Psychological intervention, antipsychotic medication or a combined treatment for adolescents with a first episode of psychosis: the MAPS feasibility three-arm RCT

Anthony P Morrison,^{1,2*} Melissa Pyle,^{1,2}
Rory Byrne,^{1,2} Matthew Broome,^{3,4,5,6}
Daniel Freeman,^{4,6} Louise Johns,^{4,6} Anthony James,^{4,6}
Nusrat Husain,^{2,7} Richard Whale,⁸
Graeme MacLennan,⁹ John Norrie,¹⁰ Jemma Hudson,⁹
Sarah Peters,² Linda Davies,² Samantha Bowe,¹
Jo Smith,¹¹ David Shiers,^{1,2} Emmeline Joyce,¹
Wendy Jones,^{1,2} Chris Hollis¹² and Daniel Maughan⁶

Declared competing interests of authors: Anthony P Morrison reports personal fees from the provision of training workshops in cognitive-behavioural therapy for psychosis and royalties from books on the topic outside the submitted work. Melissa Pyle reports fees paid to the Psychosis Research Unit from cognitive-behavioural therapy training at Greater Manchester Mental Health NHS Foundation

¹Psychosis Research Unit, Greater Manchester Mental Health NHS Foundation Trust, Manchester, UK

²Division of Psychology and Mental Health, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, UK

³Institute for Mental Health, School of Psychology, University of Birmingham, Birmingham, UK

⁴Department of Psychiatry, Medical Sciences Division, University of Oxford, Oxford, UK

⁵Centre for Human Brain Health, School of Psychology, University of Birmingham, Birmingham, UK

⁶Warneford Hospital, Oxford Health NHS Foundation Trust, Oxford, UK

⁷Early Intervention in Psychosis Service, Lancashire and South Cumbria NHS Foundation Trust, Chorley, UK

⁸Brighton and Sussex Medical School, University of Sussex, Brighton, UK

⁹Health Services Research Unit, University of Aberdeen, Aberdeen, UK

¹⁰Clinical Trials Unit, University of Edinburgh, Edinburgh, UK

¹¹School of Allied Health and Community, University of Worcester, Worcester, UK

¹²National Institute for Health Research MindTech MedTech Co-operative, Division of Psychiatry and Applied Psychology, Institute of Mental Health, University of Nottingham, Nottingham, UK

^{*}Corresponding author anthony.p.morrison@manchester.ac.uk

Trust (Manchester, UK). Rory Byrne reports personal fees from Oxford Cognitive Therapy Centre (Oxford, UK) outside the submitted work. Matthew Broom reports royalties from Oxford University Press (Oxford, UK) and personal fees from Medical Defence Union (London, UK) outside the submitted work. Daniel Freeman reports grants from the National Institute for Health Research (NIHR) and the Medical Research Council during the conduct of the study outside the submitted work. Louise Johns reports personal fees from New Harbinger Publications (Oakland, CA, USA) outside the submitted work. Nusrat Husain reports that he is the chairperson of the board of trustees of the Manchester Global Foundation (Manchester, UK), a charitable incorporated organisation registered in England and Wales; he is a past trustee of Lancashire Mind (Chorley, UK), Abaseen Foundation (Lancaster, UK) and the Pakistan Institute of Living and Learning (Karachi, Pakistan). Nusrat Husain reports that he established an independent general hospital (Remedial Centre) in Karachi, Pakistan; this is now owned and operated by his sibling, and the hospital is also attached to a pharmacy. Nusrat Husain reports that he has received an honorarium and travel grants from various pharmaceutical industries. Richard Whale reports conference attendance support from Sunovion Pharmaceuticals Inc. (Marlborough, MA, USA) and personal fees from Janssen: Pharmaceutical Companies of Johnson & Johnson (Beerse, Belgium) and from H. Lundbeck A/S (Copenhagen, Denmark) outside the submitted work. John Norrie reports membership of the following NIHR boards: cardiopulmonary resuscitation decision-making committee, Health Technology Assessment (HTA) programme Commissioning Board, HTA Commissioning Sub-board (expression of interest), HTA Funding Boards Policy Group, HTA General Board, HTA Post-Board funding teleconference, NIHR Clinical Trials Unit Standing Advisory Committee, NIHR HTA and Efficacy and Mechanism Evaluation Editorial Boards; and the Pre-exposure Prophylaxis Impact Review Panel. John Norrie also declares grants from the University of Aberdeen and the University of Edinburgh. Linda Davies reports grants from the University of Manchester during the conduct of the study. Samantha Bowe reports personal fees from private therapy practice, and personal fees from a cognitive-behavioural therapy training post at Greater Manchester Mental Health NHS Foundation Trust outside the submitted work. David Shiers reports personal fees from the National Clinical Audit of Psychosis, royalties from John Wiley & Sons, Inc. (Hoboken, NJ, USA) publication for 'Promoting Recovery in Early Psychosis' 2010 (ISBN 978-1-4051-4894-8) and reports membership of the current National Institute for Health and Care Excellence (NICE) guideline development group for rehabilitation in adults with complex psychosis and related severe mental health conditions. David Shiers is also a board member of the National Collaborating Centre for Mental Health (2013-present), expert adviser to the NICE centre for guidelines and clinical adviser to the National Clinical Audit of Psychosis outside the submitted work. Chris Hollis reports that he was chairperson of the NICE Guideline Development Group for Schizophrenia in Children & Young People (2011–13) and was chairperson of the NICE Psychosis and Schizophrenia in Children Evidence Update (2014–15) outside the submitted work.

