An intervention to improve the quality of life in children of parents with serious mental illness: the Young SMILES feasibility RCT

Kathryn M Abel,[1,2*] Penny Bee,[3] Lina Gega,[4,5]
Judith Gellatly,[1,3] Adekeye Kolade,[1] Diane Hunter,[6]
Craig Callender,[7] Lesley-Anne Carter,[8]
Rachel Meacock,[9] Peter Bower,[10] Nicky Stanley,[11]
Rachel Calam,[12] Miranda Wolpert,[13,14]
Paul Stewart,[6] Richard Emsley,[15] Kim Holt,[16]
Holly Linklater,[17] Simon Douglas,[7]
Bryony Stokes-Crossley[7] and Jonathan Green[18]

[1]Centre for Women's Mental Health, Faculty of Biology, Medicine and Health, The University of Manchester, Manchester Academic Health Science Centre, Manchester, UK
[2]Greater Manchester Mental Health NHS Foundation Trust, Manchester, UK
[3]Division of Nursing, School of Health Sciences, Faculty of Biology, Medicine and Health, The University of Manchester, Manchester Academic Health Science Centre, Manchester, UK
[4]Department of Health Sciences, University of York, York, UK
[5]Hull York Medical School, University of York, York, UK
[6]National Society for the Prevention of Cruelty to Children, London, UK
[7]Northumberland Tyne and Wear NHS Foundation Trust, St Nicholas Hospital, Newcastle upon Tyne, UK
[8]Centre for Biostatistics, Institute of Population Health, University of Manchester, Manchester, UK
[9]Manchester Centre for Health Economics, University of Manchester, Manchester, UK
[10]National Primary Care Research and Development Centre, University of Manchester, Manchester, UK
[11]School of Social Work, University of Central Lancashire, Preston, UK
[12]Faculty of Biology, Medicine and Health, Manchester Academic Health Science Centre, University of Manchester, Manchester, UK
[13]Evidence Based Practice Unit, University College London, London, UK
[14]Anna Freud Centre, London, UK
[15]Department for Biostatistics and Health Informatics, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[16]Department of Social Work, Education and Community Wellbeing, University of Northumbria, Newcastle upon Tyne, UK

[17]Department of Education and Inclusive Pedagogy, University of Edinburgh, Edinburgh, UK
[18]Division of Neuroscience and Experimental Psychology, University of Manchester, Manchester, UK

*Corresponding author kathryn.m.abel@manchester.ac.uk

Declared competing interests of authors: Kathryn M Abel is a current member of the Health Technology Assessment (HTA) General Committee (since 1 Novemeber 2018). Rachel Meacock is a current member of the Health Service and Delivery Research Funding Committee (since 1 January 2019). Richard Emsley is a current member of the HTA Clinical Evaluation and Trials Committee (since 1 November 2017).

Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

Published November 2020
DOI: 10.3310/hta24590

Scientific summary

Young SMILES RCT

Health Technology Assessment 2020; Vol. 24: No. 59
DOI: 10.3310/hta24590

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

Scientific summary

Background

Quality of life among children and adolescents living with serious parental mental illness can be impaired by an increased risk of experiencing deprivation; maltreatment and neglect; behavioural, social and educational difficulties; and mental and physical health problems. Evidence-based interventions to improve the quality of life of children and adolescents living with serious parental mental illness are scarce and pay little attention to improving coping skills and mental health literacy, which are considered important elements for such interventions by the young people themselves. We responded to a National Institute for Health Research (NIHR) Health Technology Assessment programme call to develop a child-centred intervention to improve the health-related quality of life of children and adolescents living with serious parental mental illness.

Objectives

We aimed to (1) coproduce (with stakeholders) an intervention acceptable to families and feasible to deliver in the NHS and in the community with support from health and non-health professionals; (2) determine rates of intervention uptake and adherence, and of completed follow-up measures; (3) identify appropriate measures of health-related quality of life of children and adolescents living with serious parental mental illness and estimate their data missingness; (4) develop a child resource utilisation questionnaire and estimate its data missingness; and (5) capture the experiences of children and parents who participated in the intervention and professionals who referred or supported families to participate.

