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13 July 2012

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FAST Parent programme
Research Protocol

1. Title

Long title: The FAST (First-aid Advice & Safety Training) Parent programme for the prevention of recurrent unintentional home injuries in preschool children

Short title: The FAST Parent programme for the prevention of recurrent injuries in preschool children

2. Research Team

Principle investigator:
- Dr Julie Mytton (JM), Senior Research Fellow, Faculty of Health and Life Sciences, University of the West of England, Bristol

Researchers
- Two half time research fellows to be appointed (1x 0.5WTE, University of the West of England, Bristol and 1 x 0.5 WTE University of Nottingham)

Co-applicants
- Professor Elizabeth Towner (ET), University of the West of England, Bristol
- Professor Denise Kendrick (DK), , University of Nottingham
- Professor Sarah Stewart-Brown (SSB), University of Warwick
- Professor Alan Emond (AE), , University of Bristol
- Dr Jenny Ingram (JI), University of Bristol
- Dr Pete Blair(PB), University of Bristol
- Dr Jane Powell (JP), University of the West of England, Bristol
- Dr Toity Deave (TD), University of the West of England, Bristol
- Dr Caroline Mulvaney (CM), University of Nottingham
- Dr James Thomas (JT), Institute of Education, University of London
- Mrs Barbara Potter (BP), Health Visitor, North Bristol NHS Trust

Collaborators
- Mrs Carole Hewison, Project Director, WHOOPS! Child Safety Project, Gateshead
- Mrs Pamela Park, Chief Executive, Parenting UK, London

2.1 Research team roles
Recruitment and quantitative data collection will be conducted by the research fellows (RF) appointed in Bristol and Nottingham, employed specifically for this project. JM will line manage and provide supervision for the RF in Bristol and CM will provide similar support for the RF employed in Nottingham. JM, CM and PB will analyse the quantitative data with the RFs. JI will facilitate the Parent Advisory Group and support the health visitors delivering the programme. JI will conduct the qualitative interviews in Bristol and CM will conduct those in Nottingham. JI will analyse the qualitative data supported by CM and TD. JP will collect and analyse the data for the economic analysis of the programme.

3. Background

Childhood injuries – the scale of the problem
Unintentional injury is the major cause of death in children over the age of 1 in the UK, and for each child that dies many more will suffer morbidity and possibly long term consequences. Over 2 million visits to accident and emergency departments and over 120000 admissions in children

occurred in 2005 due to unintentional injury costing the NHS in the region of £146 million.[1] Staying safe has been a fundamental component of child health policies such as Every Child Matters.[2] The type and location of child injuries varies with age and the child's stage of development. The majority of injuries occurring to preschool children occur in the home.[3-5] Between 2000 and 2002 an average of 502,000 children aged 0-4 years attended hospital every year in the UK due to a home injury, representing 78% of all injuries occurring to children in this age group. The most frequent events leading to injuries in preschool children include, in order; falls, hitting / being hit / crushed by objects, poisoning, and burns / scalds.[6] Inequalities in injury occurrence have been widely reported.[7-12]

Risk factors for injury

A number of risk factors related to the family and the child have been associated with increased risk of injury. Single parents, step families and teenage parenthood, maternal life events and maternal depression were all associated with increased risk of medically attended child injury by age 2 in the Avon Longitudinal Study of Parents and Children (ALSPAC).[3] In a randomised controlled trial in Nottingham family factors including having a teenage mother or being in a single parent family were associated with increased risk of hospital attended injuries in preschool children.[13] Family structure[14] and parental behaviours, such as excessive use of alcohol[15] have been associated with increased injury risk in children. Male sex and difficult behaviour in childhood, particularly that relating to antisocial, aggressive or overactive behaviour, have been associated with increased incidence of unintentional injuries in the UK[16;17] and in other high income countries.[18] Parental understanding of the relationship between injury risk and child behaviour and development is variable, and provision of educational anticipatory guidance has been recommended.[19]

Parenting programmes

Parenting programmes are short term interventions to promote changes in the behaviour of parents and children that result in better health and wellbeing outcomes for both. They are usually delivered as face to face programmes, either individually or in groups. Parenting programmes have been increasingly recognised as an intervention to improve the life chances of children due to their effectiveness in reducing antisocial behaviour and improving educational and mental health outcomes in children, and the improved mental health and wellbeing of parents. Low socioeconomic status, unemployment, social exclusion or isolation, young or single parenthood and learning difficulties are known to adversely affect parenting. Consequently, parenting programmes have become a core component of child and family policy.[20] Parenting programmes have been developed on the basis of two main theoretical approaches: behavioural and relational. Some programmes combine elements of both approaches. Behavioural approaches aim to develop parents understanding of the negative impact of attention to problem behaviour and lack of attention to positive behaviour, and teach positive discipline practices including praise and time out; relational programmes aim to improve interactions between parent and child, correcting misattributions and increasing understanding of developmental phases. Both have been developed to improve children's mental health, the former with a particular emphasis on the prevention and treatment of antisocial behaviour and conduct disorder.

