A randomised controlled trial evaluating the effectiveness and cost effectiveness of 'Strengthening Families, Strengthening Communities': a community led parenting programme

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Abbreviations

CCA	Cost consequences analysis
CUA	Cost utility analysis
DMEC	Data monitoring and ethics committee
EAP	Economic analysis plan
ICC	Intra cluster correlation
MCS	Millennium Cohort Study
MRC	Medical Research Council
NIHR	National Institute for Health Research
PPI	Patient and public involvement
QALYs	Quality adjusted life years
RCT	Randomised controlled trial
REF	Race Equality Foundation
SAP	Statistical analysis plan
SDQ	Strengths and Difficulties Questionnaire
SFSC	Strengthening families, strengthening communities
TMG	Trial management group
TSC	Trial steering committee
WEMWBS	Warwick and Edinburgh Mental Well Being Scale

General information

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Protocol amendments

Version number	Date	Reason for amendment	Sections affected
Version 2	08/10/19	- Names and contact details updated for: Trial manager, TSC and DMEC - Clarify gender refers to parent in randomisation stratification - Further details added on the recruitment processes. - Secondary outcome measures updated. - Additional new information provided on the UCL indemnity and insurance arrangements - Further details added on role of TSC, DMEC and TMG	General information section and appendix 1 Randomisation section Selection and recruitment section Assessment and follow-up section Indemnity/insurance section Trial supervision and oversight section

		- Addition of information on safety procedures - References updated.	Safety procedure section Reference section
Version 3	10/01/2020	-Contents Page numbering updated -Approval signatures added -Wording of the last exclusion criterion amended -Blinding status of trial manager changed to not blinded -Wording of the Progression criteria to stage 2 amended -Changes to members of TSC reflected; DEMC amended to DMEC	Contents page section General Information section Inclusion/exclusion criterion section Table 1 Section 8. Internal Pilot Appendix 1

1. Study summaries – scientific and lay

Scientific Abstract

Background Between 10-20% of UK children experience socio-emotional difficulties which can have serious implications for themselves, their families and society. Stark socioeconomic and ethnic inequalities in children's well-being exist. Giving every child the best start in life is a key strategy to reduce inequalities. Supporting parents to develop effective parenting skills is an important preventive strategy. A range of group-based parenting programs have been delivered in the UK and evidence from recent reviews showed these can be effective. However most parenting interventions have focused on early childhood (0-5 years) and have failed to engage with families from ethnic minority groups and those living in poverty. A parenting programme for families with children aged up to 18 years (*Strengthening Families, Strengthening Communities - SFSC*) has been designed by the Race Equality Foundation, a charitable community organisation focused on promoting race equality, and has been delivered across the UK for over 10 years. Small pre-post studies have produced encouraging results but no RCTs have been undertaken so far. This study aims to address this knowledge gap.

Aim: To assess the effectiveness and cost-effectiveness of the *SFSC* parenting programme in enhancing parental mental well-being and children's social and emotional well-being at 6-months follow-up.

Design: This multi-centre waiting list control RCT will evaluate the *SFSC* programme. The study will be conducted in 2 stages. Participants will be randomly allocated to intervention or control arms. Stage 1 will comprise of a 6-month internal pilot to determine the feasibility of the trial. Should progression criteria be met, stage 2 will comprise the main trial. A nested process evaluation will also assess the fidelity and acceptability of the intervention.

Setting: The study will be conducted across 7 urban English areas with ethnically and socially diverse populations where the programme is currently being delivered. Participants (n=676) will be parents of children aged 3-18 years who either self-refer or are referred by education/social care/criminal justice professionals to attend the programme.

Intervention: Based on social learning theory, the 13-week programme aims to develop parents' confidence, competence and skills through interactive group based activities. Local authorities in the 7 areas will supply staff, community venues, resources and other costs associated with delivering the intervention through existing contracts. Participants randomised to the control arm will be offered the intervention after approximately a 9-10-month wait.

Outcomes: The primary outcome will be parental mental well-being (assessed by the Warwick-Edinburgh Mental Well-Being Scale). Secondary outcomes will include child socio-emotional well-being, parenting practices, family relationships, self-efficacy, quality of life, and community engagement. Outcomes will be assessed at baseline, post intervention, 3 and 6 months follow-up.

Potential impact: If this trial demonstrates beneficial effects on both parental and child outcomes, then the potential impact, both immediate and longer term, is potentially significant. As the intervention focuses in particular on supporting families living in

poverty and those from minority ethnic communities, the intervention should also ultimately have a beneficial impact on reducing health inequalities.

Lay summary

Aim*:* We aim to assess whether parents who are offered a 13-week group-based parenting programme will feel better in themselves, more in control of their lives and generally more able to cope with looking after their families. We will also assess if the programme has any effect on children's behaviour.

Background: Childhood is an important stage of life which has long lasting effects into adulthood. Unfortunately, many children in modern society experience emotional and behavioural problems which can lead to problems within their family, school and local communities. If these are not dealt with early on, they can get much worse and cause major difficulties for all those involved. Several parenting programmes have been developed and been shown to be helpful to parents and children. However most of these have focused on families with pre-school children, and children with very severe behaviour problems, and have not included many families from Black and ethnic minority groups, and those living in poverty. For over 10 years the Race Equality Foundation, a charity working to promote race equality in the UK, has been organising group-based parenting programmes for families with older children, particularly from minority ethnic communities and those living in poverty. This programme called *Strengthening Families, Strengthening Communities* has had major success in engaging with these communities across many parts of the country. Although very popular with the families involved, the programme has not yet been fully assessed to show if it is effective in achieving its goals. The Race Equality Foundation are very keen to address this gap in knowledge and have therefore initiated this study.

Design: Across 7 urban areas of England where ethnically and socially mixed communities live, the parenting programme will be offered to families who either decide themselves that they need help or families referred by professionals for help. 676 parents agreeing to take part in the study will be randomly allocated (like flipping a coin) to either immediately starting the programme or having to wait for a 10- month period before starting it. All the parents agreeing to take part in the study will be interviewed at the start, after the programme has been completed and then 6 months later. A smaller number of parents and staff involved in delivering the programme will be interviewed about their views and experiences of it.

Public involvement*:* Parenting is a potentially sensitive and stressful issue. It is therefore vitally important that the public are fully involved in a study which aims to assess the potential value of a parenting programme. A parent and former participant in the programme has agreed to be a co-applicant to assist the team in planning and conducting the study, to ensure parents' concerns and needs are considered. In addition, 3 parent forums comprising 8-12 parents will be established to provide additional input into all aspects of the study and 2 adolescent and young peoples' forum will also be set up to involve and explore the wider impact of the intervention.

Dissemination*:* Given the current high level of research, policy and media interest into the best ways of providing parenting support to families in need, the findings of this study are likely to get a high level of attention. The team will therefore take great care in ensuring that all interested parties including the families involved in the study and their local

communities are given information about the results. The PPI co-applicant and parent forums will assist with the dissemination.

