

Radically open dialectical behaviour therapy for refractory depression: the RefraMED RCT

Thomas R Lynch,^{1*} Roelie J Hempel,¹ Ben Whalley,² Sarah Byford,³ Rampaul Chamba,⁴ Paul Clarke,⁵ Susan Clarke,⁶ David Kingdon,⁷ Heather O'Mahen,⁸ Bob Remington,¹ Sophie C Rushbrook,⁶ James Shearer,³ Maggie Stanton,⁹ Michaela Swales,¹⁰ Alan Watkins¹¹ and Ian T Russell¹¹

¹Department of Psychology, University of Southampton, Southampton, UK

²School of Psychology/Cognition Institute, Plymouth University, Plymouth, UK

³King's Health Economics, King's College London, London, UK

⁴Member of Trial Management Committee responsible for Public and Patient Involvement, Bilston, UK

⁵Institute for Social and Economic Research, University of Essex, Colchester, UK

⁶Intensive Psychological Therapies Service, Dorset HealthCare University NHS Foundation Trust, Poole, UK

⁷School of Medicine, University of Southampton, Southampton, UK

⁸Psychology, University of Exeter, Exeter, UK

⁹Psychological Services, Southern Health NHS Foundation Trust, Winchester, UK

¹⁰School of Psychology, Bangor University, Bangor, UK

¹¹Medical School, Swansea University, Swansea, UK

*Corresponding author t.lynch@soton.ac.uk

Declared competing interests of authors: Thomas R Lynch reports grants from the University of Southampton during the conduct of the study and personal fees from New Harbinger Publications and R.O.B.T Ltd outside the submitted work. Roelie J Hempel is co-owner and director of Radically Open Ltd. No money was exchanged between Roelie J Hempel and the company before, during or immediately after the study. David Kingdon reports grants from the National Institute for Health Research Efficacy and Mechanism Evaluation programme during the conduct of the study. Heather O'Mahen reports personal fees from the Charlie Waller Institute and personal fees from Increasing Access to Psychological Therapies outside the submitted work and reports being a member of the Guidelines Development Group National Institute for Health and Care Excellence (NICE) 2014 Antenatal and Postnatal Mental Health, an executive member of the British Psychological Society Perinatal Faculty, a NICE expert advisor for the Centre for Clinical Practice and a member of the Clinical Reference Group for Perinatal Mental Health. Maggie Stanton reports personal fees from British Isles DBT Training, personal fees from Stanton Psychological Services Ltd and personal fees from the Routledge, Taylor and Francis Group outside the submitted work. Michaela Swales reports personal fees from British Isles DBT Training and personal fees from Guilford Press, Taylor and Francis and Oxford University Press outside the submitted work. Ian T Russell reports grants from Health and Care Research Wales during the conduct of the study.

Published December 2018

DOI: 10.3310/eme05070

Plain English summary

The RefraMED RCT

Efficacy and Mechanism Evaluation 2018; Vol. 5: No. 7

DOI: 10.3310/eme05070

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

Plain English summary

We evaluated the clinical effectiveness and cost-effectiveness of radically open dialectical behaviour therapy (RO DBT), which is a new treatment for depression and problems of emotional overcontrol, such as misguided perfectionism and emotional loneliness, by comparing its effects with treatment as usual (TAU), the health care normally available from the NHS or private providers. From three dissimilar UK locations, we recruited adults who were diagnosed with major depressive disorder who had not responded to treatment and who scored above the threshold on a standard measure of current depression. We randomly assigned them to either 7 months of RO DBT ($n = 162$ patients) or TAU ($n = 88$ patients). Recently trained therapists delivered RO DBT over 29 weekly 1-hour individual therapy sessions and 27 weekly 2.5-hour skills group sessions. We reassessed patients at the end of the treatment and at 12 and 18 months after entering the study. After 12 months, the main time at which we assessed clinical effectiveness, both groups reported worthwhile reductions in depression scores; however, the difference could have occurred by chance. At the end of treatment, in contrast, RO DBT patients had reported a reduction in depressive symptoms that was much larger by both statistical and clinical criteria than that reported by TAU patients. Furthermore, more of participants reported that they no longer felt depressed. The economic analyses concluded that, although RO DBT had reduced the extent and cost of other health care, it was too costly in its current form to achieve cost-effectiveness by published criteria. Hence, the next challenge is to find ways of delivering RO DBT more efficiently and more sustainably.

Efficacy and Mechanism Evaluation

ISSN 2050-4365 (Print)

ISSN 2050-4373 (Online)

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 EME archive is freely available to view online at www.journalslibrary.nihr.ac.uk/eme. 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 *Efficacy and Mechanism Evaluation* journal

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

EME programme

The Efficacy and Mechanism Evaluation (EME) programme was set up in 2008 as part of the National Institute for Health Research (NIHR) and the Medical Research Council (MRC) coordinated strategy for clinical trials. The EME programme is broadly aimed at supporting 'science driven' studies with an expectation of substantial health gain and aims to support excellent clinical science with an ultimate view to improving health or patient care.

Its remit includes evaluations of new treatments, including therapeutics (small molecule and biologic), psychological interventions, public health, diagnostics and medical devices. Treatments or interventions intended to prevent disease are also included.

The EME programme supports laboratory based or similar studies that are embedded within the main study if relevant to the remit of the EME programme. Studies that use validated surrogate markers as indicators of health outcome are also considered.

For more information about the EME programme please visit the website: <http://www.nets.nihr.ac.uk/programmes/eme>

This report

The research reported in this issue of the journal was funded by the EME programme as project number 09/150/12. The contractual start date was in September 2011. The final report began editorial review in January 2017 and was accepted for publication in October 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The EME editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research. 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, the MRC, NETSCC, the EME 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 EME programme or the Department of Health and Social Care.

© Queen's Printer and Controller of HMSO 2018. This work was produced by Lynch *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 Chair of HTA and EME Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA and EME Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andrée Le May Chair of NIHR Journals Library Editorial Group (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 Scientific Advisor, NETSCC, 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 Professor of Wellbeing Research, University of Winchester, UK

Professor John Norrie Chair in Medical Statistics, University of Edinburgh, UK

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), 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 Jim Thornton Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

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

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