Analyses of longitudinal studies have shown the influence of parents on child outcomes that are related to injury risk. Research from the ALSPAC cohort has shown that positive parenting behaviour, parent-child interaction and a stimulating home environment were associated with enhanced development by the age of three[21] and improved cognitive and behavioural outcomes in children by age 5.[22] The 'better' the parenting, the more likely children are to be well adjusted and developmentally competent.[23] Other studies, for mothers with learning difficulties, have shown that supportive parent training can improve childcare practices.[24] Evidence suggests that enhanced carer supervision can help reduce injury risk to children.[25;26] Parenting interventions have the potential to reduce poor maternal mental health and increase maternal self efficacy,[27;28] to improve maternal-child interactions,[29] and to change child behaviour, especially behaviour that is challenging or could place the child at risk of injury.[27;30;31] Parenting interventions can reduce injury risk either through these mechanisms, or through increased parental knowledge of safety practices,[32] improvement in the quality of the home environment,[33] or through the use of home

safety practices such as having a fitted and functioning smoke alarm, using stair gates or keeping sharp objects safely.[34;35] Parenting programmes have shown reductions in injury risk taking behaviour in primary school aged children.[36] Health visitor interventions to support parents can reduce injury rates in both prospective studies[37] and meta-analysis of randomised controlled trials.[38] Meta-analysis of parenting interventions, primarily conducted in high-risk or disadvantaged families, have demonstrated significantly lower risks of injury, as measured by parental self-report of either medically or non-medically attended injuries.[39;40] Parents value programmes that enable the acquisition of knowledge, skills and understanding, and facilitate acceptance and support from other parents. Such outcomes reduce feelings of guilt and social isolation, increase empathy with children, and give confidence to cope with challenging child behaviour.[41] A child's medically attended injury represents a 'teachable moment' when parents are receptive to information regarding injury risk in their children.[42]

The features of parenting interventions that are most effective are becoming clearer. There is strong evidence that home safety education and the provision of safety equipment are effective in increasing a range of home safety practices.[39] A review of 'what works?' in parenting interventions has shown that interventions are more likely to be effective if they are delivered early in childhood, if intensity is proportional to need, if they include group activities where parents can benefit from the social aspect of working with peers, if they include formal programmes or manuals to maintain the consistency of the delivery of the intervention which should be delivered by trained staff, and if there is a focus on specific parenting skills and practical 'take-home' tips.[43] A review of the effectiveness of parenting support programmes in European countries where universal early intervention approaches tend to be used, suggests that positive outcomes can also be achieved when the programme is delivered by non-health workers or agencies.[44]

The cost effectiveness of parenting programmes has not been widely studied.[45] A recent systematic review of economic evaluations of child and adolescent mental health interventions demonstrated that most evaluations were small scale, had short time horizons for assessing outcomes and had limited reporting.[46] However, the cost effectiveness of parenting programmes has been established for group parenting programmes. A formal evaluation of Sure Start parenting programmes demonstrated improved child behaviour outcomes for modest cost and considered the programme value for money.[47]

Justification for this proposal

Parenting interventions, usually delivered as part of a programme to improve a range of child and family outcomes, appear to be effective in reducing self-reported or medically attended injuries in young children.[48] Due to the range of positive outcomes associated with the programmes, such as improved child behaviour, maternal self-efficacy or maternal-child interactions, it is unclear whether one of these outcomes is more effective in reducing child injury than another. We know that injury prevention education alone has not shown reduction in injury occurrence[35] but the hypothesis that injury prevention education in the context of a parenting programme may be effective remains to be tested. Furthermore, it is unclear whether group based programmes, delivered outside of the home can achieve reductions in injury occurrence similar to intensive one-to-one home based programmes. Evidence suggests that RCTs of home safety education can successfully recruit parents of recently injured children,[49;50] and that parents are interested in learning first aid.[51] We therefore propose to develop a parenting programme that provides injury prevention education through the delivery of first aid and safety training tailored to the stages of preschool child development and delivered to groups of parents in a community setting. We propose to test the feasibility of delivering that programme with a view to a future large scale randomised controlled trial.

4. Aims and objectives

4.1 Aim
To develop and test the feasibility of delivering a Children's Centre based parenting programme to prevent recurrent unintentional home injuries in children aged 0-4 years; compared to normal care for such children

4.2 Objectives
1) to develop a health professional delivered parenting programme
2) to assess the acceptability of the parenting programme to parents and professionals
3) to assess the feasibility of delivering the parenting programme
    a. to assess recruitment and retention of parents within the trial
    b. to assess compliance with the intervention during the follow up period
    c. to determine the training, equipment and facilities needed for delivery of the parenting programme
    d. to assess the collection of primary and secondary outcome measures
    e. to determine which information to collect on 'normal care'
    f. to assess which relevant resource utilisation / costing data needs to be collected
    g. to produce estimates of effect sizes to inform sample size estimation for the full trial

5. Study design
A multi-centre study using a cluster randomised controlled design will test the feasibility of delivering a parenting programme developed to prevent recurrent injuries occurring in the home for preschool children. The study will be based in Bristol and Nottingham.

