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1 **Title**: DEVELOPING AND PILOTING A PEER MENTORING INTERVENTION TO REDUCE TEENAGE PREGNANY IN LOOKED AFTER CHILDREN AND CARE LEAVERS

2 BACKGROUND

2.1 The problem

The estimated 58,000 children in England and Wales being 'looked after' by local authorities (1) are widely recognised as being more socially excluded and vulnerable and bearing a greater burden of health and social problems than the most disadvantaged children outside the care system (2); (3); (4). Compared with children living at home, looked-after children (LAC) are significantly more likely to experience poor mental health, educational difficulties and school dropout, unintended pregnancy and early parenthood, substance abuse, self injury, crime and unemployment, after adjusting for educational and physical factors (5); (6); (7); (8). Research by the Office for National Statistics (ONS) has shown that nearly three quarters (72%) of LAC in residential care have a mental disorder (8). The risk of psychiatric disorder is increased by the absence of a close relationship (9) and around three times as many LAC as young people in their own homes have no friend in whom they can confide, share secrets or disclose private things. Girls in care frequently seeking help in order to be able to talk things over (69%) or because they are worried and unhappy (36%) (10).

Reducing the incidence of pregnancies among young people aged under 18 years has been identified as a government priority in the UK and elsewhere (11). Although teenage parenthood can be a positive experience, it is associated with a wide range of adverse social and health outcomes (12) and these associations remain after adjusting for pre-existing social, economic and health problems (12;13).

LAC are also at greater risk of early sexual initiation (14);(10). 11 -17 year olds in residential care are more than three times as likely to have had sexual intercourse as those living in a foster placement (70% compared with 22%). 44% of 16-17 year olds, and 74% of 11-15 year olds stated that they had used no form of contraception on the last occasion they had sex (10). Almost a quarter had been sexually abused. Not surprisingly perhaps, LAC are at significantly higher risk of teenage parenthood; one study has indicated that as many as 40% of young women who have been in care, are mothers by age 20 (15). In 2005, the proportion of 15-17 year old women in care who were mothers was three times the usual rate in this age group overall (16). Young women who have been in care are more likely to continue a pregnancy to term (17) and to experience worse outcomes of early motherhood (18).

2. 2 The policy perspective

Because of their poorer health, education, social and economic outcomes, compared to other young people, LAC and young people who have left care have increasingly become the focus of policy interest. In the past decade, the Department of Health (DH) in England has introduced a raft of major initiatives to help promote better health care for children who have been separated from their parents. In Britain, looked-after children are recognised as a particularly vulnerable group by the *National Service Framework for Children, Young People and Maternity services(19)* and by the *Every Child Matters* (20) programme that seeks to support the ‘joining up’ of all children’s services. New Regulations and Standards for foster care, a National Healthy Care Standard, have aimed to ensure better access to health care for this population (4). On a broader policy front, the *Children (Leaving Care)* Act (2000), The *Care Matters* Green Paper (16)(17), *Care Matters: Time for Change* White Paper (21) and the *Children’s Plan* (22) all offer frameworks at the national level in England, to ensure that local authorities and primary care trusts can better support children and young people in general, particularly those facing challenging circumstances.

There is evidence that the extensive mental health and personal needs of looked after children are not adequately met by current service provision (23). The *Looked After Children* documentation and the *Quality Protects* initiative (21;24;24;24) have been criticised on the grounds that setting uniform objectives and performance criteria serves to restrict the freedom of the agencies concerned to respond to individual children's preferences and interests. There have been calls for more empowerment for children in care (25). The right of LAC to participate in decisions about themselves is enshrined in the Children Act (England & Wales) 1989 and DH Guidance encourages children's participation. Yet the views of LAC themselves point to several factors that militate against their power to exercise choice. These include lack of an advocate to take proactive action on their behalf, lack of an effective voice at reviews, lack of confidentiality and, linked to this, lack of a confidant (26); (4); (23); (27). Similarly, one of the key problems in implementing personal education plans (PEPs) for LAC, introduced in 2000 to raise the profile of their educational needs, is said to be the difficulty of ensuring the meaningful and sensitive involvement of children in their own PEPs. (28).

2.3 Breaking the cycle of deprivation

In many cases, the problems faced by LAC are a consequence, not of being in care, but of the family circumstances which led to them being taken into care. Children in care often come from highly materially and emotionally disadvantaged backgrounds, (29); (30) and the inter-generational transfer of this disadvantage is likely to be exacerbated by early childbearing.(31). For young women who have been in care, motherhood may be perceived as a means of improving on their own early experience of life (32). They are also at increased risk of early pregnancy because they lack many of the factors which are said to protect against unplanned pregnancy and early motherhood: educational engagement and achievement; self esteem; and access to parental support, communication and monitoring (33); (34);(35) ; (18); (36);(37)(32); (38);(21) . The situation is exacerbated by the fact that LAC often do not attend school (5) and so miss out on curriculum-based health promotion and sex education (6);(4).

2.4 Mounting an intervention

Both the scale and persistence of the problem demand urgent measures. Despite progress made in reducing under-18 conception rates to their lowest levels for 20 years, any further reduction may require interventions targeted at, and tailored for, those most at risk, including LAC (39). The Teenage Pregnancy Unit has already identified targeted work with LAC and care leavers as one of the factors helping to explain the decline in under-18 conception rates in some local authority areas (40). However, there is little evidence on the effectiveness of interventions to reduce the risk of pregnancy among LAC, and none using an experimental design. Personal advisors, offering one-to-one crisis management, advice and advocacy, and befriending and supporting teenagers were reportedly the most successful part of the government's 'Sure Start Plus' package aimed at supporting teenagers during and beyond pregnancy (35). Similarly, research on 'New Deal', a policy for young people (41) suggested that personal advisers could provide effective support, where none was available from parents, and achieved some success in aiding recovery from early dropout from education.

The only comprehensive systematic review of the effectiveness of peer-led health promotion interventions for young people, in which half of the included evaluations were concerned with sexual health, concluded that while the more methodologically sound studies suggested the approach was promising, it was difficult to identify what comprised an effective peer-led health promotion model, because there were so few studies (42). A recent review of peer-led sexual health interventions came to a similar conclusion and suggested future research should 'build on the successful trials conducted to date and should strive to fulfil existing quality criteria (43). One such trial, The Ripple project, employed peer-educators providing sex education within schools and was effective in reducing self-reported pregnancies by age 18 (44). An informal, peer-led approach to adolescent smoking prevention has also been shown to be effective(45).

