ISRCTN36865046 https://doi.org/10.1186/ISRCTN36865046

Young SMILES: An intervention to help children and adolescents with mentally ill parents

Submission date	Recruitment status	[X] Prospectively registered
17/12/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/12/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/11/2020	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

Many children grow up with a parent who at some point suffers from a mental illness. Most of these parents experience mild, short-term illnesses that are easily treatable; however, some parental mental illness is severe and longs-standing. Studies have shown that children living, or in regular contact with a parent with a severe mental illness, such as schizophrenia or bipolar disorder, can be vulnerable to maltreatment, neglect and stigma. These children are at risk of developing mental health or behavioural problems themselves, leading to a poor quality of life. Since late 2011, the NSPCC has been providing and evaluating a programme called “Family SMILES” which aims to boost these children’s self-esteem, enhance the parents’ protective ability and improve the parent-child relationships. This 3-year study builds on the NSPCC’s Family SMILES programme to produce an enhanced intervention, called Young SMILES, so that it has a broader reach for children of different ages and needs, aims to yield specific benefits for the children’s health and functioning, and can be flexibly delivered within and outside NHS services.

Who can participate?

Families whose children aged 6-16 have at least 10 hrs per week contact with a seriously mentally ill parent/carer, and all siblings and their parents/carers (those who are mentally ill and those who are well).

What does the study involve?

A maximum of 60 families, who have been assessed at their home and agreed to participate in the project, are randomly allocated to either access Young SMILES or to continue with whatever usual care they are receiving at the time. In Young SMILES, children attend weekly group sessions for eight weeks, and parents participate in five sessions starting at week four of the children’s sessions. Usual care varies over time in different locations depending on the family’s needs and available services. The specifics of what “usual care” means for each family at different time points is monitored and recorded. All families are visited at home by a researcher or can attend a community venue after three months to complete questionnaires about their health and functioning and to have an interview about their experiences. Some families are also invited to have visits after six and 12 months depending on whether they join the project early enough for questionnaires to be completed by the end of the project.

What are the possible benefits and risks of participating?
The NSPCC's recent evaluation of Family SMILES highlighted the following potential benefits: for children, increased social functioning and confidence, reduced social isolation and reduced blame associated with parental illness; for parents, less distress and unhappiness, shift of thinking from own need to children's needs; for families, more relaxed atmosphere, openness about parental mental health, empathy between child and parent, shared responsibilities. There are no direct risks from taking part in the study; however, talking about past experiences or about difficulties within the family may cause distress to some participants.

Where is the study run from?
1. Northumberland Tyne & Wear NHS Foundation Trust, St Nicholas Hospital, Newcastle upon Tyne (UK)
2. Barnardo's Newcastle (UK)
3. NSPCC Warrington (UK)
4. NSPCC Coventry (UK)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
National Institute for Health Research (UK)

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A community-based intervention to improve health-related quality of life in children and adolescents of parents with serious mental illness: Feasibility study

Acronym
YoungSMILES

Study objectives
The aim of this study is to develop and evaluate a community-based standardised intervention that will improve the Health Related Quality of Life (HRQoL) of Children and Adolescents of Parents with Severe Mental Illness (CAPRI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. North West - Greater Manchester East Research Ethics Committee, 13/04/2016, ref: 16/NW /0207
2. East of England - Cambridge South Research Ethics Committee, 30/05/2017, ref: 17/EE/0175

Study design
Feasibility randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Children who have parents with serious mental illness e.g. schizophrenia, bipolar disorder

Interventions
Following consent to participate, families are randomly allocated to one of two groups.

Intervention group: The proposed intervention, called YoungSMILES (Simplifying Mental Illness + Life Enhancement Skills), is based on the NSPCC's manualised Family SMILES. Children and young people attend 8 weekly group sessions lasting for approximately 2 hours after school on weekdays. Sessions are facilitated by two trained practitioners and follow a specific session format:
1. "Ice-breaker" activities and links to previous sessions: recap of main learning points and discussion of any questions from the previous session.
2. Checking in: How have things been? Anyone need individual time at end to talk over a particular problem that has arisen?
3. Setting the agenda and objectives for the session: The facilitators will set out the session's aims e.g. today we aim to learn about managing a crisis: who we can contact in a crisis; how to manage our feelings of fear in times of uncertainty; what to do when we think our parent is going into crisis etc, etc. The facilitators will then elicit the group members' ideas about what

they would like to learn or achieve during the session, or anxieties about the session.
4. Carrying out specific activities including presentation of educational information via flip charts /drawing activities for younger kids; videos, play, creative writing, case studies, scenarios and discussions, to meet the learning objectives of the session.
5. “Wrapping-up” with feedback on the session, recap of the main learning points, questions and agreeing on activities to be done between sessions.
6. Snack time with parents/other group members in communal space before going home.
Parallel work for parents is offered. Group sessions will be offered starting at week 4 of the children’s sessions.

