

Evaluation and validation of social and psychological markers in randomised trials of complex interventions in mental health: a methodological research programme

Graham Dunn,^{1,2*} Richard Emsley,^{1,2} Hanhua Liu,¹ Sabine Landau,³ Jonathan Green,⁴ Ian White⁵ and Andrew Pickles³

¹Centre for Biostatistics, Institute of Population Health, University of Manchester and Manchester Academic Health Science Centre, Manchester, UK

²Medical Research Council North West Hub for Trials Methodology Research, UK

³Department of Biostatistics, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK

⁴Institute of Brain, Behaviour and Mental Health, University of Manchester and Manchester Academic Health Science Centre, Manchester, UK

⁵Medical Research Council Biostatistics Unit, University of Cambridge, Cambridge, UK

*Corresponding author

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Plain English summary

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One of the main funding sources from the National Institute for Health Research is the Efficacy and Mechanism Evaluation programme. It funds a type of randomised clinical trial in which investigators hope to assess not only whether or not a particular intervention works ('Does it work?') but also the treatment mechanism ('How does it work?').

Clinical trial investigators have a long tradition of designing randomised clinical trials to answer the first of these two questions but very little knowledge or experience of the use of trials to answer the second. A third question that is becoming more important is finding out which treatments work for which people ('For whom does it work?') as attempts are made to develop personalised treatments. A fourth question is 'What factors involved in the treatment make it work better?'.

This report describes the development and evaluation of statistical methods for the design and valid analysis of these trials in order to answer these questions.

We have reviewed existing methods and described their limitations. We have proposed some new statistical methods that answer these questions, and importantly are explicit about the underlying assumptions. We provide numerous examples of these analyses based on trials of psychological interventions but highlight that the methods are applicable in other clinical areas too. We make recommendations for how this work could be extended in future research, in particular regarding better trial designs and use of repeated measures.

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