Given the available evidence, we believe that a system of peer-mentoring and support, involving a young person whose experience of post-care life has been positive, may be a promising approach to intervention with this group. Factors influencing decisions around pregnancy in LAC include low self esteem, loneliness, mistrust of others, lack of assertiveness and lack of perceived choices or options in life (18);(30) . The concept of resilience, associated with self esteem and self efficacy, is increasingly seen as offering a framework for intervention with young people. Resilience has been shown to be protective in the context of care, and to be enhanced by the presence of at least one secure attachment relationship (46). Having access to a trusted confidant who provides care, respect and affection, through and beyond the period of care, may go some way towards creating emotional security and improving self esteem and confidence, as well as providing an opportunity to deliver important messages and information around relationships, sexuality and pregnancy. There is evidence to suggest that this approach has the potential to assist young people in developing new identities, in making choices regarding their education and personal development; in increasing self-confidence and self esteem (47); (48) (49) and in providing real opportunities for alternative life choices (50); (51). Social support interventions (52) involving trained volunteers, have been shown to be effective in other areas of health care(53); (54) with adolescents (55) and in foster care (56). There is some evidence that mentoring can help to increase the confidence, self esteem and aspirations of young people in care (57) and may also have a positive impact on training, education and work engagement (58). Relatively less is known about the impact of peer mentoring, as opposed to adult mentoring, although LAC frequently say that they want support from people who know, understand and have experienced the care system.

We are aware of the potential pitfalls, including the challenges of accessing and engaging LAC (59), of finding positive role models (60); (61) and of sustaining such an intervention. We nevertheless believe that this approach is promising and would benefit from research geared towards intervention refinement and experimental evaluation. A crucial aim of the proposed pilot is to explore the need for, and nature of, rewards for the mentor; the training and support needs of the mentors; the means by which sustainability can be ensured; and managing the post-intervention transition in a way that supports both mentor and mentee. From the available evidence, we are convinced that, not only is this a promising route to take, given the aims of the project, but also that the systematic and rigorous exploration of peer-mentoring in this context will be generalisable and of benefit to a broader field.

3 PLANNED INVESTIGATION

3.1 Aim and objectives

The aim of this study is to develop a peer mentoring intervention to reduce teenage pregnancy in looked after children and to undertake an exploratory randomised controlled trial to assess the feasibility of evaluating the effectiveness of the intervention in a definitive trial.

The objectives are:

- Drawing on a scoping exercise and focused literature review, to develop a complex intervention to reduce teenage pregnancy in young women who are 'looked after'

- To conduct an exploratory randomised trial of the intervention in three local authorities in England, to pilot recruitment, randomisation and consent procedures, examine recruitment and retention rates and the feasibility of collecting reliable and valid data on the primary and secondary outcome measures, and estimate what might be feasible effect sizes and intervention costs for a future full-scale RCT; and

- To embed a process evaluation within the exploratory trial to assess the acceptability of the intervention and the trial procedures to looked after children and those working as mentors; and to document what comprises usual care in this context, for those looked after children randomised to the control arm.

3.2 Research design

This is a feasibility study incorporating two of the phases in the MRC's original framework for evaluating complex interventions: Phase I and Phase II (62). In Phase I, we will develop the components of the mentor intervention, based on existing evidence and qualitative interviews with key stakeholders. We will also undertake qualitative testing of the intervention's components via a pilot study with a small number (n=6) of mentor-mentee dyads. Phase II will comprise an exploratory randomised trial of this intervention in three local authority areas with 24 LAC randomised to receive the peer mentor intervention and 24 randomised to receive the usual support provided to LAC. This will inform the development of a protocol for a Phase III trial, for which separate future funding would be sought.

3.21 Phase I - Development and initial pilot of the peer mentor intervention

3.21.i Scoping exercise and targeted literature review

Existing evidence reviewed above, points to the appropriateness of a peer-mentoring approach to reducing teenage pregnancies in LAC. In Phase 1, we shall undertake further literature review, alongside a scoping exercise to define our intervention's components, logic model and delivery plan.

The further review of literature will focus on peer-mentoring interventions for LAC and other socially excluded young people and/or teen-pregnancy prevention interventions using peer-mentoring methods. Scoping will involve writing to and conducting follow up interviews where required, with various stakeholders (health and social care professionals, carers, LAC and young people who have left care, academics, Teenage Pregnancy Coordinators, Directors of Children's Services, PCTs, and governmental and nongovernmental organizations and agencies relating to LAC and teenage pregnancy) to identify existing relevant interventions and existing evaluation evidence, and explore views on the various components of these. Particular attention will be paid to the questions around the selection, training and support of mentors, the specification of the mentoring relationship (e.g. amount of contact, types of contact, and duration of relationships), exit strategies used towards the end of the intervention period, and contextual factors affecting the apparent success of these interventions. The scoping exercise will not confine itself too narrowly to pregnancy as an outcome, but will also examine evidence for beneficial effects on sexual behaviour, attitudes and relationships, psychological health and social outcomes more generally. As part of our literature review, we will search for and review evidence from published and unpublished evaluations of the interventions identified through this scoping exercise.

3.21. ii Developing the peer mentoring intervention

Drawing on the literature review and scoping exercise, we will develop the components of our intervention. A BDI (Behaviour- Determinants- Intervention) logic model (63) will be used to describe and explain the intended causal mechanism of the intervention. The BDI logic model is becoming the standard approach to developing social interventions for community health problems, including sexual health and teenage pregnancy.

3.21 iii Recruitment and training of mentors

Young women (aged 19 to 25) who have been through care, will be recruited to act as mentors for young women in the care system. Initial exploration to ensure the feasibility of recruiting mentors has been established with charities working in this area, in particular including The Who Cares Trust, Straight Talking and the National Children's Bureau. The required qualities and characteristics of the individuals who will be recruited as mentors will be developed and clarified within the scoping exercise. However the key criterion, based on the literature, is that mentors will be young adults who have themselves experienced care and are therefore familiar with the care system. A recruitment and assessment process will be set up within the local authorities to ensure that those selected are appropriate for the mentoring role, that they are safe to work with children and vulnerable young people and that common selection criteria are used in each local authority. The mentors will be supported by local project co-ordinators (see below).

Mentoring Role

Mentors will receive £40.00 vouchers a month in recognition of their work and contribution to the project. They will, in addition, receive £40.00/month, via the LA project manager, to pay for additional activities that may be involved in e.g. leisure, sporting, social etc. with their mentee. Expenses incurred through the mentoring role (e.g. travel, subsistence, etc) will also be covered. The peer mentoring experience will be accredited through the ASDAN (Award Scheme Development and Accreditation Network) system. This scheme operates a reflective, flexible and child-centred and non-bureaucratic approach and has experience in accrediting vulnerable young people. We shall either use an existing ASDAN framework, or commission ASDAN to develop one specifically for the project.

