

# Structured lifestyle education to support weight loss for people with schizophrenia, schizoaffective disorder and first episode psychosis: the STEPWISE RCT

Richard IG Holt,<sup>1,2\*</sup> Daniel Hind,<sup>3</sup>  
Rebecca Gossage-Worrall,<sup>3</sup> Michael J Bradburn,<sup>3</sup>  
David Saxon,<sup>4</sup> Paul McCrone,<sup>5</sup> Tiyi A Morris,<sup>5</sup>  
Angela Etherington,<sup>6</sup> David Shiers,<sup>7,8</sup>  
Katharine Barnard,<sup>9</sup> Lizzie Swaby,<sup>3</sup>  
Charlotte Edwardson,<sup>10</sup> Marian E Carey,<sup>11</sup>  
Melanie J Davies,<sup>10</sup> Christopher M Dickens,<sup>12</sup>  
Yvonne Doherty,<sup>11,13</sup> Paul French,<sup>7</sup>  
Kathryn E Greenwood,<sup>14,15</sup> Sridevi Kalidindi,<sup>16</sup>  
Kamlesh Khunti,<sup>11</sup> Richard Laugharne,<sup>17</sup>  
John Pendlebury,<sup>18</sup> Shanaya Rathod,<sup>19</sup>  
Najma Siddiqi,<sup>20,21</sup> Stephen Wright,<sup>22</sup>  
Glenn Waller,<sup>23,24</sup> Fiona Gaughran,<sup>25,26</sup>  
Janette Barnett<sup>11</sup> and Alison Northern<sup>11</sup>

<sup>1</sup>Human Development and Health Academic Unit, Faculty of Medicine, University of Southampton, Southampton, UK

<sup>2</sup>University Hospital Southampton NHS Foundation Trust, Southampton, UK

<sup>3</sup>Clinical Trials Research Unit, University of Sheffield, Sheffield, UK

<sup>4</sup>School of Health and Related Research, University of Sheffield, Sheffield, UK

<sup>5</sup>King's Health Economics, Institute of Psychiatry, Psychology & Neuroscience, King's College London, London, UK

<sup>6</sup>Independent service user consultant

<sup>7</sup>Psychosis Research Unit, Greater Manchester Mental Health NHS Foundation Trust, Manchester, UK

<sup>8</sup>School of Health Sciences, Division of Psychology and Mental Health, University of Manchester, Manchester, UK

<sup>9</sup>Faculty of Health & Social Sciences, Bournemouth University, Poole, UK

<sup>10</sup>Diabetes Research Centre, University of Leicester, Leicester, UK

<sup>11</sup>Leicester Diabetes Centre, University Hospitals of Leicester, Leicester, UK

<sup>12</sup>Institute of Health Research, University of Exeter Medical School, Exeter, UK

<sup>13</sup>Psychological Medicine, York Teaching Hospital NHS Foundation Trust, York, UK

<sup>14</sup>Sussex Partnership NHS Foundation Trust, Worthing, UK

- <sup>15</sup>School of Psychology, University of Sussex, Brighton, UK
- <sup>16</sup>Rehabilitation and Recovery, South London and Maudsley NHS Foundation Trust, London, UK
- <sup>17</sup>Research and Innovation, Cornwall Partnership NHS Foundation Trust, Redruth, UK
- <sup>18</sup>Retired NHS community psychiatric nurse
- <sup>19</sup>Research and Development, Southern Health NHS Foundation Trust, Southampton, UK
- <sup>20</sup>Department of Health Sciences, Hull York Medical School, University of York, York, UK
- <sup>21</sup>Bradford District Care NHS Foundation Trust, Bradford, UK
- <sup>22</sup>Leeds and York Partnership NHS Foundation Trust, Leeds, UK
- <sup>23</sup>Sheffield Health & Social Care NHS Foundation Trust, Sheffield, UK
- <sup>24</sup>Department of Psychology, University of Sheffield, Sheffield, UK
- <sup>25</sup>Department of Psychosis Studies, Institute of Psychiatry, Psychology & Neuroscience, King's College London, London, UK
- <sup>26</sup>National Psychosis Unit and Research and Development Department, South London and Maudsley NHS Foundation Trust, London, UK

\*Corresponding author [r.i.g.holt@soton.ac.uk](mailto:r.i.g.holt@soton.ac.uk)

**Declared competing interests of authors:** Richard IG Holt received fees for lecturing, consultancy work and attendance at conferences from the following companies: Boehringer Ingelheim (Ingelheim am Rhein, Germany), Eli Lilly and Company (Indianapolis, IN, USA), Janssen Pharmaceutica (Beerse, Belgium), Lundbeck (Copenhagen, Denmark), Novo Nordisk (Bagsværd, Denmark), Novartis (Basel, Switzerland), Otsuka Pharmaceutical Co., Ltd (Tokyo, Japan), Sanofi-Aventis (Paris, France) and Sunovion Pharmaceuticals, Inc. (Marlborough, MA, USA). Paul French is a member of the National Institute for Health Research (NIHR) Health Technology Assessment Mental, Psychological and Occupational Health funding panel. Melanie J Davies and Kamlesh Khunti are members of a NIHR Clinical Trials Unit. Melanie J Davies reports personal fees from Novo Nordisk, Sanofi-Aventis, Eli Lilly and Company, Merck Sharp & Dohme (Kenilworth, NJ, USA), Boehringer Ingelheim, AstraZeneca (Cambridge, UK), Janssen Pharmaceutica, Servier Laboratories (Neuilly-sur-Seine, France), Mitsubishi Tanabe Pharma Corporation (Tokyo, Japan) and Takeda Pharmaceuticals International Inc. (Canton of Zürich, Switzerland) and grants from Novo Nordisk, Sanofi-Aventis, Eli Lilly and Company, Boehringer Ingelheim and Janssen Pharmaceutica. Kamlesh Khunti has received fees for consultancy and being a speaker for Novartis, Novo Nordisk, Sanofi-Aventis, Eli Lilly and Company, Servier Laboratories and Merck Sharp & Dohme. He has received grants in support of investigator and investigator-initiated trials from Novartis, Novo Nordisk, Sanofi-Aventis, Eli Lilly and Company, Pfizer (New York, NY, USA), Boehringer Ingelheim and Merck Sharp & Dohme. Kamlesh Khunti has also received funds for research and honoraria for speaking at meetings, and has served on advisory boards for Eli Lilly and Company, Sanofi-Aventis, Merck Sharp & Dohme and Novo Nordisk. David Shiers is an expert advisor to the National Institute for Health and Care Excellence (NICE) centre for guidelines, a board member of the National Collaborating Centre for Mental Health (NCCMH) and a clinical advisor (on a paid consultancy basis) to the National Clinical Audit of Psychosis (NCAP); any views given in this report are personal and not those of NICE, NCCMH or NCAP. David Shiers reports personal fees from the Wiley-Blackwell publication *Promoting Recovery in Early Psychosis*, 2010 (ISBN 978-1-4051-4894-8), as he is a joint editor in receipt of royalties. John Pendelbury received personal fees for involvement in the study from a NIHR grant; he reports personal fees from the Greater Manchester Mental Health NHS foundation trust outside the submitted work and has published papers in the area of weight management and physical health related to mental health. Marian E Carey and Yvonne Doherty report being employed by the Leicester Diabetes Centre, an organisation (employer) jointly hosted by a NHS hospital trust and the University of Leicester and which is the holder (through the University of Leicester) of the copyright of the STEPWISE programme and of the Diabetes Education and Self-Management for Ongoing and Newly

Diagnosed (DESMOND) suite of programmes, training and intervention fidelity framework that were used in this study. Fiona Gaughran reports personal fees from Otsuka and Lundbeck and personal fees and non-financial support from Sunovion, outside the submitted work, and has a family member with professional links to Eli Lilly and Company and GlaxoSmithKline (Brentford, UK), including shares.

**Published November 2018**

DOI: 10.3310/hta22650

## Plain English summary

### The STEPWISE RCT

Health Technology Assessment 2018; Vol. 22: No. 65

DOI: 10.3310/hta22650

NIHR Journals Library [www.journalslibrary.nihr.ac.uk](http://www.journalslibrary.nihr.ac.uk)

## Plain English summary

People with schizophrenia are often overweight. Losing weight and being more active can reduce the risk of diabetes mellitus and heart disease and dying early. The NHS recommends offering a weight loss programme; however, mental health care providers do not know how best to do this.

We assessed whether or not an education programme to help people with psychosis to lose weight would be better than the usual care provided by the NHS.

A total of 414 people took part. We selected half of them at random to attend an education programme run by trained facilitators. The other half received their usual health care.

We found no important difference in weight between the two groups, at either 3 months or 12 months. We also found that the programme did not provide good value for money. In interviews, service users said that they liked the education programme and that it helped them to eat healthily and lose weight. However, we found no change in their diet and activity levels in either group. The trained staff thought that the programme could benefit service users, but were unsure if the NHS could afford it. They also wanted to know whether or not service users were losing weight during the programme.

People were interested in the trial and stayed in the trial until the end. Unfortunately, although some people benefited, the programme did not work for most people. Therefore, we need to look for better ways to help people with psychosis to lose weight.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.513

*Health Technology Assessment* is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the 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/](http://www.publicationethics.org/)).

Editorial contact: [journals.library@nhr.ac.uk](mailto:journals.library@nhr.ac.uk)

The full HTA archive is freely available to view online at [www.journalslibrary.nhr.ac.uk/hta](http://www.journalslibrary.nhr.ac.uk/hta). Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: [www.journalslibrary.nhr.ac.uk](http://www.journalslibrary.nhr.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: <http://www.nets.nhr.ac.uk/programmes/hta>

## This report

The research reported in this issue of the journal was funded by the HTA programme as project number 12/28/05. The contractual start date was in October 2013. The draft report began editorial review in October 2017 and was accepted for publication in February 2018. 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 2018. This work was produced by Holt *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.nhr.ac.uk](http://www.journalslibrary.nhr.ac.uk)), produced by Prepress Projects Ltd, Perth, Scotland ([www.prepress-projects.co.uk](http://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](http://www.journalslibrary.nihr.ac.uk/about/editors)

**Editorial contact:** [journals.library@nihr.ac.uk](mailto:journals.library@nihr.ac.uk)