5.1 Experimental group
The experimental arm of the trial will be 'normal care' plus a parenting programme. The parenting programme will be developed in collaboration with Parenting UK (a parenting programme development organisation). Engaging parents in a parenting programme following injury in their child may be difficult since the injury may result in feelings of stigmatisation, guilt or concern that the injury is believed to be intentional. Our programme will contain both home safety education ('keeping your child safe') and first aid advice as methods of primary and tertiary injury prevention. Unpublished evidence from local injury prevention projects in Gateshead and Bristol suggest that parents are interested in learning first aid and willing to attend a group to do so. The emphasis on first aid advice and safety training is hoped to enhance acceptability and diffuse any negative feelings generated by being identified for participation in the programme. Interest in learning first aid is hoped to stimulate further interest in injury prevention and parenting to reduce injury risk. The programme will be delivered in Children's Centres by **a Health Visitor and co-facilitator**, to groups of parents.

The parenting programme is likely to contain elements of existing parenting programmes that may reduce injury risk, for example, those intended to enhance parental self-efficacy and well being, improve parent/child communication, and improve child behaviour through the increased use of positive reinforcement, and the enablement of setting and maintaining boundaries.[52] Evidence-based safety components are likely to include home safety education, assessment of home hazards, guidance on types, sources and fitting of home safety equipment and tailoring advice to both the home context and understanding how a child's injury risks change as the child grows and develops (anticipatory guidance).[53]

Families in the experimental group will be invited to participate in 1 to 1 interviews after delivery of the parenting programme to explore parents' views and experience of the programme.

5.2 Control Group
The control group will receive 'normal care'. In both Bristol and Nottingham, Health Visitors are routinely sent details of children within their geographical area of responsibility that have sustained

a medically attended injury, whether at A&E, or NHS Walk-in Centre. Usually the notification is sent by fax either on the same day as the injury or on the next working day. It is usual practice that following receipt of such notification the Health Visitor Team may take a range of actions determined by the circumstances of the event and the Health Visitor's understanding of the needs of that family. Four different actions can be considered as part of 'normal care'; telephone contact, face-to-face contact, referral to services, or no action. The use of each of these four possibilities will vary between locations and between Health Visitor Teams. For example, some Health Visitors may take every fax notification as an opportunity to make contact with a family, especially in deprived or multicultural communities, where parent initiated contact with Health Visitors is low. In other areas, workload or knowledge of families will mean that Health Visitors are much more selective of those families that they will contact.

5.3 Inclusion and exclusion criteria

Children's Centres **/ Health Visitor teams**
Inclusion criteria: In both Bristol and Nottingham Children's Centres **are linked to named Health Visitor teams**. Children's Centres will be ranked according to the number of children aged 0-4 years who have attended the local Children's Accident and Emergency department in the previous year, and had a postcode that would have entitled them to access that Children's Centre. The four Children's Centres with the highest rankings in each city (i.e. centres with largest number of injury notifications) **where the Health Visitor team has the capacity to participate**, will be invited to participate in the study. If one of these Children's Centres is unable to participate then the Children's Centre with the next highest ranking **and their Health Visitor team** will be invited.
Exclusion criteria: Children's Centres **and their linked Health Visitor team** will be excluded if they are already involved in other injury prevention **research studies**.

Parents
Inclusion criteria: The parents/carers will be eligible for recruitment if they have a child under 5 years of age who has sustained an unintentional physical injury or ingestion in the home (or within the boundary of the home and garden/yard), that resulted in seeking medical attention from a health professional at an NHS Walk-In Centre, Minor Injuries Unit or in an Accident and Emergency department in secondary care during the recruitment period. Parents/carers must be living at an address within the geographical or general practice catchment area of a Children's Centre participating in the study.
Exclusion criteria: Children suffering suspected or confirmed intentional injuries will be excluded. Should an injury originally considered to be unintentional be later discovered to have been intentional, then routine referral processes for safeguarding would be activated. That parent would not be asked to withdraw from the programme, but data from that child will not be included in the analysis. Parents/carers who are unable to understand written and spoken English will be excluded from the feasibility study.

5.4 Randomisation and allocation
The unit of randomisation will be the Children's Centre. We will recruit a total of 8 Children's Centres; four in Bristol and four in Nottingham. Those agreeing to participate will be stratified by study centre (two strata) and randomly allocated within strata to treatment arm using a remote automated system available through the Bristol Randomised Trials Collaboration (BRTC) based at the University of Bristol. Two Children's Centres in each study centre will be randomly allocated to the intervention arm, and two Children's Centres in each study centre will be allocated to the control or 'normal care' arm.

To reduce post-randomisation recruitment bias, informing the Children's Centres and Health Visitor Teams of their allocation to intervention or control arms will be delayed until after recruitment of families has been completed. If allocation to intervention or control arm is indicated to the Health Visitor Team / Children's Centre at the time of recruitment, we anticipate two potential post randomisation recruitment biases; a) the Health Visitor Team could choose not to offer entry to the study if the team knew that the family were unlikely to participate or continue in the programme once commenced, and b) a family may be influenced in their decision to participate if they knew in

advance that their Children's Centre was, or was not, offering the FAST Parents programme. Therefore once recruitment has been completed Health Visiting Teams and Children's Centres will be informed of their allocation.