Each mentor will be allocated to one mentee, aged between 14 and 18, for a period of one year. No specific matching of mentors and mentees will take place e.g. around cultural concordance. However, the impact of this will be explored via qualitative interviews in the process evaluation. We will specify an age difference of at least 5 years where possible between the mentee and their allocated mentor. Contact between the mentor and their mentee will be conducted by a variety of means including: face to face meetings; email/internet; phone conversations; and texts. The mentor will keep a semi-structured diary logging the frequency, nature and content of their communication with the LAC. A mobile phone based application known as Episurveyor will be used to capture information recorded in the diary. Mentors will complete the diary either on a mobile phone or using an online form, and send it directly back to the research team where all information will be held on a secure, confidential server. All mentors will be provided with a mobile phone for the duration of the project, to enable them to facilitate communication and help sustain their involvement. Additional resources have been requested to enable mentors to spend leisure time with young people participating in, for example, occasional trips to a café. The precise mentoring 'contract' in terms of defining the mentor's role and responsibilities and clarifying what is reasonably expected of them will be elucidated through the scoping exercise and made explicit to the mentors during their training.

All mentors will receive initial training from the NCB, with additional input from Straight Talking. They will also be provided with ongoing support from the project co-ordinators, for the duration of the intervention. Key aspects to be covered within the training will be the expectations of the mentoring role, confidentiality, maintaining boundaries, facilitating the young person's help seeking and social networking; communication between the mentor and other members of the young person's care team; dealing with difficulties/crises if they arise etc. Mentors will also receive, as part of their training, a sex education module aimed at equipping them with sufficient information to provide mentees with information about where to seek advice, basic sex education awareness and information about teenage pregnancy and the rationale behind the intervention. Mentors will be expected to be aware of how and where the young person could obtain that information as well as, if requested, to accompany them to appointments, checkups etc. Given the short term nature of the intervention, the emphasis in training will be on empowering the young person, encouraging self reliance and social networking, and discouraging the development of excessive dependence within the relationship. The mentor's task will include fostering the development of social relationships for the LAC and managing the ending of the contact in a sensitive and planned way. NCB will collaborate with the research team and a specialist teenage pregnancy organisation (StraightTalking) to design the three and a half day training course and follow up support days, in ways that make it accessible to young mentors.

We will ask each local authority to identify a project coordinator, whose role will be to implement the mentoring scheme and to support the young people acting as peer mentors. NCB will train them for this role and provide ongoing support. This model of locally-based support is favoured because it is rooted in knowledge of local systems, processes, services, resources, policies and protocols, and because a) there will be local systems for back-up if the project manager is not available, and b) this ensures that capacity is built and learning retained within the local authority, and that their expertise (and responsibilities) in supporting LAC and care leavers is recognised.

Project coordinators will have regular (monthly) contact with mentors and will also provide ad hoc support and advice. NCB will coordinate and provide a group support session for mentors and project coordinators at four months and at the end of the intervention. Project coordinators will also receive regular bi monthly contact from the researchers to monitor the progress of the project and the project coordinators will be able to contact the researchers for advice/ trouble shooting on an ad hoc basis, as required.

3.21 iv Pilot study

We will undertake a three month pilot study of methods for recruiting mentors and mentees and the delivery of the intervention with a maximum of 6 mentors and 6 mentees in one local authority. The findings will be used to refine the peer mentor training programme and other intervention components, and to test the research methods and instruments to be used in the exploratory trial. Process evaluation methods used to refine the training programme and other components of the peer mentoring intervention will include observation of each stage of the training programme, a focus group discussion with mentors on the last day of training, and individual semi-structured interviews with both mentors and mentees, to be held toward the end of the three month period to explore their views on ways in which the intervention might be improved. Semi-structured interviews will also be held at the end of the 12 month intervention.

Analysis of these pilot study data will be undertaken employing the methods outlined in Section 4.3.viii, and will be used to further develop and refine elements of the intervention and evaluation for the Phase II exploratory trial.

3.22 Phase II Exploratory trial

This will take the form of an individually randomised controlled trial with mentees randomised to receive the peer mentor intervention or the usual support provided to LAC. The randomisation with be stratified by local authority with 16 mentees randomised in each of the three local authorities. Mentees in both intervention and control groups will be followed up for one year post randomisation. At this stage the peer mentoring for those in the intervention group will have concluded.

3.22.i Recruitment

48 girls and young women aged 14 -18 years who are currently under the care of the Local Authority (24) in children's homes or with foster carers, or who are care leavers(24), will be recruited as *mentees* from Ealing, Lambeth or Essex Local Authorities (LA).

The project coordinator will provide potential mentees with preliminary written information about the peer mentoring intervention and exploratory trial and talk them through this. If the potential mentee still indicates a willingness to participate, then researchers will arrange to meet with mentees to check they understand the mentoring programme, the randomised nature of the evaluation, and the nature of their involvement. Providing the potential mentee is happy to enter the trial, the researcher will complete the consent procedures. Researchers will provide mentees with a direct line of communication in case of research queries. All other problems or difficulties the mentee may be experiencing will be directed to their project coordinator. All social workers and carers involved with those recruited as mentees will receive information about the intervention and the evaluation, together with details of the local project coordinator. At this stage, the researchers will interview all mentees, using a questionnaire as a tool to collect the following baseline data:

i. Socio demographic data (age, ethnicity);
ii. Care history (current and previous);
iii. Forensic history, alcohol and drug use;
iv. Educational attainment and achievement – perceived success as well as actual attainment; school attendance; history of school, exclusions, truancy, suspension, future education/vocational intentions;
v. Sexual activity, contraception use, condom use to prevent STIs;
vi. Interpersonal and social functioning including: number of confidants/close friends; engagement in leisure/sporting activities;

Additional information, including mentees' care history, how they have been coping with their experiences in care, their sexual health, and contact with other agencies will be collected from the local authority. A questionnaire will therefore be distributed to the mentee's social worker. Consent for this information to be obtained will be sought from mentees at the baseline meeting.

3.22.ii Proposed randomisation strategy

Mentees will be individually randomised. Randomisation will stratified by local authority, using blocking and undertaken using the Bristol Randomised Controlled Trials Collaboration (BRTC http://www.bristol.ac.uk/cobm/research/brtc.html) automated randomisation service. When a researcher has obtained consent from a mentee to participate in the trial, they will contact the randomisation service to obtain the allocation. This information will be communicated to the mentee and the local project coordinator.