Control group: Families continue to receive any usual care. Usual care will not be standard but will vary depending on the needs of the parents/children/families and may change over time and across different localities.

Research staff will conduct face-to-face semi-structured interviews and collect outcome measures at baseline (randomisation) and post-randomisation at months 3 (primary follow-up), 6 and 12. We shall test the feasibility of 6- and 12-month follow-up (post-randomisation) for those participants completing the intervention early enough to allow for data collection up to month 30 (at least 32 and 12 families with 6- and 12-month follow-ups respectively).

Intervention Type
Mixed

Primary outcome(s)
1. Child psychopathology and prosocial behaviour is measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, 3, 6 and 12 months
2. Symptoms of common mental health problems are captured using the Revised Child Anxiety and Depression Scale (RCADS) at baseline, 3, 6 and 12 months
3. Health related quality of life (HRQoL) is measured using The Pediatric Quality of Life Inventory (PEDQL) and KIDSCREEN questionnaire at baseline, 3, 6 and 12 months
4. Parenting competencies are assessed using the Arnold-O’Leary Parenting Scale at baseline, 3, 6 and 12 months
5. The degree and cause of stress in a parent-child relationship is measured using the Parenting Stress Index/Short Form at baseline, 3, 6 and 12 months
6. Children’s knowledge and perceptions about serious mental illness (mental health literacy) is measured using the Mental Health Literacy Questionnaire (MHLq) with follow-up questions at baseline, 3, 6 and 12 months
7. Resource use will be assessed using the Child and Adolescent Service Use Schedule (CA-SUS) at baseline, 3, 6 and 12 months
8. Incremental health gain in quality-adjusted life years (QALYs) is estimated using the Child Health Utility 9D (CHU-9D) at baseline, 3, 6 and 12 months
9. Qualitative evaluation of the intervention is completed through interviews and focus groups with children, parents and practitioners at 3 months

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/12/2018

Eligibility

Key inclusion criteria

Children:
1. Children aged between 6 and 16 years with parents diagnosed with serious mental illness
2. Have at least 10 hours contact with the parent/carer with serious mental illness. (The children do not necessarily have to live with a mentally ill parent)
3. The children have some awareness of the parent's mental illness, confirmed by the parent and /or the appropriate care coordinator. If the children have no awareness of the parent's illness, it will be discussed how the parent and care coordinator can prepare the children before they start group work.

Parents:
1. Parents/carers with serious mental illness and their partners who may or may not have any mental health problems. The focus of our project is the children and their outcomes, rather than the parents. Therefore, we do not intend to carry out full clinical interviews with the parents and report diagnostic codes. We shall accept the primary and secondary diagnoses reported by a key health professional, such as the GP, care coordinator and key worker, as most of these parents are likely to receive secondary care or be monitored in primary care. This can be gleaned during referral into the study or, in the case of a self-referral by the parent, we shall obtain the diagnosis by contacting the parent's appropriate care coordinator, e.g. GP or CPN, following the parent's permission to do so.
2. The parents/carers/guardians understand the purpose and remit of the intervention for themselves and their children and consent to their child's attendance and completion of outcome measures and interviews.

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Children:
1. Children of parents diagnosed with common mental health problems (e.g. mild-moderate depression) or with primary substance misuse, rather than with a serious mental illness as defined in the inclusion criterion 1 above
2. The children have significant cognitive impairment or a learning disability or major mental illness or behavioural problems (as verified by their GP or other health professionals involved in the family's care) which will make it impossible or unsafe for them to participate in group work
3. The children have already participated in Family SMILES (which is not applicable in the North East where Family SMILES is not available)

Parents:
The parent is extremely unwell at the time of eligibility assessment, which makes it difficult or unsafe for them to participate in group or individual work.

Date of first enrolment
01/06/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northumberland Tyne & Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
Barnardo's Newcastle Young Peoples Support Team & Newcastle Young Carers Team
4th Floor, Arden House
Regent Centre
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3LZ

Study participating centre
NSPCC
Warrington Service Centre
Peace Drive
Warrington
United Kingdom
WA5 1HQ

Study participating centre
NSPCC
Coventry Service Centre
76 Whitefriars Lane
Coventry

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CV1 2DS

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	17/11/2020	Yes	No
Protocol article	protocol	11/10/2018	08/04/2020	Yes	No

HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes