**HTA 14/29/01**

**STUDY PROTOCOL**

Full title: A Community-Based Intervention to Improve Health-Related Quality of Life in Children and adolescents of Parents with Serious Mental Illness: Feasibility Study

Short title: Young SMILES: An intervention for children with mentally ill parents

## 1. SUMMARY OF RESEARCH STUDY

This 3-year project will develop and evaluate a standardised community-based intervention to improve health-related quality of life (HRQoL) in **C**hildren and **A**dolescents Of **P**a**R**ents with Mental **I**llness (CAPRI). In phase 1 (months 1-9), the research team and relevant stakeholders have co-produced a manualised intervention for 6-16 year olds and their parents, called Young SMILES, and the associated training materials for professionals who will support it. This intervention enhances and extends the NSPCC's existing intervention Family SMILES, which is available in few parts of the UK for 8-13 year olds. In phase 2 (months 10-30), a feasibility Randomised Controlled Trial (RCT) will compare Young SMILES added to usual care with usual care alone for 60 families. The RCT will monitor rates of trial recruitment, follow-up and withdrawals, alongside rates of intervention uptake and engagement for Young SMILES compared to usual care (which could be NHS services or no intervention). The feasibility trial will determine optimal child-reported outcomes of HRQoL and resource utilisation/costing methodologies. Phase 3 (months 31-36) will be dedicated to data analysis and reporting of the study's findings, updating the intervention materials and training resources in light of the findings, and preparing a protocol for a definitive RCT (should the findings warrant it).

We shall use two standardised child-rated questionnaires to measure child HRQoL: the PEDQOL (Calaminus et al, 2000) and the KIDSCREEN (Ravens-Sieberer et al, 2007). Both measures have been validated for our population's age group (6-16 yrs) and show sensitivity to change in quality of life domains such as physical/ mental/ emotional health and social/school functioning. Outcome measures will include the Strengths and Difficulties Questionnaire (SDQ, Goodman et al, 2000), which is routinely used by IAPT-CYP and NSPCC services, and the Revised Child Anxiety and Depression Scale (RCADS, Chorpita et al, 2005). We shall use the Mental Health Literacy Questionnaire (MHLq) (Campos et al, 2014; 2016) to assess the children's knowledge and perceptions about serious mental illness (mental health literacy) and their problem-solving skills We shall measure parenting skills and child-parent relationships using the Arnold-O'Leary parenting scale (Arnold et, 1993) and the Parenting Stress Index Short Form (Abidin, 1979). To inform a future economic evaluation, we shall use the CHU-9D (Stevens, 2012), which has been validated for children aged 7-17, to estimate incremental health gain in quality-adjusted life years (QALYs). Resource use will be assessed using a modified version of the Child and Adolescent Service Use Schedule designed in previous research (Byford et al, 2007) and has been revised for the purpose of the current trial. At baseline we will additionally ask the parent or carer and the child to complete a demographic questionnaire. A qualitative evaluation of the intervention draws upon discussion groups and individual interviews (depending on participant preference) with children, parents and practitioners at 4 months (primary end point) to evaluate their experiences and elicit their perspectives on what factors may hinder or enable the intervention's implementation.

This project was funded by the National Institute for Health Research HTA programme (14/29/01).
The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health.

## 2. BACKGROUND

Up to 65% of adults with SMI live with children/adolescents under 18 (Royal College of Psychiatrists, 2010). Parental SMI is associated with greater offspring risk of poorer mental and physical health, behavioural, social and educational difficulties, and maltreatment and neglect (Diggins, 2011). Longer-term effects extend into adulthood and include increased risk of psychiatric morbidity, socio-occupational dysfunction, alcohol or substance misuse and premature death (Stanley, 2003). The problems arise not only because parents with serious mental illness find it difficult to manage their role as carers, but also because they are often living in highly deprived circumstances and have the ongoing stressor of the children being potentially or actually moved to out-of-home care (Park, Solomon, Mandell, 2006).

We have completed the most comprehensive review to-date of available interventions to improve the quality of life in CAPRI (Bee et al 2014). We concluded that there is a significant lack of reliable/robust evidence to support the effectiveness of any current interventions for CAPRI, especially in the UK's NHS. Integrated care for CAPRI is complex because NHS adult mental health, CAMHS, social care and child protection services are located and managed separately. Added to this, many children and adolescents may not identify themselves as having a "need" for an intervention and may understandably fear stigmatisation by a "mental health service". The main challenge is in knowing when and how best to intervene with vulnerable children and families, and to demonstrate effectiveness, cost-effectiveness and the potential for non-stigmatising and non-threatening delivery of specific interventions for these children. Interventions should be placed in the context of mental health promotion, mental illness prevention or early intervention, but most importantly, must capture priorities that are considered important by the children and young people themselves. Based on children's feedback from our extensive consultation work, such interventions should focus on improving coping and mental health literacy and should be evaluated using measures that capture these children's specific needs (Bee et al, 2013).

Our proposal fits well with the European Union's recent Child and Adolescent Mental Health in Enlarged Europe CAMHEE initiative (Braddick et al, 2009; CAMHEE, 2014) to enhance evidence-based service development for CAPRI. It is also timely alongside the UK government's recent initiative to transform Children and Young People's NHS services via the Improving Access to Psychological Therapies for Children and Young People (IAPT-CYP) Programme (http://www.cypiapt.org). The IAPT-CYP programme aims to improve collaborative care, upskill the workforce involved in the care of children and young people and reinforce evidence-based practice and robust outcome monitoring in routine services. Our research will respond to the CAMHEE initiative and contribute to IAPT-CYP by developing an evidence-based intervention, establishing sensitive and meaningful outcomes for assessing its value, facilitating links between health and social care and training practitioners to support the intervention.

Several UK policy initiatives offer perspectives on children's QoL. These policies include the Every Child Matters agenda in England and Wales (Department of Children, Schools and Families, 2008), the Children's and Young People's Strategy in Northern Ireland (Macdonald et al, 2011) and the 'Getting it Right for Every Child' approach in Scotland (Scottish Government, 2009). Five broad QoL domains are shared between these initiatives and are highlighted within the current agenda for children and young people as: (1) health, (2) safety, (3) economic well-being, (4) enjoyment and achievement and (5) positive societal contribution.