6. Ethical aspects

6.1 Ethics committee approval

Approval will be sought from a Type 3 committee; South West 3 REC (Bristol Central) based at University Hospitals Bristol.

6.2 Participant consent

Parents asked to participate in this research are entitled to choose whether or not to take part. Their decision will be voluntary and they will be competent to understand what is involved. Consent forms will be designed to assure the protection of their rights.

In the eight Children's Centre areas participating in the study receipt of a notification of a medically attended injury by the Health Visitor Team will result in the team making a decision on 'normal care'. The families will be contacted after completion of 'normal care' to advise them that their local Children's Centre is participating in a study to follow up pre-school children who have had an injury and that some Children's Centres will be offering first aid advice courses for parents. Parents will be asked if their details can be passed to the research team who will tell them more about the study. Refusal to participate in the programme will not prevent access to any other routinely available services, although will be recorded as an outcome of the feasibility study along with the reason for refusal where this is provided. The Health Visitor Teams will be given a list of the inclusion and exclusion criteria to enable them to determine eligibility of families for participating in the study.

Identification of eligible families may occur through alternative routes when it is inappropriate for Health Visitor teams to undertake recruitment themselves (e.g. reduced capacity within the team). Identification may occur via Emergency Departments (ED) where generation of the notification letter occurs. Eligible families will be contacted either by telephone by a member of the ED team and asked if their details can be passed to the research team who will tell them more about the study, or by letter sent by the ED team to the parents with a reply slip to the research team. Parents will not be approached during their ED visit, but afterwards. The number of parents approached but declining to have their details passed to the research team, or failing to return a reply slip, will be noted, together with the reason for refusal where this is provided. The member of the ED team will be given a list of the inclusion and exclusion criteria to enable them to determine eligibility of families for participating in the study.

Identification may also occur via primary care as the notification letter will routinely be sent to the child's General Practitioner. Eligible families will be contacted by letter sent out by a member of the primary care team who will be provided with a list of the inclusion and exclusion criteria to enable them to determine eligible families. General Practices linked to the participating Health Visitor teams will be invited to support the study. A template letter will be provided for sending to eligible families that allows the surgery to add their own header / logo. The letter, sent from their General Practitioner, will introduce the FAST study, enclose the parent information sheet, and ask that if the parent is interested in participating they should telephone the local FAST Research Fellow (a mobile phone number will be provided) or return a reply slip in a reply paid envelop. Parents will be able to choose whether or not to respond to the letter.

Families that agree to be contacted by the research team will receive both written and verbal information. The research fellow will send a study information sheet and consent form to the family. One week later the researcher will contact the family and ask permission to visit. If the family agrees the researcher will send baseline measure questionnaires prior to the visit.

Parents living within the catchment areas of intervention and control Children's Centres will be invited to participate in the study. At the visit the researcher will verbally explain the study. The explanation will cover all the elements specified in the written information provided for the participant. The participants will be informed of the aims, methods and participation requirements of the study. They will be informed that the study is intended to help understand children's behaviour after injuries and reduce the risk of further injuries. The researcher will explain that some families will have the opportunity to attend a programme will provide the opportunity to gain first aid advice and safety information in a 'hands-on' and interactive manner, but because this is a new programme that has not previously been tested the likelihood of success is unclear. Parents will be informed that we are interested in their experience of participating in the study and the programme to help us understand how they could be improved. Parents will be advised that there are no anticipated risks to participation.

The participant will be given every opportunity to clarify any points they do not understand and if necessary ask for more information. At the end of the discussion the participant will be given time to reflect. The participant will be informed that they are at liberty to withdraw their consent to participate at any time, without prejudicing any future medical care.

The researcher will obtain the participants freely given written consent before participating in the study. The consent form will assure the participant of the confidentiality of the data collected. Participants attending Children's Centres in the experimental arm of the study will be asked permission that the interviews conducted after the parenting programme can be audio recorded and to publish anonymised quotations from the study. With the agreement of the participants, the data will be anonymised and stored in accordance with data protection guidelines and University of the West of England, Bristol good practice. Both the researcher and the participants will retain copies of the signed consent forms.

Families who drop out after initially agreeing to participate will be asked about their decision and any information offered will be recorded as an outcome of the feasibility study.

We aim to recruit 12 families from each of four Children's Centre areas in Bristol (48 families) and from each of four Children's centre areas in Nottingham (48 families). We expect that between recruitment and start of the intervention some families will drop-out of the study. We hope that about 8 families per Children's Centre will remain in the study by the start of the intervention period (total = 64 families).

7. Plan of investigation and scientific procedures

7.1 Delivery of the intervention

Health Visitors from Bristol and Nottingham will be recruited to deliver the FAST parent programme in the two Children's centres in each city during the feasibility study. They will be trained by Parenting UK to deliver the programme supported by **a co-facilitator**. The Nursery / Children's Nurse or Health Visitor in the Health Visiting Team at that Children's Centre **will be invited to support delivery of the intervention, but if unable, a Health Visitor and co-facilitator independent of the Health Visitor teams participating in the study will be available to deliver the intervention**. Crèche facilities will be provided to enable attendance at the parenting group and refreshments will be provided for parents.

