attendees: 88% of delegates felt that the summit was very or exceptionally useful; 76% rated the expert panel discussion as excellent or very good. There was consensus that quantitative and qualitative trial data are rarely integrated in analysis. A small number of studies were identified that illustrate how analytic integration can add value to health research. Attendees were in favour of the development of guidance on integrative analysis and formed a network with the intention to lead on the development of guidance in relation to feasibility, pilot and fully-powered RCTs.
5. Following the event, work has focussed on writing a position paper, *'Getting added value from mixed methods: integrating randomised controlled trial and qualitative research data'*. We have approached the editor of the BMJ Open who responded positively and advised that we consider publication in the BMJ. A draft has been prepared by Dr Hill and commented on by the other applicants for this project (Professors O'Cathain, Young, Richards and Dr Horwood). Further drafts have been written on which, prior to submission in 2018, all panel members will be able to comment.

- **Next steps**

(1) Complete draft of position paper by March 2018 and submit to BMJ.

(2) Panel members discussed the possibility of an application to MRC Methodology Panel to produce guidance but agreed that published examples and information on the application of these methods was as yet insufficiently developed.

(3) University of Exeter to set up a JISC group/WhatsApp/email group of collaborators to share learning, collate further examples and foster collaborations that may lead to other outputs.