Since late 2011, the NSPCC has been providing and evaluating an intervention called Family SMILES (Simplifying Mental Illness + Life Enhancement Skills) for families with mentally ill parents, especially (but not exclusively) where children were assessed as at-risk of abuse or neglect. Family SMILES aims to boost the children's self-esteem, enhance the parent's protective ability and improve the parent-child relationship in children aged 8-13 years. The NSPCC's preliminary evaluation of Family SMILES was a single-group pre-post-test measurement of change on self-reported outcomes of strengths and difficulties, self-esteem and child abuse risk. There is significant potential for this intervention to be extended, enhanced and manualised to achieve a much broader reach (both geographical and in terms of children's ages and needs) in the context of the NHS and with a focus on enhancing the children's quality of life (QoL). A future evaluation of this extended, enhanced and manualised intervention needs to include a comparison group, measures of quality of life, family functioning/relationships and resource use/costs and a consistent and rigorous method of data collection and analysis.

**3. RATIONALE**

Our recent HTA-funded systematic review (Bee et al, 2014) of interventions to enhance health-related quality of life (HRQoL) in CAPRI found only 3 trials relating to parents with serious mental illness (SMI) (cfd. 26 trials for parents with mild-moderate depression), all of which were conducted in the US over 20 years ago. Most interventions related to new mothers and focussed on parenting in perinatal samples. No economic evaluations and no reported outcomes for children's HRQoL or emotional wellbeing were found. We concluded that further work is required urgently to improve HRQoL and wellbeing in school-aged CAPRI by developing age-appropriate child-centred interventions and evaluating their feasibility, acceptability and cost-effectiveness.

Our proposed research will take place concurrently with the Improving Access to Psychological Therapies for Children and Young People (IAPT-CYP) Programme (http://www.cypiapt.org), which has been creating a workforce of practitioners who are perfectly placed to deliver Young SMILES in the community. In keeping with the ethos of IAPT-CYP, our research aims to work towards better integration between health and social care, upskill the workforce involved in the care of children and young people, and embed evidence-based practice and robust outcome monitoring in routine services.

Our project is also timely in view of the NSPCC's recent evaluation of Family SMILES (NSPCC, 2014) which highlighted the following potential benefits: (a) for children: increased social functioning and confidence, reduced social isolation and reduced blame associated with parental illness; (b) for parents: less distress and unhappiness, shift of thinking from own need to children's needs; (c) for families: more relaxed atmosphere, openness about parental mental health, empathy between child and parent, shared responsibilities. The project will make the most of the NSPCC's commitment and impetus to scale up provision of Family SMILES and related interventions by supporting the training and supervision of staff working with this population in the NHS and third-sector organisations.

The importance of this research for the NHS falls under the following areas:

1. EARLY INTERVENTION: We target children from the earliest point at which we can engage them in the delivery of an intervention independently of their parents and we can collect child-reported outcomes on quality of life. Early intervention in the context of our study and from a life-course

perspective relates less to the age of the children and more to the identification and management of early warning signals in these vulnerable children and young people which can escalate to major health problems and poor quality of life.

2. MENTAL HEALTH PROMOTION AND ILLNESS PREVENTION: CAPRI currently receive support/care only if child protection needs or childhood mental health or behavioural problems are identified. This research aims to maintain or improve wellbeing and functioning and to reduce risks associated with childhood illness and poor quality of life. Similarly, the intervention aims to reduce risk of social disability by enhancing the children's coping skills and the parents' protective function. Helping children become more resilient and the family become a more self-caring than self-destructive environment has the potential to reduced health and social care utilisation.

3. WORKFORCE & SERVICE DEVELOPMENT: Currently, CMHT staff work with seriously mentally ill parents, but not with their children. By contrast, CAMHS practitioners work with families only once their children develop mental health or behavioural problems. This research will promote joint work between child and adult services and support the ethos of developing proactive and preventative, rather than reactive, children and young people's services. In doing so it aims to promote improving links between health, education and social care services. We intend to contribute to the upskilling of the workforce providing NHS services to children and young people and to establish a standardised training and supervision program for staff to deliver the intervention in various settings and contexts. A qualitative process evaluation running alongside the feasibility trial will explore barriers and enablers of implementing the intervention at the interface of different services.

4. INTEGRATED CARE: In the absence of recognised child protection or mental health needs, these children and adolescents can fall between health and social care and between adult and children's services. These children's and families' needs can be complex and may be best met by multiple providers: NHS, non-NHS, health, education and social care services. Our research is important and unique as it explores the feasibility of strengthening connections between health, education and social care, adult and children services, NHS and non-NHS health service providers. Working with the NSPCC to provide the intervention in one of our research sites will act as a case study of delivering this intervention for the NHS through third sector partners.

5. STIGMA AND IMPROVED MENTAL HEALTH LITERACY: The intervention will help children and adolescents develop a better understanding of their parents' mental illness. These young people can feel stigmatised by other people's attitudes and responses towards them and their families. This can be compound by their own misconceptions or lack of knowledge about mental illness and their self-perception of being different, vulnerable or unable to cope. Providing children with the skills to find high quality information, improving their understanding about mental illness, reinforcing their ability to cope and sense of self-worth, and strengthening their internal and external support systems, will help them overcome internalised stigma and be more resilient to external stigmatising attitudes they or their families regularly face.

**4. AIMS AND OBJECTIVES**

The aim of our study is to develop and evaluate a community-based standardised intervention that will improve the Health Related Quality of Life (HRQoL) of CAPRI.

Our objectives are to:

a. Randomise children and adolescents and their parents to the intervention or treatment as usual pathways in a wait-list control design
b. Estimate uptake, intervention adherence and retention to follow-up rates in an RCT comparing the intervention with usual care.
c. Determine which child/adolescent self-completed outcome measures are able to capture the effects of the intervention over time, especially in the primary outcome measures identified as important by the stakeholders.
d. Obtain estimates of intervention effects and measures of variability on the selected outcome measures to inform sample size calculations for a definitive trial.
e. To optimise and pilot a data collection tool to capture the most relevant aspects of family's resource utilisation (including Young SMILES) over time.

**5. STUDY DESIGN**

The study includes: (a) quantitative methods (questionnaires with categorical, ordinal and continuous data) to assess the direction of the effects of the intervention in support of a definitive trial; and (b) qualitative methods (discussion groups and individual interviews) to evaluate parents', children's and practitioners' experiences of the intervention

In phase 1 (months 1-15), relevant stakeholders, including children and adolescents, parents, and practitioners (including those in managerial roles), were invited to participate in discussion groups and give individual interviews in order to co-produce Young SMILES. We offered children and adolescents the opportunity to take part in an individual interview if they wished to take part but preferred not to join a discussion group with other children. Consent was taken from all participants prior to the discussion group/interview commencing. Parents were asked to consent to their child or adolescent taking part. Participants were asked to complete a short demographic questionnaire at the beginning of the discussion (separate questionnaires were developed for each stakeholder group). Discussion groups and individual interviews were held at a convenient community location for the participants. Travel expenses were reimbursed and refreshments were provided.

14 children and adolescents, 7 parents and 31 practitioners (including 7 in managerial roles) took part. Participants were recruited via third sector services (NSPCC, Barnardo's) and the NHS (practitioners only). Some had direct experience of Family SMILES (6 children and adolescents; 10 practitioners). Interviews and focus groups were audio recorded or notes were taken and data was analysed using thematic analysis (Braun and Clarke, 2006). Key themes were identified and comparisons between participant groups identified. A stakeholder synthesis day involving practitioners, academics and managers representing third sector and NHS services attended. Half were non-trial team members. During the day the findings of the consultations with stakeholders was presented and any tensions between views were identified. A matrix was used to map out aspects of the Young SMILES intervention such as aims, content, location, delivery methods, content and activities. Where differing views existed these were discussed in groups to gain consensus.

Following the synthesis day a small group of the study members met to finalise the Young SMILES intervention guidance and produce supporting training materials. Prior to the commencement of Phase II, NSPCC staff and NHS practitioners will complete two days of training to be able to deliver Young SMILES and support our participating families.

In phase 2 (months 16-33), a feasibility Randomised Controlled Trial (RCT) will compare Young SMILES added to usual care against usual care alone. Individuals involved in Phase II will be different to those involved in the Phase I. Participants will be invited to a telephone or face-to-face eligibility screen following: a) completion of a consent-to-contact form (given to the participants via the

recruiting gatekeepers) or b) direct contact with the research team by telephone or email or c) following verbal consent to a practitioner (in which case the practitioner fills in a confirmation of consent to contact form and emails/posts it to the research team). If a participant meets the eligibility screen, the researcher will give further details of the trial, send information leaflets and a consent form by post and offer them a face-to-face appointment (either in the clinical site or the patient's own home). At the face to face interview, consent and baseline measures will be taken.

Following agreement to participate via written consent and completion of baseline outcome measures, will randomise 60 families on a 1:1 ratio either to Young SMILES or to usual care. Randomisation lists have been stratified by age group (6-11/12-16) and site (Coventry/Newcastle/ Warrington), to give 6 separate lists. These were prepared by an independent statistician and sent to the study co-ordinator to maintain blinding and allocation concealment of the trial statistician and research team. Each list was drawn up using randomised permuted blocks of size 2 and 4 for a total of 20 participants per list using online randomisation software (www.randomization.com).

To expedite start of intervention groups at sites where recruitment has been slow, we will randomise families on a 2:1 ratio (2 Young SMILES; 1 control). Additional randomisation lists stratified by age group and site will be prepared using the same online software by an independent statistician and sent to the study co-ordinator.

We aim to run a minimum of 3 sets of child and adolescent groups and 3 parallel parent groups over the three recruitment sites (NSPCC Warrington, NSPCC Coventry and Northumberland Tyne & Wear NHS Foundation Trust/Barnardo's Newcastle co-delivery) during the recruitment period. We shall offer the parenting element of the intervention to both the "ill" and the "well" parent /carer (if they both wish to participate), and we shall offer the child and adolescent-centred work to all eligible children within each family. (NB. We will only include in the analysis the data from an 'index' child or adolescent and the "ill" parent/carer; we have elaborated on this under the "Data Analysis" section).

In phase 3 (months 32-36), we shall analyse, write-up and disseminate the study's findings and the protocol for a full scale future RCT and begin developing the design of a future RCT if warranted by our findings.

## 6. INTERVENTIONS

### 6. 1. Young SMILES

The new intervention is called Young SMILES (Simplifying Mental Illness + Life Enhancement Skills) as it is based on the NSPCC's manualised Family SMILES (NSPCC, 2014) (see appended sample of workbook). Details of the content and delivery mode of Young SMILES have been finalised during consultation and development in Phase I through co-production with stakeholders. Like Family SMILES, the intervention comprises 8 group sessions for children and adolescents in 2 age-banded groups: 6-11 and 12-16 year olds. Sessions take place weekly over a 3 month period at NHS, NSPCC and other community venues. During our stakeholder consultation phase, we have determined areas of life that children have told us are important to improve through our intervention and how the intervention should be modified and delivered for different age groups.

Parallel work for parents is also offered in Young SMILES. In Family SMILES parents are offered individual sessions at their own home, whereas in Kidstime (Cooklin et al 2012) parents attend group sessions in parallel to the children's group sessions. Young SMILES offers 5 parallel group sessions to

parents. The main reason is that we believe that a group format is likely to ensure that we end up with an intervention that is feasible and where costs would be acceptable to commissioners and providers in the NHS. However, we recognise that in the evaluation of the NSPCC's Family SMILES parents reported that they saw individual support as an important part of the programme, with particular benefit to being able to work at their pace. Therefore, during the consultation process in Phase I, we have considered stakeholder opinion on group vs. individual work for parents, so that the parent element of our intervention is acceptable to the participating families and supporting practitioners, as well as remaining feasible and sustainable for long-term NHS delivery.
Each child or adolescent age-banded group session lasts 2 hours and is held either during or after school on weekdays. Sessions end with a round up when parents and kids get together to have some food and socialise.

Sessions will be facilitated by two trained practitioners. A typical session format is as follows:

- "Ice-breaker" activities and links to previous sessions: recap of main learning points and discussion of any questions from the previous session.
- Checking in: How have things been? Anyone need individual time at end to talk over a particular problem that has arisen?
- 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. 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.
- 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.
- "Wrapping-up" with feedback on the session, recap of the main learning points, questions and agreeing on activities to be done between sessions.
- Let's go for something to eat with parents/other group members in communal space before going home.

We have created a 'tool kit' of resources for practitioners to use. These are a combination of physical resources and therapeutic/communication techniques e.g. photo and word 'libraries' to facilitate children and adolescents to express themselves; 'mind mapping'; 'diamond nines'; agree-disagree and other physical activities.,.

Below is the group work format for Young SMILES which has been informed by our Phase I consultation and adapted from Family SMILES by the research team. Further details are provided in the Young SMILES programme guidance document.

CHILD AND ADOLESCENT GROUP-WORK

| Session | Desired Outcomes for children |
|---|---|
| Week 1<br>**Welcome to Young SMILES** | 1) Develop an understanding of why attending the group<br>2) Agree group rules and begin to develop a positive relationship with the facilitators<br>3) Agree a lexicon/vocabulary to be used in the group<br>4) Develop an understanding of the variances of family make-up<br>5) Begin to share family information safely |
| Week 2<br>**All about me** | 1) Begin to understand who they are and what they mean to others<br>2) Begin to understand that we all have apart to play and that some are better at some things than others<br>3) Be able to identify what they are good at<br>4) Begin to understand that enjoyment doesn't require the ability to excel |
| Week 3<br>**What happens in my family** | 1) Develop an understanding of the impact of mental illness on my family<br>2) Develop a better understanding of mental illness<br>3) Develop a better understanding of mental illness related behaviours and how they are seen by others<br>4) Will be able to identify the relevant professionals involved in the family's care and their roles |
| Week 4<br>**Things we worry about** | 1) Develop an ability to name and deal with feelings<br>2) Identify sources of stress and anxiety (what makes them scared/ worried/ upset and how that might be manifest as shyness or anger etc.<br>3) Develop understanding of healthy and unhealthy responses to the things they feel |
| Week 5<br>**Our world** | 1) Recognising key sources of stress that they experience<br>2) Begin to recognise what feels safe/unsafe /healthy/unhealthy<br>3) Develop understanding of self-care and coping strategies<br>4) Begin to understand what help them feel good/ Identify the building blocks needed to make a foundation for feeling good<br>5) |
| Week 6<br>**Where do I go when I need help** | 1) Develop an insight into obstacles to communication within the family and identified possible solutions<br>2) Identify support networks<br>3) Begin to develop problem solving skills<br>4) Know how to access help when who how where. Identify professionals roles who can help me: e.g. what is my teacher for other than teaching? |
| Week 7<br>**Enjoying being me** | 1) Understand their strengths and things they are good at |

| | |
|---|---|
| | 2) Begin to understand how to recognise and maximise opportunities<br>3) Learn to discriminate between things thy are able to shape and things that are very aspirational<br>4) Identifying building blocks for the future |
| Week 8<br>**Moving on Together** | 1) Celebrate progress<br>2) Review learning from the group<br>3) Plan for the future<br>4) Consolidating relationships |

PARENT GROUP-WORK

Commences at week 4 of children's group work

| **Session** | **Desired Outcomes for Parents** |
|---|---|
| Week 1<br>**Welcome to Young SMILES** | Develop an understanding of why attending the group<br>Agree group rules and begin to develop a positive relationship with the facilitators<br>Agree a lexicon/vocabulary to be used in the group<br>Develop an understanding of the variances of family make-up<br>Begin to share family information safely |
| Week 2<br>**What your children worry about** | Identify sources of stress and anxiety in their children (what makes them scared/ worried/ upset and how that might be manifest as shyness or anger etc.<br>Develop understanding of healthy and unhealthy responses to how their children feel |
| Week 3<br>**How to support our children** | Recognising key sources of stress that they experience<br>Begin to recognise what feels safe/unsafe /healthy/unhealthy<br>Develop understanding of self-care and coping strategies<br>Begin to understand what help them feel good/ Identify the building blocks needed to make a foundation for feeling good |
| Week 4<br>**Talking with our children** | Develop an insight into obstacles to communication within the family and identify possible solutions<br>Identify support networks<br>Begin to develop problem solving skills<br>Know how to access help when who how where Identify professionals roles who can help me: e.g. what is my teacher for other than teaching? |
| Week 5<br>**Moving on together** | Identifying building blocks for the family's future<br>Celebrate progress<br>Review learning from the group<br>Plan for the future<br>Consolidating relationships |

**6.2. Usual Care**

Usual care is not standard across the different services involved in the trial. It also varies depending on the needs of the parents/young person/families and may change over time and across different localities. We will record and monitor what "usual care" means for each family.

## 7. PARTICIPANTS

Our population are families in which parents have been diagnosed with severe and enduring mental illness (schizophrenia/psychosis, bipolar affective disorder and severe depression or personality disorder) and in which children or adolescents live or have contact with the ill parent/carer for at least 10 hours per week. The proposed sample size of 60 randomised families (30 per group as recommended for pilot studies by Lancaster, Dodd & Williamson, 2004) is adequate to facilitate the main aims of the study, such as establishing feasibility and informing a future power calculation. Formal power calculations are not appropriate for this study which is primarily aimed at establishing feasibility.

### 7.1. Recruitment

The majority of current referrals to Family SMILES come from children's services (51%). Health services (including CAMHS and Adult Mental Health) currently provide 12% of referrals. Education services provide 10% of referrals. Our aim is to maintain but broaden this diversity of referral sources by working closely with NHS practitioners and services. The project's Research Associates (RAs) and Clinical Studies Officers (CSOs) from NIHR's Clinical Research Network (CRN) North East and North Cumbria use the following recruitment pathways:

- Community Mental Health Teams and Inpatient Teams to identify parents already known to be in receipt of care. Patients in inpatient units and rehabilitation units are approached by their key workers to participate in the study when stable.
- CAMHS/CYPS services to identify children who have parents with SMI.
- Posters and flyers in the NHS and Third sector organisations.
- Referral directly from professionals during opportunistic consultations/visits.
- Referral from Third sector and charitable organisations (e.g. Barnardo's, YoungMinds).

