Clinical effectiveness and cost-effectiveness of cognitive behavioural therapy as an adjunct to pharmacotherapy for treatment-resistant depression in primary care: the CoBalT randomised controlled trial

Nicola Wiles, 1* Laura Thomas, 1 Anna Abel, 2
Maria Barnes, 1 Fran Carroll, 3 Nicola Ridgway, 4
Sofie Sherlock, 1 Nicholas Turner, 1
Katherine Button, 1 Lang'o Odondi, 5
Chris Metcalfe, 5 Amanda Owen-Smith, 3
John Campbell, 6 Anne Garland, 7 Sandra Hollinghurst, 3
Bill Jerrom, 8 David Kessler, 3 Willem Kuyken, 2
Jill Morrison, 9 Katrina Turner, 3 Chris Williams, 4
Tim Peters 10 and Glyn Lewis 11

¹Centre for Academic Mental Health, School of Social and Community Medicine, University of Bristol, Bristol, UK

²Mood Disorders Centre, University of Exeter, Exeter, UK

³Centre for Academic Primary Care, School of Social and Community Medicine, University of Bristol, Bristol, UK

⁴Academic Unit of Mental Health and Wellbeing, Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK

⁵ConDuCT Hub for Trials Methodology Research, School of Social and Community Medicine, University of Bristol, Bristol, UK

⁶Primary Care Research Group, University of Exeter Medical School, Exeter, UK ⁷Nottingham Psychotherapy Unit, Nottinghamshire Healthcare NHS Trust,

Nottingham, UK

⁸Avon and Wiltshire Mental Health Partnership NHS Trust, Chippenham, UK ⁹Institute of Health and Wellbeing, General Practice and Primary Care Group, University of Glasgow, Glasgow, UK

¹⁰School of Clinical Sciences, University of Bristol, Bristol, UK

¹¹Division of Psychiatry, University College London, London, UK

^{*}Corresponding author

Declared competing interests of authors: Chris Williams has been a past president of the British Association for Behavioural and Cognitive Psychotherapies (BABCP), a workshop leader and an author of various book and online self-help resources addressing depression. He is Director of Five Areas Ltd, which licenses cognitive behavioural therapy (CBT) self-help and training resources. Wilem Kuyken is co-founder of the Mood Disorders Centre, teaches nationally and internationally on CBT, and has co-authored a cognitive therapy book (*Collaborative Case Conceptualization*, published by Guilford Press). Anne Garland is clinical lead for the Nottingham Specialised Depression Service, principal investigator to the CLAHRC-NDL (Collaboration for Leadership in Applied Health Research and Care – Nottinghamshire, Derbyshire and Lincolnshire)-funded Depression Study, a past president of the BABCP, a CBT workshop leader, both nationally and internationally, and author of texts on depression.

Published May 2014 DOI: 10.3310/hta18310

Plain English summary

The CoBalT randomised controlled trial

Health Technology Assessment 2014; Vol. 18: No. 31

DOI: 10.3310/hta18310

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

Plain English summary

Many patients with depression who are prescribed antidepressants by their doctor do not get better after 6 weeks of treatment. Cognitive behavioural therapy (CBT) is a type of 'talking therapy' that has been shown to help patients with previously untreated depression but there is little evidence about its effectiveness as a 'next-step' treatment for those patients whose depression has not responded to medication. To answer this question we studied 469 patients with depression who had been taking antidepressants for at least 6 weeks and who had not got better. All continued with usual care from their general practitioner, including medication, but half (234) received CBT in addition. We followed up participants for 1 year and found that those who had CBT as well as usual care were approximately three times more likely to have fewer depressive symptoms than those in the usual-care group. The treatment was good value for money over the 12 months. Participants sometimes found therapy to be a challenging and difficult process, but felt that the techniques learned from CBT helped them better manage their depression. This study has provided high-quality evidence that receiving CBT, in addition to continuing on antidepressants as part of usual care, is an effective treatment for patients with depression who have not got better on medication alone.

HTA/HTA TAR

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Five-year impact factor: 5.804

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

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

Editorial contact: nihredit@southampton.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

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

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.

For more information about the HTA programme please visit the website: www.hta.ac.uk/

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 06/404/02. The contractual start date was in May 2008. The draft report began editorial review in March 2013 and was accepted for publication in July 2013. 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. 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.

© Queen's Printer and Controller of HMSO 2014. This work was produced by Wiles *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health. 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).

Editor-in-Chief of Health Technology Assessment and NIHR Journals Library

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the HTA Programme, UK

NIHR Journals Library Editors

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

Professor Andree Le May Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Professor Aileen Clarke Professor of Public Health and Health Services Research, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Peter Davidson Director of NETSCC, HTA, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Professor Elaine McColl Director, Newcastle Clinical Trials Unit, Institute of Health and Society, Newcastle University, UK

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

Professor Geoffrey Meads Professor of Health Sciences Research, Faculty of Education, University of Winchester, UK

Professor Jane Norman Professor of Maternal and Fetal Health, 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 Professorial Research Associate, University College London, UK

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

Please visit the website for a list of members of the NIHR Journals Library Board: www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: nihredit@southampton.ac.uk