2. Background

Between 10-20% of UK children and adolescents experience socio-emotional difficulties[1] which have serious implications for the individuals affected, their families and wider society. Parents are a fundamental influence on their child's development and well-being, and parental mental health has a profound effect on family life, relationships and parenting practices[2]. Data from the UK Millennium Cohort Study show that approximately a third of mothers (33%) and fathers (30%) reported depressive symptoms[3]. Stark socio-economic and ethnic inequalities exist for both socio-emotional difficulties in childhood and mental health problems in parents[4–8]. Consequently, giving every child the best start in life has been identified as a key public health strategy to combat health inequalities[5]. An important element of this strategy is supporting parents to develop effective parenting practices and skills. Four Cochrane reviews of universal and targeted group-based parenting programmes have demonstrated a variety of positive effects on both child and parental outcomes[9–12]. These reviews however highlighted the need for larger scale and well-designed trials that target older children and families from ethnic and socially disadvantaged backgrounds, and also include comprehensive economic evaluations.

Strengthening Families, Strengthening Communities (SFSC) is a group based parenting intervention designed to support parents with children aged 0-18 years from socially and ethnically diverse communities. SFSC has been delivered by community organisations across the country since 2000 with the support of the Race Equality Foundation. Several uncontrolled studies have evaluated the programme and demonstrated encouraging positive outcomes for both children and parents[13–17]. However to date no RCTs of the programme have been conducted, hence the need for this study. A trial evaluating SFSC will directly address the knowledge gaps identified in the Cochrane reviews of parenting interventions[9–12] - as a universal programme, it will focus on families with older children, specifically targeting families from ethnically and socially diverse communities.

Risks and benefits

There is a small risk that participation in the SFSC programme with open and frank discussion with other parents on family life, may potentially lead to feelings of inadequacy or guilt, cause a degree of stress and anxiety, and result in participants questioning their parenting skills and abilities. However the SFSC programme is delivered by highly trained and experienced practitioners supported by a well-developed quality assurance system that ensures participants are fully supported in the programme. Indeed the aim of the SFSC programme is to develop parents' self-esteem and their confidence and competence in parenting through empowerment and participation in interactive group methods and skills development techniques. These methods help to improve child-parent communication and relationships, and also improve access to local community groups and organisations that support families.

Rationale for current study

Although a range of parenting programmes including Triple P, Mellow Bumps, Family Nurse Partnership and Incredible Years are currently included in the NIHR research portfolio, all these programmes concentrate on early childhood and do not directly focus on meeting the needs of families from ethnically diverse communities. One NIHR funded trial to evaluate a parenting intervention for toddlers is currently underway, the E-SEE trial[18]. This trial is evaluating the Incredible Years Infant and Toddler (0-2 years)

Parenting Programme focusing exclusively on the 0-2 year age range. Another trial currently underway, the Strengthening Families Programme 10-14 UK (SFP 10-14 UK) is a Welsh study which aims to assess the effectiveness of a 7-week programme on preventing alcohol and drug misuse in young people[19]. This very specific intervention targets both parents and young people and is completely different in nature, methodology and focus from the SFSC programme, and there is no organisational connection between them.

Giving every child the best start in life is a key policy recommendation to reduce health and social inequalities[5]. Stark and persistent socio-economic and ethnic inequalities exist in the UK in both children's and parents' health and well-being. Supporting parents to develop effective parenting practices is an important core strategy to tackle inequalities in childhood and adolescence but major gaps remain in the evidence base for universal parenting programmes, especially for older children and families from disadvantaged and diverse ethnic backgrounds. This proposal to evaluate the SFSC programme therefore directly addresses ethnic and socio-economic inequalities.

Socio-economic position and health inequalities
A range of measures will be taken to ensure that the study conduct and intervention delivery take account of the socio-economic and ethnic background of participants. The study will be conducted in seven urban areas across England where the SFSC programme has successfully engaged with parents from disadvantaged socio-economic and very diverse ethnic backgrounds. Our pilot data has demonstrated the disadvantaged and ethnically diverse nature of parents recruited to the SFSC programme and the encouraging ways in which the programme is designed to empower parents through the development of a range of parenting skills and practices, and ways to access community resources and local support[14,15,20]. Our research team will be trained to ensure that they are fully equipped to communicate in an appropriate and accommodating manner when interacting with participants. Based upon experience of delivering the SFSC programmes over the last 10 years, although approximately 50% of parents recruited into the study will be from a minority ethnic group, the majority (approximately 90%) of SFSC programmes will be delivered in English to parents from a diverse range of ethnic backgrounds but who are able and comfortable speaking in English. Approximately 10% of participants will require language support as they will not be able to complete interviews in English. Somali, Sylheti, Bengali and Arabic are the most commonly spoken languages after English in our research sites. Building on the experience of one of the co-applicants (Butt) of conducting structured interviews in community languages in an ESRC funded study of ageing[21] we will use experienced community language interviewers to conduct these interviews with training in the use of translated versions of the research instruments.

Depending on the exact socio-demographic nature and diversity of the sample once the recruitment stage is completed, exploratory sub-group analysis will investigate different aspects of inequalities in the effectiveness of the intervention across the study population.

3. Aims and objectives

Study aim

To assess the effectiveness and cost-effectiveness of the SFSC programme in enhancing parental mental well-being and children's social and emotional well-being at 6-months follow up across 7 English urban areas.

Stage 1 objectives (internal pilot)

1. To establish that the engagement and recruitment plans are effective across 10 pilot clusters (5 programme clusters and 5 waitlist clusters)
2. To determine that the intervention uptake is satisfactory in terms of the proportion of participants attending the majority of the SFSC programme sessions
3. To assess the fidelity of the SFSC programme through facilitator self-assessments and independent quality assessment.
4. To establish the acceptability of the outcome measures

(See later section for a detailed description of the progression criteria to stage 2)

Stage 2 objectives (main trial)

1. To assess the effectiveness of the SFSC programme in enhancing parental mental well-being and children's social and emotional well-being compared to waiting list controls at 6-months follow-up
2. To examine the cost effectiveness of the SFSC programme
3. To assess in a nested process evaluation the SFSC programme fidelity and acceptability, and determine implementation barriers/facilitators

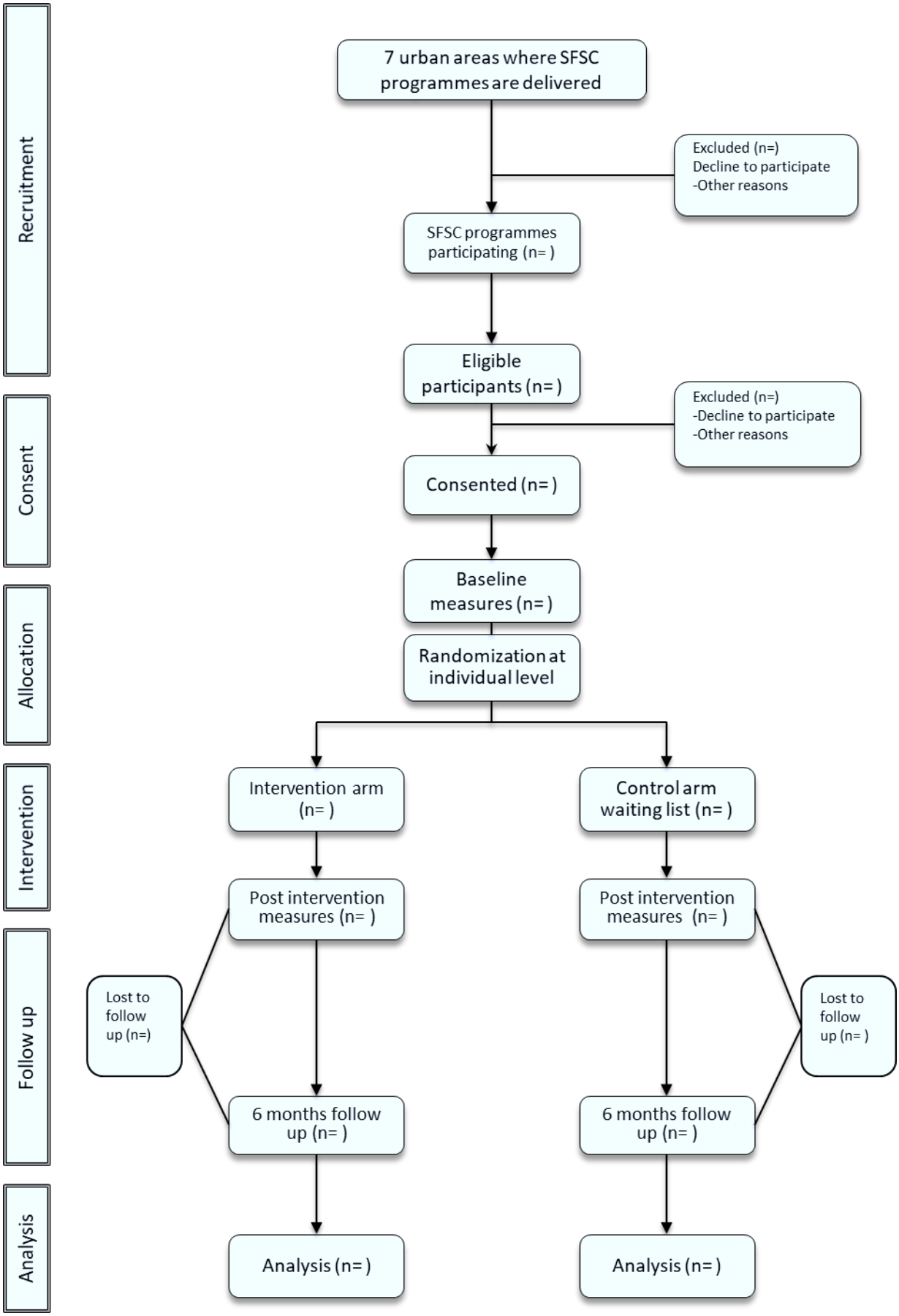
Research question (PICO)

In an ethnically diverse population of families with children aged 3-18 years living in socially disadvantaged areas across England (P), does the offer of the SFSC parenting programme (I) compared to waiting list controls (C) significantly enhance parental well-being and child social and emotional well-being (O), as measured by Warwick-Edinburgh Mental Well-Being Scale and Strengths and Difficulties Questionnaire?

4. Trial design

This study is a multi-centre, waiting list control, randomised trial designed to assess the effectiveness and cost effectiveness of SFSC programmes delivered across 7 urban areas in England. The study will be conducted in 2 stages. Stage 1 will comprise a 6-month internal pilot to determine the feasibility of the trial. Should progression criteria be met, stage 2 will comprise the main trial conducted over a 34-month period. A nested process evaluation will also assess the fidelity and acceptability of the intervention. See figure 1 for study flow chart.

Figure 1. Study flow chart



Study population

Study setting
The study will take place in community settings with various delivery agents of SFSC across 7 urban areas with ethnically diverse populations and high levels of deprivation. The areas have been selected as they are the locations where the SFSC intervention is currently commissioned and delivered. The delivery agents within these areas are usually Local Authorities or community organisations who have been commissioned by Local Authorities to deliver SFSC within a specific locality of the area.

The seven urban areas and Local Authority locations include:

- Greater Manchester (Manchester City)
- Yorkshire/Humberside (Calderdale; Hull; Kirklees)
- South London (Lewisham; Lambeth; Southwark; Wandsworth)
- North London (Islington; Brent; Enfield; Barnet)
- West London (Hammersmith and Fulham; Kensington and Chelsea; Ealing; Westminster)
- East London (Tower Hamlets; Waltham Forest; Hackney; Barking and Dagenham)
- Home counties (Luton; Hertfordshire)

Two additional areas (Bristol and Stockton) have been identified as potential reserves should recruitment problems arise in the above seven areas.

Study participants
The SFSC programme is designed to reach a wide range of parents with children aged up to 18 years, including both mothers and fathers, lone parents, families living in deprived neighbourhoods and parents from Black and minority ethnic communities. Parents attending the programme include self-referrals and those referred by social work, health, family support or criminal justice professionals.

Recent data (2014-2017)[20,22] collected by the Race Equality Foundation provide a profile of the diversity of participants attending SFSC programmes:

- Nearly 60% of programmes included both mothers and fathers
- Over 40% of participants were lone parents
- Around half (48%) of participants were from Black and minority ethnic communities
- Nearly 70% of participants' highest qualification was from secondary school

Inclusion/exclusion criteria
An important feature of the SFSC programme is its universal and inclusive nature.
Inclusion criteria include:

- Parents[1] with children aged 3-18 years

Exclusion criteria include:

- Parents with children under 3 years and over the age of 18 years

[1] Parents are defined as a person with parenting responsibilities for the index child including biological parents, step parents, foster parents and legal guardians. When more than one parent are attending the intervention programme they will be asked to agree the nominated parent for the study.

- Unable or unwilling to provide written informed consent to participate
- Already participating in another research study
- Parents where there is an active court proceeding relating to separation between parent and child

Methods used to protect against bias
Blinding procedures
Due to the nature of the intervention it is clearly not possible to undertake a double blind trial. However the researchers involved in conducting the research interviews will be blinded – all participants will be politely asked not to disclose their allocation to the data collectors at the start of all research interviews. The researchers will also complete a perception questionnaire once all the data has been collected to determine their perception of group allocation for each participant. The trial statisticians will remain blind while the study is in progress and while conducting the data analysis. The researchers involved in collecting the process evaluation data after the six months follow-up will not be blinded. Further details of the blinding procedures are outlined in table 1 below.

Table 1 – Overview of blinding procedures

Trial role	**Blinding status**	**Explanatory notes**
Chief investigator and co-applicants	Blinded	
Referral sources	Blinded	
Participants	Not blinded	
SFSC facilitators	Not blinded	
Researchers – outcome interviews	Blinded	
Researchers – process evaluation	Not blinded	
Trial manager	Not blinded	
Data entry	Blinded	
Data managers	Blinded	In certain circumstances (adherence and attendance at programmes) data maybe unblinded but this would be kept in separate section of database
Statisticians	Blinded during study and for main analysis	Not blinded for subsequent analysis as defined in the SAP
NWORTH IT developers	Not blinded	Will only have limited access to the unblinding codes and will require authorisation to access
DMEC	Blinded	DMEC will be presented with partially blinded reports and can ask for unblinding if required for safety concerns.

TSC	Blinded	TSC will not have access to the same level of data as DMEC but can request unblinding if concerns are raised.

Attrition bias

The experienced research team will use every effort to encourage participants to remain in the trial to reduce attrition bias and loss to follow-up. Having multiple mobile phone contact numbers for participants and their family members/close friends, use of their social media and ensuring researchers adopt a flexible and accommodating approach when agreeing appointments all have helped to minimise attrition in previous community studies. The sample size has accounted for 20% attrition.

Outcome measures

Primary outcome

Parental mental well-being: This is an important outcome in itself, as well as being a key determinant of child developmental outcomes[10]

Secondary outcomes

Key secondary outcome

Child socio-emotional well-being: This is an important contemporary marker of healthy development in childhood, while also being closely related to later life health and well-being[5]

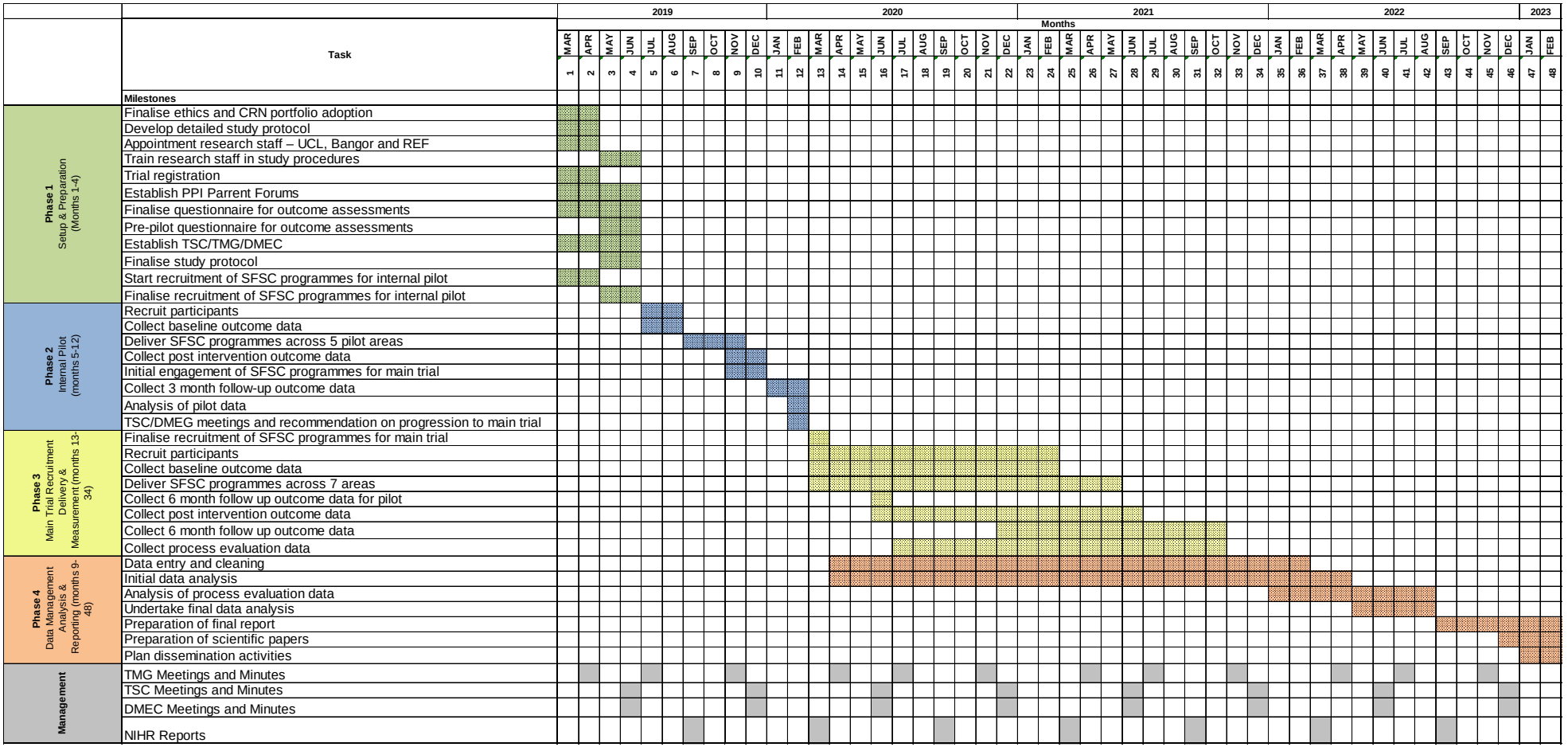
Other secondary outcomes

- Parenting practices (positive & negative, including use of harsh punishment)
- Self-efficacy
- Family relationships including family conflict
- Parental quality of life
- Community engagement and use of local services
- Use of NHS, social care, criminal justice system and mainstream/special education services.

5. Study Gantt chart and milestones

The trial will comprise four phases delivered across a total of 48 months as outlined in the Gantt chart (see figure 2 below).

Figure 2. Study Gantt chart



Milestones
Specific project milestones are outlined in table 2 (see below).

Table 2 – study milestones

Month	Milestones
Phase 1	Set up and preparation (months 1-4)
0-2	Finalise ethics and CRN portfolio adoption
0-2	Develop detailed study protocol
0-2	Appointment research staff – UCL, Bangor and REF
2-4	Train research staff in study procedures
0-2	Trial registration
0-4	Establish PPI parent forums
0-4	Finalise questionnaire for outcome assessments
2-4	Pre-pilot questionnaire for outcome assessments
0-4	Establish TSC/TMG/DMEC
2-4	Finalise study protocol
0-2	Start recruitment of SFSC programmes for internal pilot
2-4	Finalise recruitment of SFSC programmes for internal pilot
Phase 2	Internal pilot (months 5-12)
5-6	Recruit participants
5-6	Collect baseline outcome data
7-9	Deliver SFSC programmes across 5 pilot clusters
9-10	Collect post intervention outcome data
9-10	Initial engagement of SFSC programmes for main trial
11-12	Collect 3 month follow-up outcome data
12	Analysis of pilot data
12	TSC/DMEC meetings and recommendation on progression to main trial
Phase 3	Main trial recruitment, delivery and measurement (months 13-34)
13	Finalise recruitment of SFSC programmes for main trial
13-24	Recruit participants
13-24	Collect baseline outcome data
13-27	Deliver SFSC programmes across 7 areas
16	Collect 6 month follow-up outcome data for pilot
16-28	Collect post intervention outcome data
22-32	Collect 6 month follow-up outcome data
17-32	Collect process evaluation data
Phase 4	Data management, analysis and reporting (months 9-48)
14-36	Data entry and cleaning
14-38	Initial data analysis
35-42	Analysis of process evaluation data
39-42	Undertake final data analysis
43-48	Preparation of final report
46-48	Preparation of scientific papers
47-48	Plan dissemination activities

6. Selection, recruitment and withdrawal of participants

Participants (parents) enrolling on the SFSC programmes (n=52 clusters in total: 26 programme clusters and 26 waitlist controls) across the 7 areas will be approached to participate in the study, consent sought and agreed, baseline outcome data collected and then individually randomised to intervention or waiting list controls. Those randomised to the wait list control arm will be offered a place in a parenting programme or other parenting support once the 6-month follow-up data have been collected. Further details are now given on each step in the recruitment and consenting process.

Step 1 – Referral to SFSC programme

Parents attending the SFSC programme either self-refer or are referred by social work, family support or criminal justice professionals. In the SFSC programmes involved in the study, programme staff will initially give general information about the study, discuss what the study involves, provide a summary of the project, and for those individuals interested, gain their verbal consent for their contact details to be passed onto the research team or will arrange an initial face-to-face meeting with a researcher if preferred. A researcher will then contact the parent by phone or will meet the parent to verify their interest, to check their eligibility. , If interested, a face-to-face meeting is arranged either in their own home, a community venue or where the SFSC programme is delivered.

Step 2 - Research visit

During the face-to-face meeting the researcher will explain more details of the study, confirm eligibility, provide information sheet and obtain written informed consent. If a parent requires time to think about or discuss participation with friends/family, a period of 7 days will be proposed, after which the parent will receive another visit to establish if they wish to participate. Once consent has been gained, the baseline questionnaire interview will be completed and the participant will then be randomised. The parent will receive written confirmation of their allocation in the form of a letter and business card. Parents randomised to SFSC will be asked to select the programme they plan to attend and will be provided with a leaflet detailing the dates, venue and contact for the facilitators. All parents will then receive a debriefing leaflet outlining a list of national and local services on offer.

Step 3 – Commencement on SFSC programme

Those participants randomised to the programme will then immediately enrol on next programme available. Those randomised to the control arm will then be placed on 10-month wait list.

In recognition of the importance of establishing rapport and trust with the participants at the initial approach and consenting stage of the recruitment process, in the internal pilot we will assess the feasibility and acceptability of these initial steps being carried out by either the programme facilitators and researchers as outlined above, or solely by the programme facilitators. The programme facilitators will be trained in the consenting and data collection process. As part of the process evaluation individual interviews will be conducted with a sample of participants and programme facilitators to assess their views of the consenting process and other elements of the trial (See section 12 – process evaluation for further details).

Support for those whom English is not first language
The Race Equality Foundation estimates that approximately 10% of participants (n=70) will require language support to complete the recruitment, consenting and data collection procedures. Based upon previous experience in other studies undertaken with SFSC participants, community language interviewers fluent in either Somali, Sylheti, Bengali and Arabic (the most commonly spoken languages after English) will be employed to assist where language support is needed. The community language interviewers will receive training in the study procedures.

Incentives for participants and SFSC programmes
As a gesture of thanks, participants will receive a £10 gift voucher and study pen for each completed interview. Participants involved in any process evaluation interviews will also receive a £10 voucher. SFSC programmes involved in the study will receive a £250 voucher as a gesture of thanks. In addition the study team intend to apply for excess treatment costs from NIHR which will then be allocated to the programmes involved in the study.

Participant withdrawal
Participants can withdraw from the study at any point without needing to give any reason or explanation. If participants decide to withdraw from the study, this will not affect their ability to access and complete the SFSC programme. The study information sheets explain these details so that participants are fully aware of their right to withdraw should they desire to do so.

7. Randomisation

Randomisation will be via a secure online system using a sequentially randomised dynamic adaptive algorithm[23], stratified by site, gender (parent) and if self-referred or not. Once consent and baseline questionnaires have been completed then a member of the research team will log onto the online system provided by NWORTH and enter the required details. Upon confirmation of those details the participant will be randomised results can be provided on screen and via confirmation/notification emails as defined in the randomisation specification. This will be done with regard to the blinded status of the individuals.

8. Internal pilot (Stage 1)

Over a 6-month period the feasibility of the trial will be tested across 5 sites/SFSC programmes. The internal pilot will assess recruitment and randomisation procedures, and retention rates at 3 months follow-up. In addition, we will evaluate the acceptability of outcomes and intervention fidelity. Should the internal pilot progress to the full-scale trial, we will assess whether pilot data can be used in the main dataset.

Progression criteria to stage 2 (Main trial)

We propose to use the RAG progression criteria[24] to assess sufficient randomisation, retention and intervention attendance. The RAG progression criteria are a traffic light system of progression where *green* indicates direct progression, *amber* will require review of the situation with both the funder and the independent advisory groups (Trial Steering Committee and Data Management and Ethics Committee), and *red* will indicate termination of the study.

- Randomisation of 130 participants across 5 sites/programmes over the first 6 months. We will consider performance EITHER (a) across all 5 sites/programmes OR (b) if one or two sites/programmes significantly underperforms, across the best 4 or 3 sites/programmes. GREEN: there are 104 (a) or 84 (b) randomisations (80% of the target). AMBER: If there are 52 (a) or 42 (b) randomisations (between 40% and 80% of that expected). RED: If there are <52 (a) or <42 (b) randomisations (less than 40% recruitment)
- Retention: GREEN: 85% retention at 3 months follow-up (6 months from baseline). AMBER: Retention is between 50% and 85%. RED: If retention is less than 50% at 3 months follow up
- Attendance: GREEN: 70% of participants attended at least 9 out of the 13 programme sessions. AMBER: between 50% and 70% attended at least 9 out of the 13 programme sessions. RED: if less than 50% attended 9 out of the 13 programme sessions

In addition, before the progression to the main train, we will evaluate the acceptability of outcomes by assessing the completeness of data, as well as intervention fidelity.

Data completion: Less than 20% missing data on outcome measures at baseline and post intervention will indicate the acceptability of the measure to be continued into the full study

Intervention fidelity: Intervention fidelity will demonstrated through facilitator self-assessments and quality assessment.

Finally, ACCEPT criteria will be used to determine whether pilot data can be included in the main trial[25]. These criteria around the data will encompass areas such as the eligibility criteria, trial design, intervention fidelity, data quality and be in line with the RAG criteria outlined above. If significant protocol modifications are required, resulting in uncertainty, we will review recruitment targets on transition to full trial[25].

9. Sample size

A sample of 676 participants will be required to detect an effect size of 0.3 with 90% power at a 5% significance level and assuming an intraclass correlation coefficient (ICC) of 0.05. This assumes 26 clusters of 13 participants per cluster within the intervention arm (n=338) and n=338 recruited to the waiting list control arm.

The assumption of the ICC is indicated by Kidger and colleagues[26]. This sample includes an attrition rate of 20% indicating we expect 10 parents to complete per cluster from the 13 recruited. Although the cluster effect only applies to the intervention arm, due to concerns over differential dropout in the waiting list controls, recruitment to the control arm will be 'inflated'. The ICC assumption will be checked at the internal pilot stage and impact on the sample size considered.

An effect size of 0.3 on the WEMWBS is indicative of a change of 3 on the scale stated as clinically relevant by the scale manual[27] and assuming a standard deviation of 10 seen in a similar population[28].

For the total SDQ score for the key secondary outcome, a minimal clinically significant change indicated by Ford and colleagues[29] is 2, together with a SD of 6 taken from normative

data held by youthinmind[30] on the SDQ, this indicates an effect size of 0.33. If the ICC is assumed equivalent to that of the parental outcome then a sample of 676 indicates 87% power; with a reduced ICC of 0.025 this power increases to 92%.

10. Intervention

Intervention overview

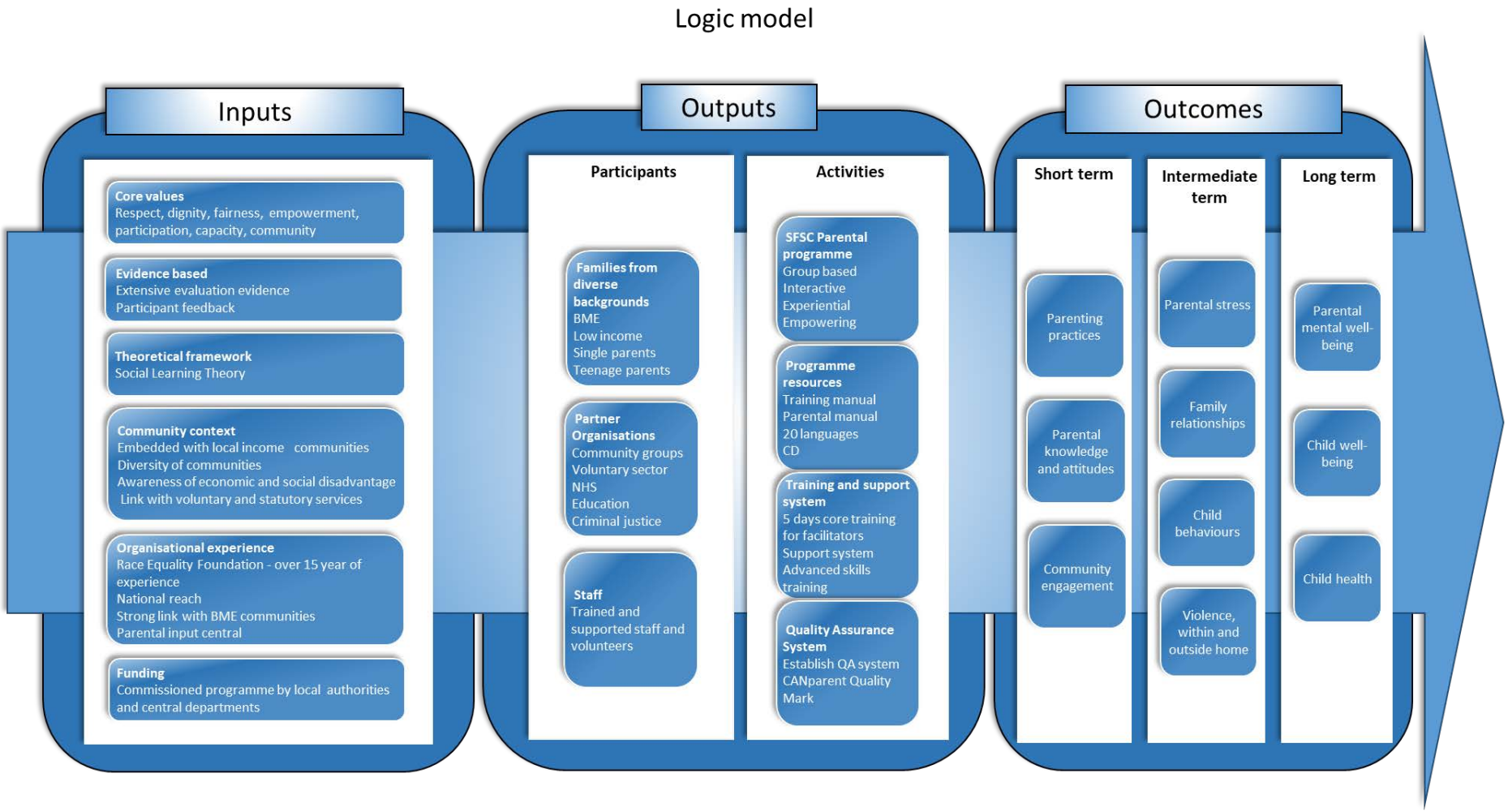
SFSC is a group based universal parenting programme designed to support parents with children aged up to 18 years to improve their well-being, confidence and competence in parenting; develop better relationships with their children; explore strategies to put appropriate boundaries in place; support their children to minimise risky behaviours; and help children transition through childhood to adulthood. In addition, it aims to empower parents to play a more active role in their local communities.

Originally developed in the US, the Race Equality Foundation (an independent charitable community organisation committed to race equality) has adapted the programme for the UK. Since 2000 it has been delivered by family and social care organisations across England. Based upon social learning theory [31], it uses interactive methods to encourage parents to share their experiences and undertake practical activities to develop their skills, confidence and self-esteem. The 13-week programme is structured into 5 themes:

- Rites of passage
- Cultural/spiritual influences on beliefs and behaviours
- Enhancing parent-child relationships
- Community involvement
- Process of discipline

A logic model has been developed to describe the intervention inputs, outputs and evaluation outcomes (short-term, intermediate and longer term) – see figure 3.

Figure 3. Study logic model



Intervention delivery
The programme is run in a wide variety of community settings and is delivered by trained practitioners. It is manualised to ensure implementation fidelity, is supported by an extensive quality assurance process and has received the CANparent Quality Mark[32] It has been successful in engaging with a diverse range of parents such as ethnic minority communities and those living in poverty, many of whom have felt marginalised or stigmatised by mainstream services. Evaluation has highlighted very positive feedback and high levels of user satisfaction. Retention rates at the end of programmes are typically very high at around 85%, and 93% attended the majority of the 13-weekly sessions.

Control group
The control arm of this trial will comprise a waiting list control – the participants randomised to the control arm will be offered a programme or other support after approximately 10 months to enable follow-up data to be collected. Waiting-list controls are a suitable option for the evaluation of group-based community interventions. Indeed in the Cochrane Review of group-based parenting programmes for children with early-onset conduct problems, all 13 trials that were deemed to be of sufficient quality had adopted this design[12]. All study participants in both trial arms will continue to have access to a full range of locally available health and social care services including referral to Child and Adolescent Mental Health Services (CAMHS). Details of local services will be given to participants when they have been randomised to the control arm.

11. Assessment and follow-up procedures

Outcome data will be collected at baseline (time point 0), end of programme (time point 3 months), 3 months follow-up (time point 6 months) and then 6 months follow-up (time point 9 months). The baseline data will be collected through face-to-face interviews and the subsequent interviews will either be conducted through face-to-face or telephone interviews depending upon the participants' preference. All selected measures are either validated instruments.

Primary outcome

- Parental mental well-being will be measured using the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)[33]. The WEMWBS covers both hedonic and eudaimonic aspects of mental health including positive affect, life satisfaction, satisfying interpersonal relationships and positive functioning. The WEMWBS has been widely used in the evaluation of parenting programmes including SFSC[28]. The psychometric properties of the WEMWBS have been demonstrated including good content validity, high levels of construct validity and good test-retest reliability[34]. The scale has also been shown to be a suitable instrument for detecting change in well-being status[35]. In a mixed methods study the instrument has undergone a comprehensive cross cultural evaluation and has been demonstrated to be a robust, reliable and acceptable measure of mental well-being in an ethnically diverse community sample[30]. The WEMWBS has been translated (including full back-translation) into a number of languages.

Secondary outcomes
Key secondary outcome

- Child socio-emotional well-being will be measured by the Strengths and Difficulties Questionnaire (SDQ) – parent report[36]. The Total Difficulties score will be used which includes 4 scales measuring: emotional symptoms; conduct problems; hyperactivity; and peer problems. There is also a pro-social scale to measure positive behaviours and an impact scale measuring the extent of impact of the child's difficulties on family, school and community. The SDQ has been extensively used in the evaluation of parenting interventions[12,35]. Psychometric testing of the SDQ has shown it to be a robust and valid instrument of children's socio-emotional well-being and behaviour[37]. In our pilot work evaluating the SFSC programme we have shown that the SDQ is a sensitive measure able to detect change in various child outcomes in a socially and ethnically diverse community sample of families[20,22]. The SDQ has also been extensively translated (including full back-translation) for use in a very wide range of languages.

Other secondary outcomes

- Self-efficacy – measured by the Pearlin scale[38]
- Parenting practices – measured by Multidimensional Assessment of Parenting Scale (MAPS)[39]
- Parent-child relationship – measured by Child-Parent Relationship Scale (short version)[40]
- Partner relationships - measured using the Quality of Marriage Index[41]
- Community cohesion – measured by the adapted Buckner scale[42]
- Health-related quality of life – measured by the EQ-5D-5L[43]
- Use of NHS, social care, criminal justice system and mainstream/special education services - measured using retrospective questionnaires, adapted from previous measures on the Database of Instruments for Resource Use Measurement (http://www.dirum.org/)

The length and general acceptability of the questionnaire will be assessed in a pre-pilot with a group of parents in phase 1 of the study. Should the questionnaire be considered too long, then revisions will be made to ensure that it is an acceptable length.

12. Process evaluation

In line with MRC guidelines[44,45], a nested mixed methods process evaluation will be undertaken. Specifically we propose:

(a) To describe implementation of the intervention assessing intervention fidelity to programme aims, methods, materials and ethos.
(b) Within the internal pilot we will support the effective implementation of the trial through the collection of quantitative programme activity data and a qualitative investigation of recruitment and randomisation processes and outcome assessment methods.
(c) Finally, within the context of the full trial we will develop and extend the procedures described above to focus the process evaluation on whether, and how, intervention delivery and outcome generation are influenced, either positively or negatively, by contextual factors.

Data collection

The process evaluation will have a mixed methods design. Quantitative components will run continuously through both the internal pilot and full trial phases. Notably we will collect the following data throughout:

- Routine data on programme recruitment, registration, referrals, attendance, retention and staffing. Client engagement – participation, reach, dose received (number of sessions attended), and retention rate (overall rates and in particular with reference to disadvantaged and ethnic diversity of sample) will also be recorded.
- Fidelity measure to be completed by staff delivering the programme at the end of each session and completion of programme
- Researcher observation of programme sessions (independent assessment of fidelity) in random sample of programmes delivered across the seven areas where programme is delivered

During the *Internal Pilot* we will conduct individual semi-structured qualitative interviews with staff and participants.

- Interviews (n=10) will also be conducted with participants (parents) who attended the SFSC programme across the five pilot areas to explore their perceptions and views of study procedures including recruitment, consenting, data collection and randomisation. The response of experimental and control group participants to their randomisation will be a key focus. We will also explore views on the SFSC programme delivery and content.
- Interviews (n=10) will be conducted with staff involved in delivering the programme across the five pilot areas to explore staff's perceptions and views of study procedures including recruitment, consenting, data collection and randomisation.

During the *Full Trial* qualitative data collection will be extended to include:

- Individual semi-structured key informant interviews will be held with lead commissioners (n=7) and SFSC programme coordinators (n=7) across each area.

During the full trial we will also continue to complete individual semi-structured interview staff and participants:

- Interviews (n=21) will be conducted with staff involved in delivering the programme across the seven areas.
- Interviews (n=20) will also be conducted with participants (parents). A purposive sample will be selected to ensure the participants represent range and diversity in terms of study centre, age of index child, ethnicity and other demographic characteristics. In addition parental comments from open questions contained within intervention evaluation forms will be assessed and summarised.

Analysis

Quantitative data on fidelity, engagement (attendance and retention) and service activity will be subject to descriptive analyses using SPSS. All the qualitative interviews will be audio recorded, professionally verbatim transcribed and subjected to a thematic analysis[46]. This will be supported by use off Nvivo and involve initial data organisation through coding, category development and then testing. Analysis will focus in particular on exploring the range of views on the relevance, appropriateness and acceptability of the programme, perceived barriers and facilitators to change in parenting approaches and how the programme helped or hindered this in the family environment.

In this way the process evaluation design will be informed by the a priori logic model (see figure) and will generate empirical data which will enable mechanisms of action to be described and the underlying theory of change to be evaluated. The work undertaken in parallel with the trial will support interpretation of trial outcome data, thereby increasing the explanatory potential of the study while also potentially informing strategies for downstream implementation of the intervention.

13. Statistical and economic analysis

Phase 1 – internal pilot

As the intention of the internal pilot is to identify continuation into full trial the analysis of the data at this point will be based around the criteria for progression. At this stage we would also assess the current ICC evident in the data to ensure that this is in line with what was predicted. An assessment of the impact of this on the required sample size will be completed at this stage.

If termination of the trial is indicated, then exploratory analysis of the data collected so far will be completed to provide as much information as possible from the work conducted. A plan will be drafted for this if required.

Phase 2 – main trial

A fully documented Statistical Analysis Plan (SAP) will be written and agreed by the co-applicants and the Data Monitoring and Ethics Committee (DMEC) before data collection has been completed.

Analysis will be conducted on an intention to treat basis, blind to treatment allocation. Baseline data will be presented descriptively by allocated group and overall. The main analysis for primary and secondary outcomes at 3 and 6 months, post intervention will be mixed effects models adjusted for baseline score, allocation group, and stratification variables. Site will be included as a random effect. The aim is to minimise missing data; however, predictors of missingness will be investigated using regression models and any predictors found will be considered for inclusion in the models. Multiple imputation will be employed to address missing scores where appropriate. Analysis of complete case data will be completed as a sensitivity analysis to establish the sensitivity of the treatment effect estimates to the missing data. All treatment effect estimates will be presented with 95% confidence intervals.

Additional regression analyses will explore factors associated with effectiveness. Exploratory analysis will initially look at including a measure of adherence within the models to assess the levels of effectiveness.

Economic evaluation
A fully documented Economic Analysis Plan (EAP) will be written and agreed by the co-applicants before data collection has been completed.

A prospective economic evaluation will be integrated into the trial. The economic evaluation will adhere to the recommendations of the NICE Public Health Reference Case[47]. The main analysis will take a public sector perspective; in sensitivity analyses we will also take a societal perspective. We will estimate cost and cost-effectiveness for the 'within-trial' period, evaluating cost-effectiveness using a cost-utility analysis (CUA) and cost-consequences analysis (CCA).

We will undertake a detailed cost analysis to estimate the costs of the delivering the SFSC programme, including: development and training of accredited providers; the cost of delivering the group sessions; participant monitoring activities; and; any, follow-up/management. Broader resource utilization over and above the costs of the SFSC programme will be captured via parent/carer questionnaires administered at baseline (time point 0), end of programme (time point 3 months), 3 months follow-up (time point 6 months) and then 6 months follow-up (time point 9-10 months). Resource use data will be collected on NHS, social care, criminal justice system, and education contacts. To facilitate analyses taking a societal perspective we will also collect direct costs to trial participants and families (e.g., travel costs to attend group sessions), informal care provided by family and friends, and productivity losses. Unit costs for public sector resources will largely be derived from local and national sources and estimated in line with best practice. Primary research using established accounting methods may also be required to estimate unit costs. Costs will be standardised to constant prices.

Outcomes for the economic evaluation will include WEMWBS (the primary outcome in the trial), the full range of secondary outcomes, and parent quality-adjusted life years (QALYs); all of these will be included in the CCA; the last of these will be used to undertake a CUA. For this, parent health-related quality of life, measured at baseline, end of programme and then 6 months later using the EuroQol EQ-5D-5L will be converted into health utilities using established utility algorithms to estimate QALYs [48]. Parent-specific utility profiles will be constructed assuming a straight line relation between each of the participant's EQ-5D scores at each follow-up point. The QALYs experienced from baseline to final follow-up days will be calculated as the area underneath this profile. We will calculate QALYs for all parents/carers involved in the study; we acknowledge that some families in the study will be single-parent families, but the proportion of single-parent families will be similar in both trial arms. We will not include child QALYs given that some children in the trial may be as young as three years of age and there are no validated health-related quality of life measures in young children.