3.22.iii Sample size

The sample size in this exploratory trial is not intended to yield sufficient power to detect a significant difference in the primary outcome measure. The sample size, however, should be sufficient to test whether the trial methods are robust and provide sufficient data to check the reliability of the psychometric measures being used as secondary outcome measures.

3.22.iv Planned inclusion/exclusion criteria

We will rely on the LA project co-ordinator, individual homes and social workers /care staff to suggest young people to be approached to explore their interest in participating in the mentoring scheme. Ideally, the young people will have had three or more placements in care, on the basis that they represent the most vulnerable group (although this will not be specified as a necessary criterion). We shall not specify whether the young people are sexually active, or have been pregnant as part of their inclusion. However, these data will be collected at baseline and follow up.

3.22.v Outcome measures

Primary outcome measure

As the key purpose of the intervention is to reduce rates of pregnancy, the ideal would be to have pregnancy the primary outcome for this exploratory trial and in any subsequent definitive trial. However, this only makes sense if there is a reasonable chance of detecting a meaningful reduction in the rate of pregnancy between intervention and control groups in a phase III trial. The difficulty is accurately estimating what the rate of pregnancy is for looked after children and teenagers. Some studies have suggested the rate may be as high as 40%. Data collected on live births to LACs in combination with routine data on teenage conceptions and abortions for the population as a whole in England, however, suggests that the rate may be 10% (64). If we assume that it would not be feasible to mount a phase III trial with more than 1000 LACs randomised to intervention and control, then the table below suggests that if pregnancy rates of in LAC are between 20% and 40% and an effect size of 10% is deemed reasonable, then using pregnancy as the primary outcome measure in a definitive trial would be possible. However, as the lower part of the table indicates, if the pregnancy rate for LAC is nearer 10%, then the intervention would have to have the effect of halving the pregnancy rate in the intervention group to have a reasonable chance of detecting this change.

Pregnancy rate (%) Control group	Pregnancy rate (%) Intervention group	Power	Number required in each group
40	35	80	1511
40	30	80	376
35	30	80	1417
35	25	80	349
20	15	80	945
20	10	80	219
10	8	80	3313
10	7	80	1422
10	6	80	771
10	5	80	474
10	4	80	316

Computed with a 5% false positive rate

While data are routinely recorded on live births to LAC, routine data on abortions for women under the age of 18 do not distinguish between those who are looked after and those not in care. Thus, it is not possible to calculate a pregnancy rate for this group. Our estimate of a pregnancy rate of 10% rests on an assumption that the ratio of live births to termination of pregnancy in LAC is the same as that for all teenagers, even though there is some suggestion that this may not be the case. In addition, we propose to target the peer mentoring intervention at the most vulnerable group of LAC: those that have had three or more placements, and these young women may have higher rates of pregnancy. Given this uncertainty, an important function of this exploratory trial will be to: i. conduct further analyses of routine data on births to LAC and conception and abortion rates in teenage women, to produce more robust estimates of the pregnancy rate in the subgroup of LAC that our intervention is designed for; ii. explore the feasibility of collecting pregnancy data from the young people themselves (by interview using a structured questionnaire) but also to extract data from GP records; and iii. to consider, in detail what other surrogate measures for pregnancy could be used as a primary outcome measure in a phase III trial, should it become clear that using pregnancy as the primary outcome is not feasible. Current candidate surrogate measures we will consider include: age of first sexual intercourse, use of contraception versus incidents of unprotected sex in past 3 month period, sexual competence, number / nature of sexual relationships, and sexually transmitted illnesses (STIs). Of these, our primary surrogate markers will be age of first sexual intercourse and use of contraception, versus incidents of unprotected sex in the past 3 month period. We shall examine whether all the effects of our intervention are mediated through and reflected in the surrogate measures as well as in the primary clinical outcome.

Local authorities have a statutory duty to maintain contact with LAC after they leave care until they are 25 because, during this time, LAC are entitled to fully funded support through higher education. It should therefore be possible to keep rates of loss to follow up due to loss of contact relatively low even if the young people have left care. An issue for this feasibility study, however, is to document the rate of withdrawal of participation in the exploratory trial following randomisation as it is this, rather than losing touch with participants, that may be the most important determinant of the loss to follow up.

Secondary outcome measures

Data on a number of secondary outcome measures will be collected by conducting an interview with all mentees and also by distributing a questionnaire to their social worker, including:

i. Pregnancy outcome (live birth, still birth, termination, miscarriage);
ii. Initiation of sexual activity; use of contraception; sexually transmitted infection;
iii. General help seeking;
iv. Alcohol and drug use over the last year;
v. Contact with police and criminal justice system;
vi. Educational /vocational performance **-** school attendance, truancy rates, exclusions, educational attainment
vii. Interpersonal and social functioning including: number of confidants/close friends; engagement in leisure/sporting activities
viii. Physical and Psychological health.

Explanatory variables

We will also collect data on a small number of variables that may help to explain the mechanisms by which the intervention achieves any effect. These will include self esteem and locus of control and any relevant variables identified in the Behaviour- Determinants Intervention logic model.

Outcome data for Mentors

In assessing the effectiveness of this intervention in a phase III trial, it will be important to measure any benefits, or potential harms to the mentors. In addition to the process evaluation data collection involving mentors, we will also ask them to complete a short questionnaire at the outset of mentoring on which they will record baseline data including socio demographic data (age, ethnicity, employment status, educational attainment); care history and three psychological measures : Self Esteem Scale (65); General Health Questionnaire (66); and Locus of Control (67) to assess the impact of the peer mentoring on them. These data will be collected again after the mentors complete their mentoring role to assess the impact of peer mentoring on them.

3.22.vi Process evaluation

A detailed process evaluation will be undertaken to examine implementation and receipt of the intervention in order to assess feasibility and fidelity, accessibility, acceptability and contextual factors affecting these. In addition, the process evaluation will be used to gain insights into the mechanism of action of the intervention and develop hypotheses to guide secondary outcome analyses, for example by sub-group or on-treatment. The process evaluation will be of use in informing any further adjustments to the intervention, prior to a phase-III trial, as well as to the measures of fidelity to be used within such a trial.

In order to assess feasibility for a phase-III trial, the process evaluation will explore the following domains:

- Availability of eligible participants for a phase-III trial
- Feasibility of recruiting mentors and mentees
- Willingness and acceptability to consent and randomisation
- Retention of participants
- Evidence of harm to participants
- Characteristics and appropriateness of proposed outcome measures
- Costs for a full trial
- Definition of ‘usual care’
- Ability to manualise the intervention

A mixture of quantitative and qualitative research methods will be employed for the process evaluation. Observation of training sessions will be undertaken, both to collect quantitative data to assess whether specific components are delivered and to use qualitative data to assess the appropriateness of the approaches used. At the beginning of the training and at the end of each day, all peer mentors will complete short questionnaires about the training. The peer mentors will also participate in a focus group discussion on the last day to explore their views about the training. The trainers will provide feedback on the training to the researchers.

In the course of intervention delivery, we will conduct semi-structured interviews with the project coordinators, Senior Managers, and social workers from the three local authorities involved in the study. The purpose of these interviews will be to understand individual experiences of participant identification and referral to the study, and also barriers to recruitment. Interviews will be conducted either in person or on the telephone, and will be digitally recorded and transcribed verbatim.

In addition to individual interviews, a questionnaire will be emailed to all social workers whose details have been provided by Ealing, Lambeth and Essex local authorities. The questionnaire will explore their knowledge of the study, their involvement with recruitment, and barriers to recruitment.

We will also conduct focus groups with LAC and staff working with LAC in order to examine their views on the intervention and to assess feasibility. Each focus group will comprise 6-8 participants. Two focus group discussions will be held with (i) LAC and (ii) care leavers in London Borough of Barking & Dagenham local authority, in order to ascertain the views of young people not currently involved in the study. Two focus group discussions will be delivered in each of the three local authorities involved in the study, comprising (iii) health and education staff, and foster carers supporting LAC; and (iv) social workers working with LAC and care leavers. All focus groups will be conducted by trained researchers with CRB checks. Focus groups will be digitally recorded and transcribed verbatim.

Further assessment of feasibility for a phase-III trial will be captured via national surveys to both LAC and local authority staff.

(i) A survey will be advertised online to two groups of young women: LAC aged 14-18; and care leavers aged 19-25. The purpose of the survey will be to examine views from a more extensive audience on the feasibility of recruitment, randomisation and the intervention. The survey will be advertised through the 'Who Cares Trust' magazine, Twitter and Facebook forums.
(ii) Each Local Authority in England and Wales will be asked to complete an survey. The survey will assess availability of eligible participants and interest in participating in a phase-III trial.

As it will not be possible to observe the peer mentors 'at work' the mentors will keep a semi-structured diary logging the frequency, nature and content of their communication with their mentees, as well as allowing them the opportunity to record their feelings and views about their mentoring experiences. Guidance on completion of the diary will be covered in mentors' training. We will also conduct snapshot surveys with both mentors and mentees at three time points over the duration of the intervention. The surveys will be conducted by telephone and will explore weekly activities and feelings towards the mentoring.

At the end of the intervention period, we will conduct follow-up semi-structured interviews with all three project coordinators and a sample of 15 mentors and 15 mentees. These will be sampled purposively to ensure that we have a varied sample according to LA and the age of mentee. The interviews will explore their experiences of the intervention and the research. Regarding the former, we explore experiences of the mentoring relationship in terms of its acceptability, appropriateness and apparent impact, including attitudes to relationships, pregnancy and contraception; educational engagement, aspirations regarding education and work; impact on social relationships more generally; views of whether mentoring is effective; how it effects change and suggestions for how mentoring could be enhanced. With regard to the research, we will examine their views on consent and randomisation procedures, the reliability of questionnaire responses and the possibility and extent of any 'contamination' whereby intervention benefits are passed on to those in the control group (we are confident that these will be minimal (68) but wish to confirm this empirically). In addition, we will also seek to conduct interviews with any mentors or mentees who leave the programme early, in order to understand their reasons for dropping out.

The interview-administered follow-up questionnaire will examine process as well as outcomes. Questions will be developed informed by previous instruments and emerging findings from interviews.

Following informed consent of the mentee and their carer, we will conduct semi-structured telephone interviews with foster carers or keyworkers. The purpose of these interviews is to assess changes in behaviour and also any evidence of harm sustained as a result of the mentoring relationship.

3.22.vii Assessment of costs

During this exploratory trial the main aim of the economic evaluation element will be to determine the costs of the various components of the peer mentor intervention and separately the costs of the outcome assessment and process evaluation. These data will provide invaluable information for appropriately costing a Phase III trial (to include a full economic evaluation). We will develop weekly timesheets for project coordinators in LAs to record the time they spent delivering aspects of the peer mentoring scheme and time spent assisting recruitment to the exploratory trial. We will also ask them to record details of expenses associated with any of these activities. In addition we will record the costs of delivering the peer mentor training in both the pilot study and exploratory trial and develop an instrument for comprehensively recording this information. The diary that the peer mentors will be asked to complete will include a section for recording the time that they spend on this activity. We will also retain records of all their expenses and payment for undertaking their role.

The secondary aim will be to attempt, using the literature, to develop a model of the connection between the value added by the intervention and the probabilities of various medium to long term outcomes for the young women and any children they may have. It is in this area that the significant benefits of the intervention are expected to lie.

3.22.viii Methods of data analysis

Qualitative data analysis

Qualitative data will be entered into the data analysis package NVivo, which will be used to manage and code data. Qualitative data from the process evaluation will be subjected to a thematic content analysis. Codes will be applied to transcripts in the course of reading full transcripts. These will identify key themes and how these inter-relate in order to develop an analytical framework. The analysis will be looking for themes, common threads, contrasts and differences, as well as silences. Each transcript will be coded to indicate the type of participant, local authority area and date, allowing analytical themes to be explored in relation to different groups' experiences and to compare processes across areas. Drawing on methods associated with 'grounded theory', we will make constant comparisons and examine deviant cases to refine our analysis. During analysis, different propositions will be developed, amended and/or abandoned through a constant process of testing against findings from other transcripts.

The data from mentors and mentees will be used to explore the process of mentoring and relationship building and the progress of relationships. The positive elements, which are central to the success of the intervention, will be analysed together with those elements of the relationships that did not work. The analysis undertaken will enable us to explore: how both mentor and mentee experienced this relationship; mentors and mentees expectations about the workings/dynamic of the relationship; whether they felt the relationship was appropriate and safe; whether this supportive relationship had some impact on their relational life. This analysis will enable the recruitment, training and support for mentors, targeting of mentees, and the specification of the intervention to be refined.

Qualitative data will also examine the structure and components of the intervention, which will be examined through follow-up questionnaire data and mentors' diaries, enabling triangulation of data.

We shall specify that at least one of the research assistants has substantial qualitative research experience and the other researcher has experience of conducting randomised controlled trials. The researchers day to day work will be directly managed and supervised by (NM), and SG will be responsible for supervision and the initial understanding and analytic approach to the qualitative data. Emerging analysis will be brought to the research team and the Advisory Group, in order that a broad range of interpretive perspectives can inform the analysis process.

As stated above, analysis undertaken in the pilot will inform conclusions about overall feasibility and acceptability, refinement of our logic model and measures of fidelity, and possible causal pathways. It will also explore the appropriateness of our research procedures. The process evaluation will also draw on analyses of the quantitative data to assess intervention accessibility, acceptability and fidelity. This approach will ensure that we can refine the intervention from the experiential perspective of both mentor and mentee.

Quantitative data analysis
A detailed analysis strategy for addressing the quantitative process evaluation and the analysis of outcomes will be developed by SW and SB and ratified by the research team prior to the end of data collection.
Quantitative outcome data will be analysed using multi variable regression models adjusting for local authority. As noted above, the exploratory trial is neither powered nor designed generally to provide a definitive comparison of the two arms (intervention and control). It will, however, identify the potential magnitude of any effect to be subsequently demonstrated in the Phase III trial. A full analysis plan for the Phase III trial will be developed. All analyses will be conducted using Stata version 11.0.

3.22.ix Research governance and ethical issues

The research will be reviewed and approved by the Research and Ethics Committee, based at the London School of Hygiene and Tropical Medicine and will be consistent with the highest standards of research practice, as well as the principles of good practice set out in the Data Protection Act (1998). Permission for the study to be conducted will be obtained from the Association of Directors of Children's Services. We will also ensure that we meet the standards for research governance set by the individual Local Authorities.

Care will be taken to ensure that all interviews are conducted with the freely given, informed, written consent of participants. All participants will be informed of their right to refuse to answer any questions, and to withdraw from the study at any time without explanation. Fraser guidelines will be followed where information on sexual behaviour and sexual health outcomes is requested of young people aged under 16.

All data will be stored anonymously, and any quotes used in reports and publications arising from the research will be anonymised. This information will be provided verbally to all young people (as well as professionals and carers) participating in the study, with the opportunity for questions at each stage of explanation. In addition, a leaflet, summarising information about the study, explaining confidentiality, and including contact details for the research team, will be provided for all those invited to take part in the research. All mentees will be provided with contact details of the local project coordinator, who they can contact in the event of any concerns about the mentoring role, their relationship with their mentor, or any difficulties they may be experiencing.

Mentors will be carefully selected and assessed for the study according to specific criteria which will be established through the preparatory stages of the intervention. A degree of emotional and psychological resilience will be required to take on this role and we shall rely on recommendations by local carers. We would not expect to recruit mentors who are pregnant, however, having a child would not automatically exclude them from participating. We are very aware of the need to establish clear boundaries around the relationship between mentor and mentee, both to protect the participants (mentor and mentee) and to discourage excessive dependency. It is important that the mentors are firmly embedded in the existing network of carers for LAC and do not feel that they bear sole responsibility for their mentee's care and welfare. These issues will be addressed and monitored by the local project co-ordinator through monthly meetings.

Support and supervision will be provided to mentors throughout the duration of the intervention by the local project coordinator. This will include monthly shared group meetings, as well as individual support and advice, as and when issues arise throughout the intervention phase. The project co-ordinator will liaise with other members of the mentee's network of carers if any difficulties arise. Clear lines of responsibility and accountability for mentors, project coordinator, NCB trainers and the researchers will be established. If a mentoring relationship breaks down for some reason, or a mentee requests a change of mentor, this will be accommodated for up to two occasions.

The involvement of local project coordinators will ensure that mentors complement the work of other social care, health, education and other professionals likely to come into contact with the young people participating in the intervention. Throughout the planning phases of the intervention, careful attention will also be paid to devising an exit strategy for when the mentors stop working with the young people. Young people's views and experiences will be vital in making decisions about how best to manage this latter phase of the intervention.

We will develop clear protocols (in consultation with the local authorities involved) to deal with a disclosure of significant risk or on-going harm involving a mentor or menteed young person, and will ensure that responsibilities and clear lines of accountability are established with regard to dealing safely and appropriately with such matters. Mentees will be made aware at the outset of the limits of confidentiality and these matters will also form key components of the NCB training programme.

3.3 DATA SYNTHESIS AND DEVELOPMENT OF FULL TRIAL PROTOCOL

A synthesis of quantitative and qualitative analysis will be used to develop a full trial protocol of the intervention. Qualitative analyses will be used to inform the development of hypotheses to be tested in quantitative analyses, for example of subgroup and on-treatment effects and causal pathway models. Conversely, where quantitative analysis suggest intervention effects on quantative outcome measures, qualitative analysis will be used to offer insight into the possible processes at work. Where findings are complementary, qualitative data will offer detailed guidelines for refining and implementing the mentoring intervention.

Following established principles for synthesising quantitative and qualitative data (69), where there are tensions between datasets, qualitative data will indicate heterogeneity in the participant populations (LAC and mentors) where specific, targetted guidelines are needed to ensure the intervention's effectiveness.The mentoring 'contract ' will be further refined in response to this data synthesis.

Finally, the detailed process evaluation undertaken here will allow a protocol to be written for a randomised controlled trial of this peer mentoring intervention. Key process variables identified (for example, specific qualities of mentors, frequency of contact, specific activities engaged in) that are associated with changes in outcome will enable the intervention to be refined and manualised. An indication will be given of outcomes where association with the intervention can be expected. Relating these changes in outcomes to published figures on teenage pregnancy rates will guide an estimate of a clinically meaningful effect of the intervention informing a power calculation.

We will receive support from DECIPHer (http://www.decipher.uk.net/) and the BRTC throughout this feasibility study and in developing the full RCT protocol, Both have extensive experience in supporting complex intervention studies in the public and mental health fields. The BRTC is an NCRI accredited trials centre.

3.4 ADVISORY GROUP

An Advisory group will be set up which will include, in addition to the applicants and members of the research team:

Alison Hadley (Teenage Pregnancy Unit)
Ann Phoenix (Institute of Education)
Chris Bonell (LSHTM)
Geraldine McCormick (TPC Lambeth)
Kaye Wellings (LSHTM)
Khatija Hafesji (user representative identified through Straight Talking and the Who Cares Trust).
Natasha Finlayson (Chief Executive; The Who Cares Trust);
Peter Jordan (Health Economist)
Rajinder Nagra (Barnardo's)
Ravinder Barn (Royal Holloway)
Rona Campbell (Bristol)
Sarah Brookes – (Bristol)
Sheryl Burton (NCB)

The Advisory Group will meet on 6 occasions during the 30 months duration of the project.