To ensure fidelity in delivery of the programme the researcher in each study centre will attend the training in how to deliver the programme and will observe and record fidelity of programme delivery. In addition, Health Visitors delivering the programme will participate in teleconference discussions with each other and Parenting UK after the delivery of each session to raise issues, concerns and ensure the programme is delivered in as consistent a manner as possible.

Furthermore, the health economist (JP) will observe a selection of sessions to ensure that all resource costs are correctly included in the economic evaluation.

7.2 Post intervention data collection

7.2.1 Qualitative data collection – Part 1
After completion of the FAST Parent programme experienced qualitative researchers in the research team (JI and CM) will conduct interviews with parents in the experimental arm of the trial that agree to be interviewed to explore their experience of participating in the programme. Interviews will take place at their home or another convenient location. Interviews will also take place with members of the Health Visitor Teams, the Children's Centres, and the Project Manager, and will aim to evaluate the process of the delivering the parenting programme and assess its feasibility for scaling up to a main trial. Interviews will be digitally recorded, transcribed, anonymised and analysed using thematic analysis techniques of coding the transcripts and developing themes and sub-themes. A qualitative analysis package, such as NVIVO8, will facilitate the analysis.

7.2.2 Quantitative data collection
Once the programme intervention has been delivered, a six month period of follow up of families in the experimental and control arms of the trial will commence. All families will be given a diary to record any injuries to the study child (and injuries to any siblings under the age of 5) in the following 3 months. A full explanation of how to complete the diary, including a clear definition of what constitutes 'an injury' will be given, together with a mobile telephone number to call in case of any queries.

At three months into the follow up period, parents will be contacted by the researcher to arrange a visit. A child behaviour questionnaire will be sent in advance of the visit. At the visit the researcher will collect the behaviour questionnaire, the first injury diary and provide a second diary to be completed as for the first diary, over the next 3 months.

At the end of the six months follow up period, the researcher will contact the family and ask permission to visit. Prior to the visit secondary outcome questionnaires will be sent to the family. At the visit the researcher will collect the last injury diary for the index child and will collect data for all the secondary outcome measures, offering support to complete the questionnaires if required.

The primary purpose of the home visits during the follow up period is to achieve high response rates for questionnaire outcome information during the feasibility study and home visits do not form part of the intervention.

7.2.3 Qualitative data collection – Part 2
After completion of the six month home visit, parents in the intervention and control arms of the study will be offered a telephone interview (conducted by JI and CM) to collect information on their experience of participation in the study from initial contact through to completion of follow up. Interviews will be digitally recorded, transcribed, anonymised and analysed using thematic analysis techniques as for the face to face interviews.

7.3 Interview conduct
Topic guides will be used in order to assist questioning during both face-to-face and telephone interviews. These guides are designed to direct but not dictate data collection and will incorporate considerable flexibility to allow participants to introduce new issues not anticipated by the researchers. The topic guides will be modified as necessary throughout the course of the study to reflect findings as they emerge. The researcher will use open-ended questioning techniques to elicit participants' own experiences and views, and participants will be asked to provide examples. Face-to-face interviews for both parents and professionals are anticipated to last approximately 30 minutes. Telephone interviews may be briefer than 30 minutes.

7.4 Outcome measures

The outcome measures have been chosen to identify whether the parenting programme can reduce injury occurrence and the mechanism by which any change occurs.

7.4.1 Primary outcome measures
The number of injuries to the study child or preschool siblings occurring in a home setting, where 'home' includes any garden / yard (i.e. within the home boundary) during the period of follow up. Injuries occurring in the child's own home will be recorded separately to those occurring in other people's homes (e.g. relatives, friends or neighbours). Two measures will be collected:

a) *parent-reported medically attended injuries to the study child*
b) *parent-reported medically attended injuries to the preschool siblings of the study child*

Where 'medically attended' is defined as injuries that resulted in the parent/carer taking the child to A&E, to a Walk-In Centre, or to the GPs surgery

Validation of parent-reported medically attended injuries will be conducted by the researcher in Bristol and Nottingham, using A&E, Walk-in Centre and Primary Care records. The Health Visitors of all children attending an A&E in Bristol and Nottingham are routinely sent a notification of attendance for injury, and this will provide an additional method of validating parent-reported injuries requiring medical attention in A&E.

We will ensure that at recruitment to the study, parental consent will be requested to contact the General Practitioner of the index child and their siblings, and to search Walk-In Centre and A&E records for attendance.

7.4.2 Secondary outcome measures
Two further injury measures and five non-injury measures (to provide data on potential mechanisms of injury prevention) will be collected. Parents will be offered a voucher (Mothercare or similar) at both baseline and at the end of the six month follow up period to encourage completion of secondary outcome measures. Secondary outcome measures will include:

a) *parent-reported injuries to the study child that did not require medical attention* (e.g. those treated at home or not requiring treatment)
b) *parent-reported injuries to the preschool siblings of the study child that did not require medical attention* (e.g. those treated at home or not requiring treatment).
c) *Child behaviour*. We will use the Strengths and Difficulties Questionnaire (SDQ) for children over the age of 2 years, **and the Infant Behaviour Questionnaire – Revised, Very Short Form for children aged 3-12 months.**
d) *First aid knowledge*. The four-item Nottingham Safe at Home Project Questionnaire will be used to assess parental knowledge of how to respond to four common first aid scenarios (burns, cuts, choking and bleach ingestion)
e) *Parent-reported safety practices and possession and use of safety equipment*. We will use the home safety measure validated during a trial of the effectiveness of the provision of home safety equipment to prevent injuries conducted by one of the applicants (Denise Kendrick).[54;55]
f) *Maternal wellbeing*. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS) is a new well validated measure of mental wellbeing which has proved sensitive to change over the course of three different parenting programmes.[56]
g) *Parenting measure* – The Parent Supervision Attributes Profile Questionnaire[57] – a 29 item measure assessing protectiveness, supervision, tolerance for children's risk taking and belief in fate as a determinant of children's safety.

7.4.3 Process outcome measures

a) *Acceptability* of the intervention will be assessed through feedback from parents at the end of each session of the parenting programme to identify features of that session that were most and least enjoyable and most and least helpful. Acceptability will be explored during the face-to-face and telephone qualitative interviews with parents and professionals

b) *Feasibility of delivering the intervention* will be assessed by the interviews with health professionals delivering the FAST Parent programme and also by documenting process measures including
   i. the number of sessions delivered in each centre
   ii. the duration of each session
   iii. the number of attendees at each session
   iv. the extent to which each session followed the "curriculum" for that session
   v. the number of sessions attended by parents
   vi. the completion of any home based activities for participating families, e.g. completion of a home safety assessment.
c) *Recruitment* to the feasibility study will be assessed by recording
   i. the numbers of Children's Centres and families eligible to participate
   ii. the numbers approached to participate and the numbers agreeing to participate.

   Children's Centres and families choosing not to participate will be asked to complete a brief questionnaire to determine reasons for non-participation.
d) *Retention* in the feasibility study will be assessed for both Children's Centres and families.
e) *Collation of information on 'normal care'* by Health Visitor Teams on receipt of an injury notification.

7.4.4 Economic evaluation measures

a) *Resource use – costs.* Programme delivery will be physically observed by the researcher conducting the economic analysis and monitored against a standard checklist of usual resource use or cost categories in economic evaluations (for example, programme development costs, recruitment costs, programme delivery, materials and overhead costs).[58] NHS costs relating to use of A&E, Minor Injuries Units or General practice visits due to an injury during the follow up period will be included using published cost-per-visit estimates.
b) *Utility outcomes.* Incremental cost per unit of change in score for outcome tool and confidence intervals will be calculated following the approach used by Tudor-Edwards and others in a recent rigorous economic evaluation of a similar programme.[47] The resultant incremental cost effectiveness ratio (ICER) will be assessed for feasibility in measuring the cost-effectiveness of the parenting programme in the main study.[59]

7.5 Data analysis

7.5.1 Quantitative analysis

Descriptive statistics (means, standard deviations and non-parametric measures where appropriate) will be used to describe the characteristics of the families, centres and children along with the primary and secondary outcome measures.

At recruitment to the trial, parents will be asked to report the number of siblings (both pre-school, and school age or older) in the index child's household. If another pre-school sibling in the same family is injured during the recruitment period, the family will only be recruited to the study once. Through this data collection at recruitment, the research team will have a denominator for analysis of injuries in the siblings of the index child. The numerator for injuries in siblings will be identified through parental report and objective measures such as attendance at A&E and Walk-In Centres as detailed above. It will therefore be possible to calculate a rate of injury occurrence per unit period of follow up in the index children and in their siblings.

We know that the number of siblings a child has is associated with the risk of injury occurrence. The greater the number of siblings and having older siblings are both factors associated with increased risk of injuries in a child. Clustering of injuries within families is likely. The primary outcome measures of injuries requiring medical attention and those not requiring medical attention will therefore be analysed using hierarchical modelling, using the child as the unit of analysis, in recognition of the fact that these variables are not independent.

Outcome measures such as child behaviour or use of safety equipment will be assessed although the emphasis of the analytical strategy will be on point estimates of differences and their associated confidence intervals rather than p-values. Between-group comparisons will be conducted using multi-level modelling and will be used as an exploratory technique in preparation for a larger trial.

The injury diaries and behaviour questionnaire data will not be used in any form of interim analysis. All injury data will be pooled for analysis at six months.

7.5.2 Qualitative analysis
All audio-recorded data will be fully transcribed, anonymised, checked for accuracy and then imported into a software package, NVivo8. Analysis will begin shortly after data collection starts, will be ongoing and iterative. Analysis will inform further data collection; for instance, analytic insights gathered in earlier interviews will shape the questions covered during later interviews. Thematic analysis will be used to scrutinise the data in order to identify and analyse patterns and themes of particular salience for participants and across the dataset using constant comparison techniques. Firstly the transcripts will be read several times to gain familiarisation with the data and initial ideas noted. The transcripts will then be examined on a line-by-line basis with inductive codes being assigned to the segments of the data that provide insight in to the participants' views and understanding of their experiences and assist in the development of an initial coding frame. New data will be compared initially to the previous data and then to the properties of emerging categories that contain the main themes. The process of constant comparison will allow for the generation of new themes, reclassify themes and incorporate themes within other themes. The coding frame will be modified, if needed as the analysis develops. The analysis will enable the research team to arrive initially at a descriptive account which will be developed into a theoretical account in the light of existing theoretical and applied literature.