Recruiting gatekeepers will provide potential families with a study information pack including an invitation letter, information sheet and a consent to contact form. The information pack has been generated during Phase I in consultation with stakeholders. Different packs, containing the same information, are given to parents and children/young people. The participant information sheet provides details of the trial, the Young SMILES intervention and the parents' and young person's potential involvement. If a parent or young person is interested in the study, they are asked to complete the consent-to-contact form and return it in a freepost envelope or email it directly to the research team. Following completion of a consent-to-contact form, potential participating families will be invited to a telephone or face-to-face eligibility screen. The eligibility screen will be adapted according to whether it is the child/young person or the parent who contacts the research team.

For a parent we will elicit information about:
a) whether it is themselves or the other parent that experience mental health problems and what type of mental health problems they or the other parent have been diagnosed with,
b) how many children or adolescents they have and how old they are,
c) whether the ill parent lives with their child or adolescent, and if not, how many hours contact they have with their ill parent;
d) whether they are aware that their parent is experiencing mental health problems and
e) whether they would be able to attend group sessions with other parents who may or may not have mental health problems and whether their child or adolescent will be able to attend group sessions with others.
f) whether they would be happy for us to approach one or more of their children or adolescents to ask them to participate in the study.

For children/young people we will elicit information about:
a) how old they are
b) what type of mental health problems their parents have, and if they do not know the diagnosis, what sort of things they notice in their parent's behaviour when they are unwell.
c) whether they have any siblings and how old their siblings are,
d) whether they live with their parents and if not, how often they see them and for how long.
e) whether they would be able to participate in group sessions with other young people whose parents also have a serious mental illness.
f) whether they would be happy for us to approach one or both their parents to ask them to participate in the study.

If a family meets the eligibility screen, the researcher will give further details of the trial, send information leaflets and a consent form by post and offer them a face–to-face appointment (either in the clinical site or the patient's own home). At the face to face interview, consent and baseline measures will be taken.

Following agreement to participate via written consent, we will randomise 60 families either to Young SMILES or to usual care. Half of the families will receive the Young SMILES intervention alongside usual care and half will receive usual care alone. We shall offer the parenting element of the intervention to both the "ill" and the "well" parent /carer (if they both wish to participate), and we shall offer the child-centred work to all eligible children and adolescents within each family.

The participating families' general practitioners and relevant care coordinators (if available) will be informed of their taking part in the RCT via a letter.

We are estimating the yield and cost from different referral pathways and the proportion of participants successfully randomised from each. This indicates the most effective recruitment methods for a subsequent full-scale RCT.

We are alert to the fact that working with hard-to-reach families with complex needs can be challenging. We have already had discussions throughout Phase I with service user representatives, practitioners and managers to understand what factors may hinder or facilitate successful delivery of this research. Some eligible families may not take part in the trial because of perceived stigma or misconceptions (e.g. if social care practitioners or the NSPCC is involved, it may mean that I am a bad parent or they may take away my children) or because of attitudes/preferences against research or against the proposed intervention (e.g. group work, having to complete questionnaires, randomisation to 'no intervention'). To improve trial recruitment, we will explore the effect of these preferences (and researchers' responses to them) on trial participation rates, and where necessary identify or develop new strategies to improve or sustain recruitment.

Another factor which may influence retention pre-randomisation is the potentially long lead-in time from participant expression-of-interest to participant randomisation. To minimise attrition, we shall maintain monthly contact with families by phone/email or face-to-face depending on preference. We shall also encourage the families to contact us if they need any information or to raise any concerns before randomisation.

### 7.2. Inclusion Criteria

1. Children and adolescents aged 6-16 years with serious parental mental illness.
2. Parents/carers with a 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 adolescents and their outcomes, rather than the parents. Therefore, we do not intend to carry out full clinical interviews with the parents or 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 professional 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.
3. Children and adolescents must have at least 10 hours of contact with the parent/carer with serious mental illness. (The child/ adolescent does not have to live with a mentally ill parent necessarily).
4. The parents/carers/guardians understand the purpose and remit of the intervention for themselves and their child/ adolescent and consent to their attendance and completion of outcome measures and interviews.
5. Children/ adolescents must have some awareness of the parent's mental illness, confirmed by the parent and/or the appropriate care coordinator. If they have no awareness of the parent's illness, we discuss how the parent and care coordinator can prepare the children/ adolescents before they start group work.

### 7.3. Exclusion Criteria

1. Children/ adolescents 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/adolescents 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 makes it impossible or unsafe for them to participate in group work.
3. 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. (It is acknowledged that these children/adolescents may be those especially in need of support and therefore this will be judged on a case-by case basis by experienced practitioners).
4. The children/adolescents have already participated in Family SMILES (which is not applicable in the North East where Family SMILES is not available).

## 8. SETTING/CONTEXT

The study will take place in two different service settings. i. a Third Sector organisation (the NSPCC); ii. within NHS services. The intervention is primarily supported by practitioners who have completed relevant training (e.g. the Improving Access to Psychological Therapies Children and Young People (IAPT-CYP) Programme or Family Therapy or Cognitive Behaviour Therapy or Social Work or Nursing) and have experience working with children/adolescents, young people and families. Supporting practitioners work for the NHS or the Third Sector (e.g. Barnardo's, NSPCC). NHS CYP services routinely offer interventions to children and young people who have emerging or diagnosable

mental health or behavioural problems and the NSPCC is often associated with children who are at risk of maltreatment. This research offers Young SMILES to all children and young people/adolescents, including those without risk or without emerging or diagnosable health or social problems. Group sessions as part of the Young SMILES intervention will be offered in a range of community settings and assessments mostly take place in the family's home.

**9. TRAINING AND SUPERVISION OF PRACTITIONERS SUPPORTING THE INTERVENTION**

Practitioners will receive two days training delivered by experienced members of the study team. The training will provide information about the context of the study and will use a variety of training methods to familiarise attendees with the Young SMILES intervention content and delivery methods, including role play. The training will be facilitated by the Young SMILES programme guidance document. Training will be developed so that it could be delivered independently of the research study in NHS and third sector settings should the intervention be implemented in other sites following exploration of feasibility and effectiveness.

Given the training will take place some months prior to the start of the delivery of the intervention top-up training will be provided to all practitioners prior to the initial group start date. Practitioners supporting children and adolescents and their parent using Young SMILES will receive supervision from experienced clinicians on the study team.

**10. DATA COLLECTION**

Research staff conduct face-to-face semi-structured interviews and collect outcome measures at baseline (randomisation) and post-randomisation at months 4 (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).

We use two standardised questionnaires to measure child HRQoL: the PEDQOL (Calaminus et al, 2000) and the KIDSCREEN (Ravens-Sieberer et al, 2007). The PEDQOL covers 5-18 years age range, allows child and parent ratings to be collected and comprises 23 items capturing physical and emotional health and social and school functioning. The 52-item KIDSCREEN has been internationally validated with 8-18 year olds. It can be completed by either the child or their parent(s), and covers physical and psychological health, self-perception, autonomy, relationships, home life, social support, bullying/social acceptance and financial resources.

We include the Strengths and Difficulties Questionnaire (SDQ, Goodman et al, 2000) because it is the primary outcome measure routinely used by IAPT-CYP services, and has also been used as one of the main assessments in the NSPCC's Family SMILES evaluation. We include the Revised Child Anxiety and Depression Scale (RCADS, Chorpita et al, 2005), which is also used routinely by IAPT-CYP services, to capture symptoms of common mental health problems in children.

We shall use the Mental Health Literacy Questionnaire (MHLq) (Campos et al, 2014; 2016) to assess the children's improved knowledge and perceptions about serious mental illness (mental health literacy) and their problem-solving skills. These have been identified as important outcomes by the children themselves in the NSPCC's evaluation (NSPCC, 2014) and our recent systematic review (Bee et al, 2014).

To inform a future economic evaluation, we shall use the CHU-9D (Stevens, 2012), which has been validated for children aged 7-17, to estimate incremental health gain in quality-adjusted life years (QALYs). This measure is in addition to PEDQL and KIDSCREEN which do not have corresponding utility weights so they cannot be used to calculate QALYs.

We shall also use the Arnold-O'Leary parenting scale (Arnold et al, 1993) to assess parenting competencies (lower scores indicating more adaptive parenting strategies). It is a 30-item scale in which the over-reactivity and verbosity factors map onto potentially maltreating parenting styles. We shall include the Parenting Stress Index/Short Form (Abidin, 1979), a 36-item parent-rated questionnaire to measure the degree and cause of stress in a parent–child relationship. It includes three subscales; parental distress, parent-child dysfunctional interaction and difficult child. Both measures are useful benchmarks with other studies in the field.

Resource use will be assessed using the Child & Adolescent Service Use Schedule (CA-SUS) (Byford et al, 1999) which has been revised to collect information on receipt of care and services by each family in relation to children's needs and services from the NHS, social care, education, voluntary and third sector organisations. The cost of this resource use will be primarily calculated from the NHS and PSS perspective, with a secondary wider societal perspective estimate also calculated in light of the societal/community context of the intervention.

At baseline we will additionally ask the parent or carer and the child to complete a demographic questionnaire to collect data on age, gender, living situation, number of children in family, and parental SMI experienced.

Qualitative evaluation of the intervention will involve discussion groups and individual interviews (depending on participant preference) with children/adolescents, parents and practitioners at 4 months (primary end point) to evaluate their experiences and to understand what may hinder or enable the intervention's implementation.

## 11. DATA ANALYSIS

### 11.1. Statistical Analysis Plan

The main focus is on tabulated and associated graphical summaries of the key indicators of success of the study, including recruitment and participant flow. We shall report data in line with the CONSORT statement (ref). We shall also report the numbers of participants who drop out from the intervention, withdraw their consent and do not provide follow up outcome data. In order to inform a future definitive trial, we shall use standard linear regression to examine change in our HRQoL measures, PEDQOL and KIDSCREEN, adjusting for baseline scores and child's gender. The presentation of the analysis will focus on point estimates and associated 95% confidence intervals. After obtaining point estimates of intervention effect and measure of variability of the outcomes we will be able to design a definitive trial. If multiple children and parents are recruited from the same family, for the main analysis we will identify an index child and parent for inclusion in the analysis from whom data will be collected. Other sibling(s) will still be offered the opportunity to attend Young SMILES (if their family is randomised to the intervention group). Siblings will attend different groups. We shall ask parents to nominate the index child. We will discuss with parents which child should be 'nominated' as the index child. Parents will not be party to any data collected from this

child. Since outcome data is collected for all children and parents, in a secondary analysis we shall include all available data and use robust standard errors to account for clustering within families. Within-cluster variation due to the group intervention will be estimated for the main clinical outcomes in order to inform plausible intra-cluster correlations for sample size calculation of the main cluster RCT.

### 11.2. Economic Analysis

A prospective economic evaluation will be rehearsed to develop and refine methods for a subsequent definitive RCT. The main focus will be on how to accurately identify, quantify and value costs of delivering Young SMILES as an addition to usual care, and its potential resource implications for the NHS, versus usual care alone, during our follow-up period. The CA-SUS tool has been adapted for use in the context of Young SMILES to capture resource use accurately by families in relation to children's needs and services across the NHS, social care, and voluntary/ third sector organisations. We shall identify appropriate unit costs for each area of resource use. We shall obtain these unit costs from a combination of local and national sources and assess the feasibility of this measure for use in a future economic evaluation. The corresponding preference weights will be applied to CHU-9D scores to calculate quality-adjusted life years (QALYs) between baseline and follow-up. Completion rates of the questionnaire will be assessed, along with correlations with the primary and secondary outcome measures, and changes in these measures over time. We shall rehearse the methods to estimate an incremental cost-effectiveness ratio for Young SMILES plus usual care versus usual care alone, in terms of HRQoL years gained.

### 11.3. Qualitative Analysis Plan

All interviews will be recorded, transcribed verbatim and subject to framework analysis (Ritchie & Spencer 1994), a popular way of analysing primary qualitative data pertaining to health care practices with policy relevance (Dixon-Woods, 2011). Framework analysis permits both deductive and inductive coding, enabling potentially important themes or concepts which have been identified a priori to be combined with additional themes emerging de novo. Data coding will be undertaken independently by two researchers (one academic with qualitative expertise and one trained service user researcher), with regular meetings to ensure that the emerging codes remain grounded in the original data. The final coding framework and example codes will be presented to the wider research team and project advisory panel to confirm coherence and conceptual relevance.

## 12. DISSEMINATION AND PROJECTED OUTPUTS

Our plans for disseminating the findings of this feasibility study are detailed below.

We will aim to develop a dedicated website on the University of Manchester's server and other social media (e.g. Twitter and Facebook) to detail the work being undertaken. The website will be kept as a research tool throughout the life of the project with progress reports and recruitment advertisements. Upon completion, we shall partner with the NSPCC and seek additional funding to maintain the website as a free-to-access e-health information resource for children, parents/families and voluntary and statutory sector workers (Abel has done this previously). We shall also liaise with IT departments of mental health Trusts and primary care providers to incorporate the relevant resources into their websites.

We shall publish the results in a variety of high quality, peer reviewed, scientific journals for different professional groups including psychiatry, nursing, social work, psychology, psychotherapy and education. We shall present at national and international conferences for service users, non-governmental organisations, policy-makers and those responsible for service design and commissioning. We shall arrange a stakeholder conference to discuss our findings as well as publish a lay summary of findings on the website and through our partner networks in Young Carers, NSPCC and Mind.

We shall work with the NSPCC as part of our dissemination plan to draw up an open IP licence agreement which will enable the large-scale use of Young SMILES on a not-for-profit basis. This is an important pathway to research impact. We shall draw on Northumbria University's Research Impact Fund to maximise the reach of the research. We shall work with national and local service user groups and agencies, such as Rethink Mental Illness and Young Carers, to communicate the findings of our research, drawing on these organisations' existing partnerships and knowledge transfer programmes.

We shall approach universities and other organisations who offer training and development courses to professionals working with mentally ill people (such as social workers and community psychiatric nurses) so that they become aware of the intervention and explore the most appropriate ways of offering Young SMILES as optional skills training.

## 13. ETHICAL AND REGULATORY CONSIDERATIONS

### 13.1. Research Ethics Committee (REC) Reviews and Reports

We have sought the review and approval of the project's protocol and research materials from the NHS National Research Ethics Service (NRES) and from the Research and Governance Managers in Northumberland and Tyne and Wear (NTW) NHS Trust. Ethics approval for Phase I was obtained 13.4.16 (North West - Greater Manchester East Research Ethics Committee 16/NW/0207). Approval from the HRA experienced delays and was granted 3.8.16.

Separate ethics and research governance approval will be sought for Phases II and III. We shall comply with all practice and clinical governance standards within all the organisations involved in the trial to respond to the following possible clinical and ethical concerns:

• RISK: If the research team identifies a child as being at risk of maltreatment (including abuse and neglect) or if the parent appears at risk, either of harming themselves (and this risk has not been previously identified) or in other ways as a result of their mental state, we shall ask the parent/carer's and/or a competent child's permission that we liaise with the relevant support services (e.g. social care/child protection/mental health). If the level of risk warrants it, the research team will contact directly the relevant support services, having obtained informed consent from the participants before they entered the study, which will allows us to break confidentiality due to risk. If the family already receives support, or has a history of receiving support, from social care/child protection/mental health services, we shall ask the parent/carer to allow us to record the relevant details and we shall liaise with the relevant professional to inform them of the family's participation

in the study and notify them in the case of escalating risk for the child or parent. This will not affect the family's participation in the trial.

• ADVERSE EVENTS: We shall monitor any adverse events (e.g. distress, misunderstandings, deteriorating mental state) for the parents and the children receiving the intervention during their scheduled weekly group sessions facilitated by trained professionals. We shall encourage the participants to speak one-to-one with the professionals who facilitate the group sessions if the parents or children feel that they cannot discuss their issues in a group. If participants become distressed during the study, we shall offer additional support to them, the option to withdraw from the study, and onward referral to appropriate services.

• CONCURRENT RECEIPT OF OTHER INTERVENTIONS (E.G. MEDICATION) OR SERVICES: Participation in the trial will not preclude access to other services. If a child has a diagnosable mental health problem, such as anxiety or depression, then they will be offered access to normal care pathways (such as psychological therapy) and will still be able to continue with the study. Receipt of concurrent interventions during the study will be captured by our service use schedule, a questionnaire that gathers information about health and social care utilisation for use in the economic analysis.

• INFORMATION SHARING AND CONFIDENTIALITY: The study will involve two or more members from each family. For members of the family not involved in the study, no names or other personal identifiers (gender, age, occupation) will be elicited or asked about them from the researchers, unless the participants disclose serious concerns or mental state deterioration for the non-participating members of the family. In this case, the research team will either support the participating members of the family to seek appropriate help or we shall liaise with appropriate services with the participating family member' agreement. We shall help our participating families understand at the outset the distinction between giving personal information about their family members and giving general information about their mental health or other aspects of their life that may affect the children's quality of life.

**13.2. Patient and Public Involvement**

The NSPCC was involved as a stakeholder in the initial development and qualitative evaluation of Family SMILES for high risk CAPRI, from which the justification for the current proposal extends. We shall build on our existing collaborations developed from our previous projects to ensure user and carer representation from mental health and children's and young people's health services, (e.g. RETHINK, Young Minds, NSPCC) and other allied organisations (e.g. the MHRN's Young Person's Mental Health Advisory Group). We have strong links with existing PPI networks (such as the North West People in Research Forum) to support us in identifying patients and carers with lived experience of SMI to provide input over the lifetime of the project. To facilitate the engagement of children and adolecents/young people, separate panels will be established for young people and for parents, and for policy makers and professionals from children's health and social care services. Stakeholders will assist the project management by providing specific guidance and input as and where required (e.g. in refining intervention components or judgments).

Service user representatives are contributing to our study management and advisory panels and will continue to support the development of study documentation and preparation of publications and lay summaries of our findings for dissemination. Additionally, we shall offer service user

representatives formal training in interviewing techniques should they wish to conduct a proportion of the Phase 2 qualitative interviews. Service users acting in an advisory capacity will also contribute to the analysis of the interviews via independent verification of emergent themes to enhance the trustworthiness and credibility of our findings.

## 14. REFERENCES


Abidin, R.R. (1997) Parenting Stress Index: A measure of the parent–child system . In Zalaquett, CP. & Wood, R.J (Eds), Evaluating stress: A book of resources. Lanham, MD, US: Scarecrow Education, pp. 277-291.