Methods

Semistructured interviews and focus groups with children and young people ($n = 14$), parents ($n = 7$), and practitioners from social, educational and health-related sectors ($n = 31$) informed the production of a manualised intervention called Young Simplifying Mental Illness plus Life Enhancement Skills (SMILES). Three key themes guided the design of activities within the Young SMILES manual: mental health literacy, communication and problem-solving.

Young SMILES was delivered as an eight-session weekly group programme, with four to six children and adolescents living with serious parental mental illness per age-appropriate group (6–11 and 12–16 years). At week 4, a five-session parallel weekly programme was offered to the parents/carers. Two practitioners from the National Society for the Prevention of Cruelty to Children (NSPCC), Barnardo's and the NHS co-facilitated each of the children's and parents' sessions, which lasted 2 hours each, including time for breaks.

Families were recruited in two ways: first, via NHS staff identifying eligible families from their patient caseloads or by screening patient records within adult community mental health teams, and, second, via an opportunistic approach of identifying families who contacted children's charities during the study recruitment period. Children aged 6–16 years were eligible to participate if they had at least 10 hours of contact per week with a parent/carer with severe mental illness. Both ill and well parents/carers were eligible to participate.

Families were randomised via a web-based system to either Young SMILES or usual care. All children and parents completed questionnaires at randomisation and at 4 and 6 months post randomisation. Health-related quality of life was self-reported by children and proxy-reported by parents using the Paediatric Quality of Life questionnaire and the KIDSCREEN. An additional quality-of-life measure, the Child Health Utility 9D, was used to estimate incremental health gain in quality-adjusted life-years to inform a future economic evaluation.

Additional outcome measures, self-reported by children and proxy-reported by parents, included the Revised Child Anxiety and Depression Scale 25-item brief version, and the Strengths and Difficulties Questionnaire. Children also completed a mental health literacy questionnaire, which assessed their help-seeking and first-aid skills, their knowledge and stereotypes of mental health problems and their self-help strategies. Parents self-reported their parenting competencies using the Arnold–O'Leary parenting scale; they reported the degree and cause of stress in their parent–child relationship using the Parent Stress Index – Short Form.

The Child and Adolescent Service Use Schedule was adapted for the study and piloted as a data collection tool for child resource utilisation. We used the tool to identify the most important aspects of resource utilisation and to assess the feasibility of collecting information on receipt of care and services in relation to children's needs and services from the NHS and social care, education, and voluntary and third-sector organisations.

Semistructured interviews with parents and children who participated in the Young SMILES groups gathered information about their motivation to sign up to the study, their experiences of participating in the group sessions and their perceived changes in themselves and their family members following the intervention. Further interviews with individual referrers gathered information about challenges to recruitment and randomisation. Two focus groups with practitioners who facilitated the intervention explored parents' and children's views of the format and content of the Young SMILES manual and their suggestions for changes.

Results

We recruited 35 families, of which 20 were randomly allocated to Young SMILES and 15 to receive their usual care. Twenty-eight families provided follow-up data at the primary end point (4 months post baseline): 15 out of 20 (75%) in the intervention group and 13/15 (87%) in the control group. Children and adolescents typically had high adherence to the intervention, completing seven of the eight offered sessions, whereas parental adherence was not as good (average attendance three out of five sessions). The majority of recruited parents were mothers, but there was a balance of sexes among participating children and adolescents living with serious parental mental illness.

At baseline, children's self-reported health-related quality of life and functioning were high and their emotional and mental health needs were below the clinical threshold within each outcome measure and across all time points. There were noticeable differences in mean scores at baseline between the two randomised groups across all outcome measures. This was not surprising given the small size and heterogeneity of our sample.

Visual inspection of the child-reported outcome data at both follow-up points across all outcome measures revealed neither alarming results nor an obvious and consistent direction of scores in relation to time or outcomes. We did not formally test for between-group comparisons as this was a feasibility study, which was not sufficiently powered to do so.

Parents' proxy-reported scores consistently tended to overestimate areas of difficulty for their children and to underestimate their health-related quality of life compared with the children's corresponding self-reported scores. Parent self-reported outcomes indicated that parents in our sample were, on average, below the cut-off scores for distress and difficulties with their children and that their parenting style was positive. Scores for 'verbosity' (i.e. parents' expressed disapproval and reproach of their child) were above the clinical cut-off point at all time points.

At all time points, there were high response rates (> 90% of all participants) to questions in the resource utilisation questionnaire relating to accommodation, education, hospital and community care, outpatient hospital appointments, ambulance use, accident and emergency attendance, and general practitioner appointments. Social worker or family support worker input was a notable area of resource use reported by families. Response rates were zero for questions about medication prescriptions and very low for questions concerning interactions with the criminal justice system.

Reflecting on their experiences of attending Young SMILES, parents ($n = 14$) generally expressed positive views – becoming more insightful about how their mental health affected their children. The intervention instilled a sense of hope for the future through recognition of the improvements that they had observed. Most were in favour of the group approach that facilitated the ability to communicate and connect with other parents in similar situations. Parents' narratives acknowledged that, post intervention, children demonstrated specific improvements in well-being and behaviour, and in their knowledge about parental mental illness.

Young SMILES was viewed by the children ($n = 17$) as an enabling environment. Their initial fears about fitting in and being accepted by the group were alleviated by the fact that all the children in the trial were facing similar circumstances linked to parental mental illness. The peer group environment reduced the children's feelings of isolation and increased their perceived ability to help themselves, more so than in other one-to-one support mechanisms (e.g. with a social worker), or in day-to-day interactions with peers who do not have experience of parental mental illness.

The facilitators ($n = 16$) regarded Young SMILES as a meaningful and distinctive intervention with great potential to fill a critical gap in current services. The intervention drew on existing skills and underlying philosophies, but individuals not experienced in working with children and adolescents living with serious parental mental illness or working in groups needed more supervision to fill gaps in their knowledge and perceived ability to deliver the intervention.

The interviews with individual referrers ($n = 5$) indicated that barriers to referring families to the study did not relate to the intervention itself or to how the intervention fitted within current working service models. Instead, referrers were uneasy with the research process having to impose inclusion/exclusion criteria and randomisation, because once the families gathered interest in participating, they were disappointed if they were not eligible or were allocated to usual care.

Conclusions

Providing mental health services is expensive, mostly because of the ongoing cost of training and employing clinical staff to deliver such services. Young SMILES is a non-clinical intervention, as the majority of children and adolescents living with serious parental mental illness do not have mental health problems. A much broader public health approach potentially can use Young SMILES as a targeted preventative intervention to mitigate risk factors associated with reduced quality of life in these young people.

Any future randomised controlled trial should be preceded by a pilot with clear progression criteria. It also needs to focus on recruiting eligible families via screening of clinical caseloads in NHS services and by communicating with clinicians who look after ill parents. Stratification by the child's sex and age is necessary to reduce imbalances at baseline. Preparatory work with referrers and practitioners prior to recruitment can address their misgivings about randomisation.

Health-related quality of life may not be sensitive to the needs of children and adolescents living with parental severe mental illness. Future studies should consider child-centred outcome measures that are more likely to capture change in individual risk factors for poorer quality of life and unmet needs, rather than in an aggregate construct of health-related quality of life overall. Mental health literacy outcomes, such as knowledge about mental illness, help-seeking and coping strategies, need to include relevant family context for children and adolescents living with serious parental mental illness. Parenting sessions and outcomes need to include a more personalised needs-based approach centred on parent experiences. Additional methods of collecting child resource utilisation data, such as medical records, need to supplement the standard parent proxy-report questionnaire.

Trial registration

This trial is registered as ISRCTN36865046.

Funding

This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 24, No. 59. See the NIHR Journals Library website for further project information.

Health Technology Assessment

HTA/HTA TAR

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 14/29/01. The contractual start date was in January 2016. The draft report began editorial review in March 2019 and was accepted for publication in March 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.

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 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 John Norrie Chair in Medical Statistics, University of Edinburgh, 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

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