Trial data and documentation will be retained securely by the principal investigator in Bristol according to local codes of research conduct (6 years in Bristol).

7.6 Researcher safety
The researchers will follow the University of the West of England's Researcher Safety Guidance when conducting any field work away from university premises. This will involve undertaking an assessment of risk prior to arranging an interview, prior informing a designated person from the study team the details of an interview, and calling in when the interview has been completed at an agreed time. If the designated person is not contacted at the agreed time, the designated person will contact the researcher's mobile phone. If there is no answer, the designated person will phone the participant's house. If contact has still not been made, the designated person will phone the police and ask them to visit the participant's house.

7.7 Research governance
The sponsor for the research will be the University of the West of England, Bristol. A research fellow (Project Manager) will be appointed in both Bristol and Nottingham to oversee the day to day running of the project. The Project Manager will be supervised by Julie Mytton in Bristol and Caroline Mulvaney in Nottingham.

Governance of the feasibility study will be through a management group comprising the co-applicants and collaborators. The management group will meet monthly at the beginning and end of the study and bimonthly during the study. Meetings will be in person where possible and by teleconference were necessary. The management group will oversee the progress of the study and adherence to timescales and the project plan. Not all co-applicants will be required for every management group meeting. The principle investigator (JM) will report to a Trial Steering Committee (TSC) that will meet four times during the course of the study. The requirement for a Data monitoring and Ethics Committee (DMC) will be the decision of the Chair of the TSC. As this is a feasibility study, and there are no plans for interim data analysis that could potentially lead to

early closure of the trial, we consider the trial to be low risk and do not anticipate the need for a DMC.

7.8 Writing up and dissemination

Findings of the study will be made available to the participating families. They will also be disseminated to the Parents Advisory Group (see below) and to Health Visiting teams and Children's Centre managers at intervention and control sites. The findings of the feasibility study will be written in non-specialist language so that they may be accessible to families and a range of professionals. Any quotations from participant or professional's interviews will be anonymised prior to inclusion in the study report.

We anticipate that a subsequent main trial would generate outcomes of interest to the health community, local authorities, the public and to academics. Care would be required not to disseminate the findings too widely after the feasibility study before a main trial; otherwise recruitment to the main trial may be compromised. We would however provide local feedback in Bristol and Nottingham and would prepare papers for publication and a UK conference presentation.

8.0 Service Users

The parent perspective on the development, implementation and management of this project are recognised as very important to the success of the research. The ability to engage parents in the programme in a non-stigmatising way is vital to the project's success. The research team have therefore elected to work with a Parents Advisory Group rather than one or two named parents. We have identified a group of parents that currently regularly meet at a Children's Centre in Bristol. One of these parents has worked with Dr Jenny Ingram on a previous project, and formally provided feedback during the development of this study. Dr Ingram would help facilitate the Parent Advisory Group to advise the research team, and will feedback on a regular basis to the management group and to the Trials Steering Committee. Feedback will either be by direct representation by a parent at the TSG meetings or through the facilitator (JI).We anticipate the group would meet at least four times during the course of the study. We believe that a Parent Advisory Group is a valuable resource which provides a critical mass and collective support to express parent's perspectives.