Arnold DS, O'Leary SG, Wolff LS, Acker MM. (1993) The Parenting Scale: a measure of dysfunctional parenting in discipline situations. Psychological Assessment, 5: 137–44.

Bee P, Berzins K, Calam R, Pryjmachuk S, Abel KM. (2013) Defining quality of life in the children of parents with severe mental illness: a preliminary stakeholder-led model. PLoS One, 8(9):e73739.

Bee P, Bower P, Byford S, Churchill R, Calam R, Stallard P, Pryjmachuk S, Berzins K, Cary M, Wan M, Abel KM. (2014) The clinical effectiveness, cost-effectiveness and acceptability of community-based interventions aimed at improving or maintaining quality of life in children of parents with serious mental illness: a systematic review. Health Technology Assessment, 18(8), 1-250.

Braddick, F., Carral, V., Jenkins, R., & Jane-Llopis, E. (2009). Child and Adolescent Mental Health in Europe: Infrastructures, Policy and Programmes. Luxembourg: European Communities. URL: ec.europa.eu/health/mental_health/eu_compass/policy_recommendations_declarations/camhee_development.pdf (accessed 11/01/205)

Braun,V. & Clarke,V. (2006) Using thematic analysis in psychology. Qualitative Research

in Psychology 3, 77-101.

Byford S, Harrington RC, Torgerson D, Kerfoot M, Dyer E, Harrington V. et al. (1999) Cost-effectiveness analysis of a home-based social work intervention for children and adolescents who have deliberately poisoned themselves: the results of a randomized controlled trial, British Journal of Psychiatry, 174, 56–62.

Byford S, Barrett B, Roberts C, (2007) Cost-effectiveness of selective serotonin reuptake inhibitors and routine specialist care with and without cognitive behavioural therapy in adolescents with major depression. The British Journal of Psychiatry 191(6): 521–527. Google Scholar Medline

Calaminus G, Weinspach S, Teske C, et al. (2000) Quality of life in children and adolescents with cancer. First results of an evaluation of 49 patients with the PEDQOL questionnaire. Klin Padiatr, 212, 211–15.

CAMHEE (2014) Child and Adolescent Mental Health in Enlarged Europe: development of effective policies and practices (CAMHEE). http://www.uni-ulm.de/psychiatrieII/en_projects/camhee.htm (accessed 11/01/205)

Campos L, Dias P and Palha F. (2014) Finding Space to Mental Health1 - Promoting mental health in adolescents: Pilot study. Education and Health, 32(1), 23-29.

Campos L, Dias P and Palha F Duarte A and Veiga E. (2016) Development and Psychometric Properties of a New Questionnaire for Assessing Mental Health Literacy in Young People. Universitas Psychologica, 15(2), 61-72.

Carr, R. & Prakash, F. (2014) Evaluation of Family SMILES: Interim Report. NSPCC Evaluation Department, London. URL: http://www.nspcc.org.uk/globalassets/documents/evaluation--of-services/family-smiles-interim-report.pdf

Chorpita BF, Moffitt CE, Gray JA (2005) Psychometric properties of the Revised Child Anxiety and Depression Scale in a clinical sample. Behaviour Research and Therapy, 43, 309-322.

Cooklin A, Bishop P, Francis D, Fagin L, and Asen E (2012) The Kidstime workshops – A multi-family social intervention for the effects of parental mental illness: manual. CAMHS Publications, London.

Department of Children, Schools and Families (2008) Every Child Matters Outcomes Framework. URL: http://cw.routledge.com/textbooks/9780415485586/data/EveryChildMatters-OutcomesFramework.pdf (accessed 11/01/2015)

Diggins M (2011) Think Child, Think Parent, Think Family: a Guide to Parental Mental Health and Child Welfare. Social Care Institute for Excellence, London.

Dixon-Woods, M. (2011) Using framework-based synthesis for conducting reviews of qualitative studies BMC Medicine 9: 39.

Goodman R, Ford T, Simmons H, Gatward R, Meltzer H (2000) Using the Strengths and Difficulties Questionnaire (SDQ) to screen for child psychiatric disorders in a community sample. British Journal of Psychiatry, 177, 534-539.

IAPT & NHS (2015) Children & Young People's IAPT. http://www.cypiapt.org/ (accessed 11/01/2015)

Lancaster GA, Dodd S, Williamson PR. (2004) Design and analysis of pilot studies: recommendations for good practice. Journal of Evaluation in Clinical Practice, 10: 307-312

Macdonald G, Livingstone N, Davidson G, Sloan S, Fargas M, McSherry D. (2011) Improving the Mental Health of Northern Ireland's Children and Young People. Queens University, Belfast: Institute of Child Care Research;. URL: www.publichealth.hscni.net/sites/default/files/Children&YoungPeople.pdf (accessed 11 January 2015).

Park J, Solomon P, Mandell D (2006) Involvement in the child welfare system among mothers with serious mental illness. Psychiatric Services 57, 493–7.

Ravens-Sieberer U, Auquier P, Erhart M, et al. (2007) The KIDSCREEN-27 quality of life measure for children and adolescents—psychometric results from a crosscultural survey in 13 European countries. Quality of Life Research, 16, 1347–56.

Ritchie J., Spencer L. (1994) Qualitative data analysis for applied policy research. In Bryman A, Burgess RG (eds) Analyzing Qualitative Data. London: Routledge.

Royal College of Psychiatrists (2010) Parents as Patients: Supporting the Needs of Patients Who are Parents and Their Children. URL: www.rcpsych.ac.uk/publications/collegereports/cr/ cr164.aspx (accessed 26 April 2012).

SCIE (2011) Think child, think parent, think family: a guide to parental mental health and child welfare. Family & Children's Services Guide 30. Available: http://www.scie.org.uk/publications/guides/guide30/index.asp. Accessed 17 December 2012.

Scottish Government. (2009) Towards A Mentally Flourishing Scotland: Policy and Action Plan2009–2011. Edinburgh: Scottish Government.

Stanley N. (2003) Working on the interface: identifying professional responses to families with mental health and child-care needs. Health & Social Care in the Community, 11, 208–18.

Stevens K. (2012) Valuation of the Child Health Utility 9D Index. Pharmacoeconomics, 30(8), 729-747.

**TRIAL FLOW CHART**