Multiple imputation by chained equations will be used to deal with missing resource use and EQ-5D-5L values. Subsequent analyses of imputed data will include variance correction factors to account for additional variability introduced into parameter values as a result of the imputation process.

Cost-effectiveness in the CUA will be calculated as the mean cost difference between the SFSC programme versus control divided by the mean difference in QALYs to give the incremental cost-effectiveness ratio (ICER). We will undertake extensive sensitivity analyses. Non-parametric bootstrap estimation will be used to derive 95% confidence intervals for mean cost differences between the trial groups and to calculate 95% confidence intervals for incremental cost effectiveness ratios[49]. The bootstrap replications will also be used to construct a cost-effectiveness acceptability curve, which will show the probability the SFSC programme is cost-effective for different values of the public sector's willingness to pay for an additional QALY. A series of deterministic sensitivity analyses will explore the implications of uncertainty on the incremental cost-effectiveness ratios and will consider the broader issue of the generalisability of the results. One such analysis will adopt a societal perspective incorporating direct costs to trial participants and families, informal care provided by family and friends, and productivity losses.

14. Patient and Public Involvement (PPI)

Public involvement is essential in all stages of public health research. It is particularly important in the evaluation of complex interventions that seek to support and empower families living in challenging circumstances and from marginalised communities to further develop their parenting skills and abilities. Karlet Manning as a co-applicant has assisted the team in developing and refining this application based upon her experience as a parent and previous participant in the SFSC programme. In particular Karlet has provided very useful input and feedback on the practicalities of engaging and recruiting families into the proposed study and the accessibility and clarity of the study description in this application.

PPI plans

The PPI element of this study has 3 main strands. A PPI co-applicant (Karlet Manning) will join the trial management group (TMG) and provide input into all decisions taken by the research team across the full duration of the study. In addition, 3 PPI parent forums comprising of 8-12 previous users of the SFSC programme will be established in 3 of the study locations (South London, North London and Manchester). They will meet 3 times a year, facilitated by experienced members of the study team. One of the difficulties with working with PPI in deprived areas is that recruits may initially lack confidence and find it hard to contribute effectively. Each group will have an introductory training session designed to demonstrate how their input can ensure that the research is relevant, practical and to build their confidence in expressing their views. The PPI parent forums will provide invaluable input into all aspects of the study but in particular provide insights on:

- best ways of engaging with potential participants,
- recruitment strategies,

- formatting and design of outcome measures, and
- reporting and dissemination of study results.

In addition to the PPI parent forum, it is important to also involve and understand the views and perspectives of young people in the study. To address this important issue, two PPI adolescent and young peoples forums will be established in London and Manchester. These groups will comprise of adolescents and young people aged 14-18 years whose parent(s) previously attended a SFSC programme. The adolescent and young people's forums will particularly explore their views and perspectives of the SFSC programme and its perceived impact on their parent(s), family dynamics and their own behaviour and feelings.

15. Trial supervision and oversight

UCL will act as sponsor for the trial. Three committees will be established to oversee the supervision and governance of this trial:

- the Trial Steering Committee (TSC) will provide overall supervision for the trial on behalf of the sponsor/ funder. The ultimate decision concerning recommendations to the sponsor and the funder about the continuation of the trial lies with the TSC,
- the Data Monitoring and Ethics Committee (DMEC) is to review the accruing trial data and to assess whether there are any concerns about the safety of the intervention. DMEC is responsible for considering any newly published research data which might affect the trial, they may recommend to the Trial Steering Committee that the trial be stopped or amended if sufficient evidence emerges that the trial intervention is clearly indicted or contra-indicated.
- the Trial Management Group (TMG) is responsible for the day-to-day running and management of the trial and will meeting frequently during set up and subsequently on an agreed periodic basis once the trial is open to recruitment.

These committees will function in accordance with the Bangor CTU standard operating procedures. The TSC and DMEC will meet as a minimum on a 6-monthly basis and the TMG quarterly. Membership of the trial committees is listed in appendix 1.

16. Assessment of safety and safety reporting

The trial is designed and conducted to achieve what is considered to be ethical and best practice in research. The research involves a number of structured interviews and an assessment of mental wellbeing where it is possible that a participant may report high levels of distress. The study also involves the assessment of parenting practices that may raise concern about a child's safety/welfare. Processes relating to safeguarding issues are described in the 'Child safeguarding' and the 'Parental distress' Standard Operating Procedures (SOPs). A standard operating procedure for reporting Serious Adverse Events (SAE) describes the process to be followed and the reporting requirements if an SAE occurs during the trial. In addition, the research involves interviewing research participants in their own homes, or a community setting. Informed by UCL policy, a 'Lone Worker Protocol' outlines the steps that should be taken to ensure the safety of both the researcher and the

participant(s) involved and mitigate any risks when working off-site (i.e. outside of UCL premises).

17. Data handling and record keeping

A data management plan will be developed to document the process of data from source to statistician at which point the statistical analysis plan will describe details of the analysis.

18. Publication policy

The chief investigator and all co-applicants will prepare and agree a publication policy to agree on authorship of future papers and other outputs from the study.

19. Finance

The study is funded by the National Institute of Health Research (NIHR) Public Health Research (16/122/35) and a contract has been agreed between UCL and NIHR. Sub-contracts have also been agreed between UCL and the other partners including the Race Equality Foundation and Imperial College London, Bristol University, University of Bangor, Middlesex University and the University of Cambridge.

20. Ethics – approval procedures

Ethical approval for the study was given by the UCL Research Ethics Committee (reference 1538/002) on the 27th February 2019.

21. Indemnity/insurance

The Trial Sponsor, UCL insures the trial against the potential legal liability of the sponsor for harm to participants arising from the conduct and management of the trial.

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Appendices

Appendix 1

Trial Steering Committee (TSC):

- Professor John Wildman, Professor of Health Economics, University of Newcastle.
- Professor James Nazroo (Chair), Professor Sociology, University of Manchester.
- Jennifer Bostock, PPI Representative.
- Paul Levy-Adophy, PPI Representative.
- Dr Fiona Reid, Senior Lecturer in Medical Statistics, Kings College London.
- Professor Sarah Salway, Professor of Public Health, University of Sheffield.
- Pushpsen Joshi, JRO, UCLH, Sponsor.
- Meg Wiggins, UCL Institute of Education, UCL

Data Management and Ethics Committee (DMEC)

- Professor Chris McKevitt (Chair), Professor of Social Sciences and Health, Kings College London.
- Dr Sheena Ramsay, Senior Lecturer in Public Health, University of Newcastle.
- Dr Paul Bassett, Freelance statistical consultant.

Trial Management Group (TMG):

- Leandra Box
- Jabeer Butt
- Professor Mike Crawford
- Dr Anja Heilmann
- Dr Zoe Hoare
- Dr Saffron Karlsen
- Professor Yvonne Kelly
- Karlet Manning
- Dr Anita Mehay
- Professor Stephen Morris
- Professor Paul Ramchandani
- Renato Venturelli
- Dr Tim Weaver
- Professor Richard G Watt