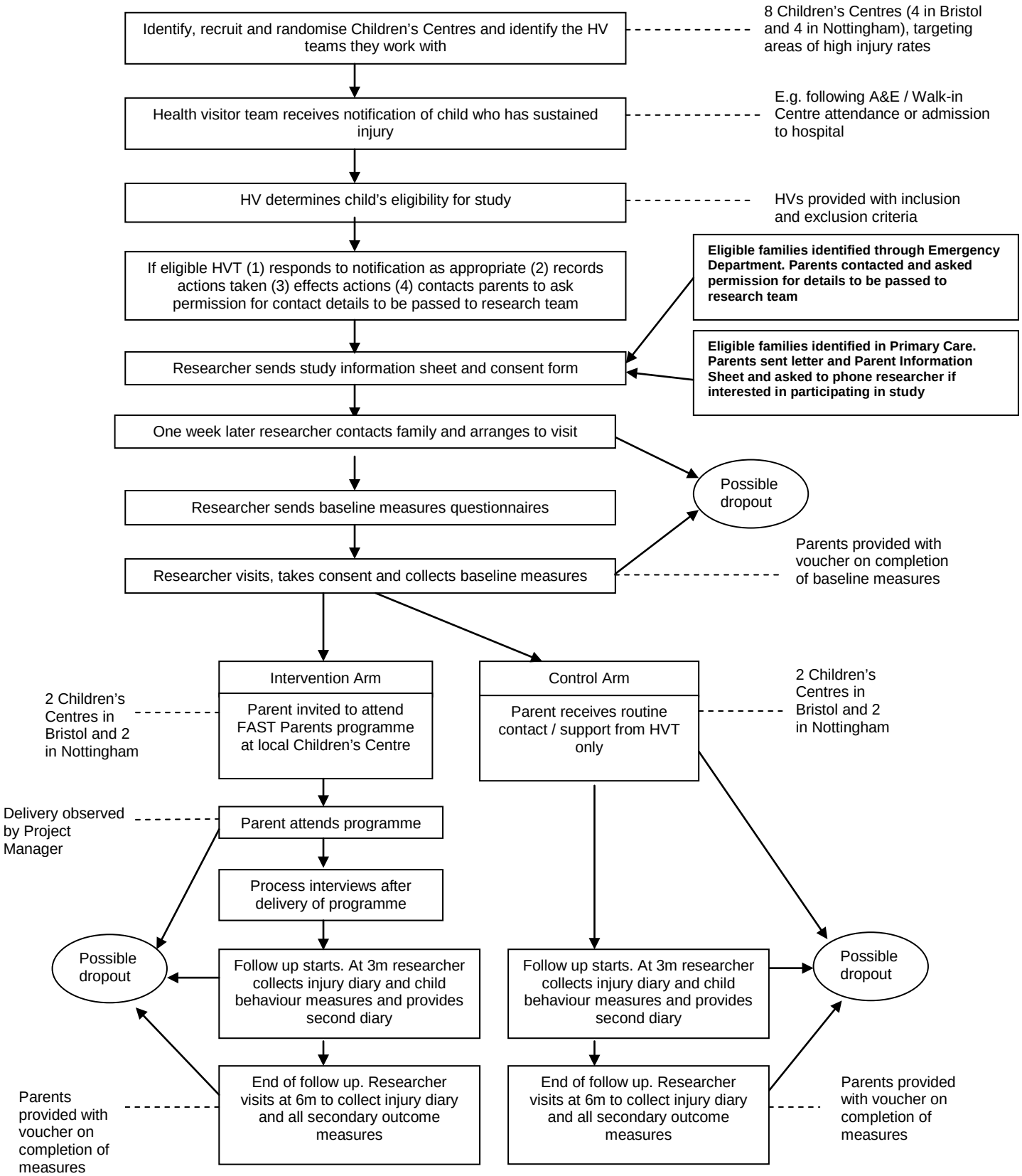
The group have advised us on the preparation of the information sheets and consent forms. They will advise on the study process to help maximise acceptability, engagement, retention and compliance. We will ask them to help us prepare the final reports of the feasibility study in an accessible format for participating families.

There is a risk that lay advisors to research projects may lack confidence in their role and their ability to influence decision making. The University of the West of England, Bristol has an innovative new system to support the participation of lay research partners in projects. The system not only helps researchers identify lay partners where necessary, but can help fund expenses to enable lay partners attend meetings, and help them gain confidence in contributing their perspective by offering them formal status as a research partner by providing them with a staff card, access to the UWE library, ATHENS log in etc. We will be working closely with this group to enable successful parent inclusion in the research management and offer these benefits to the parents leading our advisory group.

Project timetable and milestones

Calendar year		2011												2012											
Study year		Study Year 1												Study Year 2											
Month number	-3	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Month		J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Study progress																									
Ethics and local R & D approval																									
Establish parent advisory group																									
Commission parenting programme development organisation																									
Appoint research fellow s for project manager posts (Bristol and Nottingham)																									
Update systematic review of parenting programmes and injury prevention																									
Systematic review of barriers and facilitators to parent engagement in programmes																									
Selection & randomisation of Children's Centres																									
Advisory groups of parents, HVs and Children's Centre staff																									
Parenting organisation develops FAST Parents programme content																									
Parenting organisation develops and produces materials & equipment for programme																									
Parenting organisation trains lead HVs and Project Managers in delivery of programme																									
Training of health visitor teams to identify and invite eligible parents & collect process measures																									
Prospective recruitment of parents at CCs starts as soon as HVTs are trained																									
Project Manager collects baseline measures from parents as recruited																									
Delivery of FAST Parents Programme in CCs (ends mid Sept) [non observed time]																									
Distribution of 3 month injury diary (mid Sept) [start of 6m observed time]																									
Collation of process measures (e.g. Number of sessions, duration, attendance, drop out etc)																									
Analysis of process measures																									
Semi structured interview s w ith parents w ho have been on programme																									
Semi structured interview s w ith HVTs and managers of CCs																									
Interveiw s from HVTs and managers transcribed and analysed																									
Project Manager visits family, collects 1st injury diary, a behaviour measure, & distributes 2nd diary (mid Feb)																									
Project manager prepares interim report and drafts final report up to completion of programme delivery																									
Project Manager collects 2nd injury diary & post intervention measures (mid May) [end of observed time]																									
Semi structured interview s w ith parents begin after parents had opportunity to use injury diary																									
Parents interview s transcribed and analysed																									
Analysis of post intervention measures																									
Writing up report and preparation of findings for dissemination																									
Feedback findings to parents advisory group, HVTs & CC staff																									
Governance arrangements																									
Project management group meetings (n=15)																									
Trial Steering Committee (TSC) meetings (number and timing to be advised by Chair)																									
Parent advisory group meetings (meets prior to TSC to allow feedback)																									
NETSCC Monitoring meeting (timing to be advised)																									

Flow diagram



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