Published January 2021 DOI: 10.3310/hta25040

Plain English summary

The MAPS feasibility three-arm RCT Health Technology Assessment 2021; Vol. 25: No. 4

DOI: 10.3310/hta25040

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Plain English summary

Psychosis is a mental health problem that can involve hearing, seeing or believing things that others do not. Although many young people who experience psychosis recover well from their first episode of psychosis, others can have more serious, longer-lasting problems. There has not been a large amount of research into the treatment of psychosis in young people; therefore, it is important to test different treatments against each other in clinical trials. 'Feasibility' trials, such as the one we carried out [Managing Adolescent first-episode Psychosis: a feasibility Study (MAPS)], test whether or not it is possible to run larger trials.

MAPS was a small trial that was run in seven locations in the UK. People who were aged 14–18 years and experiencing psychosis were able to take part. Each participant was randomly assigned to receive psychological treatment (cognitive–behavioural therapy and optional family therapy), antipsychotic medication or a combination of both. All of the participants met with a trial research assistant three times for assessments about well-being and symptoms. Some clinicians, participants and family members were interviewed about their opinions of the trial and treatments. The trial also had patient and public involvement; service user researchers were involved in design, interview data collection, analysis and report writing.

Sixty-one young people took part in MAPS, which was around 68% of our target number. In total, 84% completed the assessments with research assistants. The results showed that, overall, all treatments were acceptable to young people and their family members. However, a higher percentage of young people actually received the 'minimum dose' of psychological treatment than the 'minimum dose' of antipsychotic medication (82% vs. 65%). Results showed that it was possible to run a larger trial such as this. However, some changes would be required to run a larger trial, such as location (focusing on urban areas with well established early intervention in psychosis teams), increasing involvement of psychiatrists and increasing the age limit for participation to 25 years.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.370

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the Health Technology Assessment journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 15/31/04. The contractual start date was in March 2017. The draft report began editorial review in September 2019 and was accepted for publication in May 2020. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

© Queen's Printer and Controller of HMSO 2021. This work was produced by Morrison *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

NIHR Journals Library Editor-in-Chief

Professor Ken Stein Professor of Public Health, University of Exeter Medical School, UK

NIHR Journals Library Editors

Professor John Powell Chair of HTA and EME Editorial Board and Editor-in-Chief of HTA and EME journals. Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK, and Professor of Digital Health Care, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Professor Andrée Le May Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals) and Editor-in-Chief of HS&DR, PGfAR, PHR journals

Professor Matthias Beck Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson Consultant Advisor, Wessex Institute, University of Southampton, UK

Ms Tara Lamont Senior Scientific Adviser (Evidence Use), Wessex Institute, University of Southampton, UK

Dr Catriona McDaid Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Emeritus Professor of Wellbeing Research, University of Winchester, UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, UCL Great Ormond Street Institute of Child Health, UK

Professor Jonathan Ross Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Ken Stein Professor of Public Health, University of Exeter Medical School, UK

Professor Jim Thornton Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Please visit the website for a list of editors: www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: journals.library@nihr.ac.uk