08/20/03

PROJECT TIMETABLE

DEVELOPING AN EFFECTIVE INTERVENTION TO REDUCE PREGNANCY IN CHILDREN AND YOUNG WOMEN WHO HAVE BEEN IN CARE

Year		2011												2012												2013							
Month	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A
Phase I – Development of Peer Mentoring Intervention																																	
Scoping exercise & further literature review to develop components of the intervention				■	■	■	■																										
Focus groups to explore views of the proposed peer mentoring intervention											■	■																					
Development of training	░	░	░	░	░	░	░																										
Recruit mentors and mentees for pilot study; train mentors						■	■	■	■	■																							
Pilot peer mentoring intervention										■	■	■	░	░	░	░	░	░	░	░	░												
Process evaluation and further refinement of peer mentoring intervention											■	■	■																				
Refinement of training									░	░	░	░																					
Phase II – Exploratory Trial																																	
Recruit and train peer mentors and collect baseline data													■	■	■																		
Recruit and randomise peer mentees and collect baseline data													■	■	■																		
Process evaluation														■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■				
Assessment of intervention costs and development of model for phase III trial													■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■				
Implement peer mentoring intervention														■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Follow up data collection																												■	■				
Data preparation, analysis and synthesis																												■	■	■	■	■	■
Preparation of intervention manual, final report & development of phase III trial protocol																														■	■	■	■
Month	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A
Year		**2011**												**2012**												**2013**							

5 EXPERTISE

Applicants:

Gill Mezey –Principal applicant. Expertise in health care research, psychological measures, abuse and domestic violence. Quantitative and qualitative methodologies. Responsible for design and development of the project, overall responsibility for management of project, supervision of researchers, contribution to data analysis, writing up of results and delivery of outcomes to time.
Rona Campbell – extensive practical experience of the development, evaluation by RCT, and implementation of complex health care interventions. She is Co Director of the UKCRC DECIPHer Centre (**http://www.decipher.uk.net/**) whose primary purpose is the development and evalution of interventions to improve the public health of children and young people. She has particular knowledge of peer interventions having been co PI on the ASSIST trial of a successful school-based smoking prevention for adolescents. RC also has expertise in the use of qualitative research methods within RCTs. RC will provide research design and operational advice throughout the project and will assist with the data management, data analysis and writing up of the project.
Chris Bonell –expertise in undertaking sexual health research with young people and developing and evaluating complex interventions. Particular expertise in process evaluation and in integrating analysis of quantitative and qualitative data. Chair of steering group of the Centre for the Evaluation of Public Health Interventions at LSHTM which will offer advice to the project throughout its duration. Advice on all aspects of research design, process evaluation,analysis (including the integration of qualitative and quantitative data) write-up and dissemination.
Kaye Wellings - Extensive experience in sexual and reproductive health and evaluation research, including teenage pregnancy. Kaye will provide support and advice in designing the study, in drafting the research instruments, and in interpreting the data.
Alison Hadley – Director of the Teenage Pregnancy Unit (TPU). National governmental policy /strategy re. teenage pregnancy. Advice on design of project, dissemination and policy implications.
Steve Gillard – health and social science researcher. User involvement in research. Design , development, interpretation and analysis of qualitative material; advice and input specifically re. user involvement. Supervision of qualitative data analysis with researchers
Ann Phoenix – Professor and Co-director of the Thomas Coram Research Unit. Expertise on motherhood, social identities, young people and gender.
Nadia Mantovani – expertise in research in looked after children. Involved in design and development of the project..
Sarah White – Statistical advisor with particular interest in complex interventions. Involved in design, data analysis (quantitative) and writing up project.
Ravinder Barn – social work/social sciences research specifically in looked after children and ethnicity. Involvement in development of the intervention and writing up of results.
Sara Brookes – Member of Bristol Randomised Trials Collaboration. Will provide expertise on the design and analysis of the quantitative aspects of the trial and the writing up of the project.

Collaborators: Peter Jordan – health economic strategy and analysis; Natasha Finlayson (The Who Cares Trust) – input and advice on recruitment, dissemination and the users perspective; Sheryl Burton NCB – supervising peer mentoring trainer; Local Authority Leads (Evette Grant and Cheryl Campbell - Ealing, Jacquie Wilkes - Essex, Lorraine Wilson and Ann-Marie Simpson - Lambeth); Geraldine McCormick (Teenage Pregnancy Coordinator – Lambeth) - Teenage pregnancy coordination expertise and practical experience in health service delivery around teenage pregnancy; Hilary Pannack (Director Straight Talking – National Teenage Pregnancy Charity) – expertise peer mentoring and teenage pregnancy; Robyn Kemp - NCB associate expertise in social pedagogy and training; Heather Owen – peer mentoring and teenage pregnancy expertise.

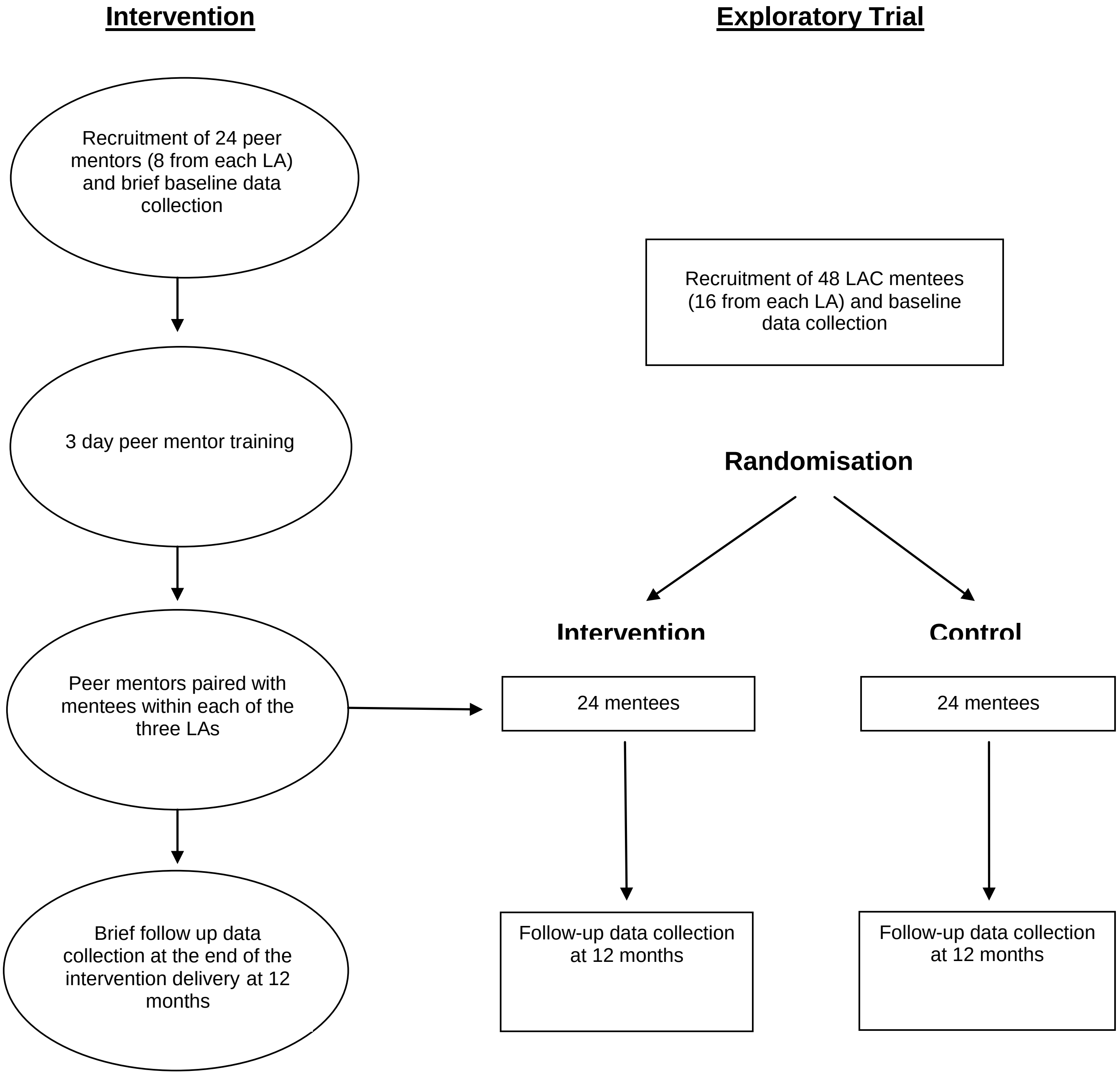
6 SERVICE USERS

We are consulting with and will systematically involve service users of charities for children in care (identification and recruitment of two service users to the Advisory group will be led by NF (Who Cares Trust) and HP (Straight Talking) and the National Children's Bureau (CS/JS). Service users will also pay an integral role in the project through delivering the mentoring intervention for LAC (see intervention, above) and in modelling the intervention (through focus groups with service users). The Division of Mental Health has a strong track record in involving service users in research (SG) which, combined with the specific LAC expertise of the Who Cares Trust and NCB and experience of working with teenage parents (Straight Talking) will ensure that this involvement is meaningful, well supported and adds value to the research process.

7. JUSTIFICATION OF SUPPORT REQUIRED

Two researchers will be appointed at grade 24 and 28. The more senior (higher grade) researcher is necessary because of the sensitivity of the subject matter being explored. Both researchers will be involved in the Scoping Exercise and targeted literature review. The more senior researcher will take the lead in maintaining contact with the project coordinators although both will provide advice, support and 'troubleshoot' throughout the 30 month project. The involvement of the Bristol Randomised Trials Collaboration (BRTC), a UKCRC/NCRI accredited trials unit, will include database development and maintenance and the automated BRTC randomisation system. There are 12 applicants and a number of collaborators on this project. Two of the applicants (AH and CS) are not costed on the application, as their input is free. The other applicants, from 5 different institutions each provide vital and distinct expertise and input to the project, which has been costed (FEC) accordingly and reflect their likely input to the research programme. Costing for a health economist (PJ) reflects his likely input throughout the project. A number of other collaborators (HP, NF, Local Authority leads) have not required payment. Other members of the Advisory group have only required travel costs to attend 6 meetings. The cost of the a 3 and a half day training programme for mentors and project coordinators, with follow up training and support, designed and provided by the NCB, with input from a teenage pregnancy training consultant (HO) is included, as well as the cost of accrediting the mentoring programme (for mentors and mentees). We believe this represents good value for money. Travel has been costed at basic public transport rates: for researchers to conduct all interviews in the 3 local authorities (Ealing, Lambeth and Essex); for members of the Advisory Group to attend regular meetings; for mentors to attend meetings and training provided by the NCB. All LAC and care leavers, who participate in the pilot and exploratory trial of the intervention, will be paid £10.00 for each individual interview (including completion of psychological measures) and £20.00 for participating in focus groups. Psychological measures which are copyright have been costed. A small amount of funding (£40.00 vouchers/month) has been requested to allow mentors to engage in social and leisure activities with their mentees. Mentors will also receive payment of £40.00 per month in recognition of their work. The costs of mobile phone contracts, to enable mentors to maintain communication with mentees, local project coordinators and the researchers, has been calculated, as well as the cost of diaries, recording the frequency and nature of each mentors contact with their mentees. Digital recorders and costs of transcribing have been calculated as well as 2 desktop computers to be located at SGUL for sole use on this project, as well as appropriate software packages. Costs of transcribing qualitative interviews and focus group discussions have been calculated. We have costed for administrative support, 2 days per week for the duration of the project.

8. FLOW DIAGRAM PHASE II EXPLORATORY TRIAL



Psychological Measures;

- *Self Esteem Scale* (65) Self report measure of global self esteem with a 10 item scale. Answers are on a four-point scale ranging from strongly agree to strongly disagree. Demonstrated reliability and validity with young people.
- *General Health Questionnaire* (66) - 12 item scale to detect symptoms of anxiety or depression . A score of 4 or more defines common mental disorder with a maximum score of 12 indicating a high likelihood of psychiatric illness.
- *General Help Seeking Questionnaire* (GHSQ) (70) 8 item scale: each identifies intentions to seek help from different sources. Good reliability and validity with young people. In this study the problems presented will be : experiencing abuse from a partner and pregnancy. Sources of help include 6 formal (e.g. social worker); 2 informal e.g. mentor sources of help, and 'none'

- *Locus of control* (67) 29 item scale which measures generalized expectancies for internal versus external control of reinforcement (internal locus of control characterises those seeing their own actions determining life events; external locus of control those seeing events in life as generally outside their control. Scores range from 0 to 13. A low score indicates internal control and a high score external control.
- *Attachment Style* (71). Self report questionnaire classifying four attachment styles: secure , fearful, dismissive and preoccupied. Good reliability and validity, including for use with adolescents (72).

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