

# The feasibility of using a parenting programme for the prevention of unintentional home injuries in the under-fives: a cluster randomised controlled trial

Julie Mytton,<sup>1\*</sup> Jenny Ingram,<sup>2</sup> Sarah Manns,<sup>1</sup> Tony Stevens,<sup>3</sup> Caroline Mulvaney,<sup>3</sup> Peter Blair,<sup>2</sup> Jane Powell,<sup>1</sup> Barbara Potter,<sup>4</sup> Elizabeth Towner,<sup>1</sup> Alan Emond,<sup>2</sup> Toity Deave,<sup>1</sup> James Thomas,<sup>5</sup> Denise Kendrick<sup>3</sup> and Sarah Stewart-Brown<sup>6</sup>

<sup>1</sup>Faculty of Health and Applied Sciences, University of the West of England, Bristol, UK

<sup>2</sup>School of Social and Community Medicine, University of Bristol, Bristol, UK

<sup>3</sup>Division of Primary Care, University of Nottingham, Nottingham, UK

<sup>4</sup>Wellspring Healthy Living Centre, Bristol, UK

<sup>5</sup>Institute of Education, University of London, London, UK

<sup>6</sup>Division of Health Sciences, University of Warwick, Coventry, UK

\*Corresponding author

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## Scientific summary

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# Scientific summary

## Background

Unintentional injury is a major cause of death and disability in children globally, and the leading cause of preventable death in children over the age of 1 year in the UK. The majority of injuries to preschool children occur at home, with the type of injury varying with age and developmental stage of the child. Half a million children aged 0–4 years attend UK hospitals every year owing to a home injury, representing 78% of all injuries occurring to children in this age group. Injuries occur inequitably, with the most disadvantaged being at greatest risk. Children who have sustained one injury are at increased risk of further injuries. The majority of the injury events occurring to preschool children happen in predictable patterns that allow opportunities for prevention.

Parenting programmes are short-term interventions to promote changes in the behaviour of parents that support children. They have been shown to lead to better outcomes in children with behaviour difficulties and to improve children's educational attainment, as well as mental health and well-being outcomes in children and their parents. Such programmes can help parents understand the negative impact of paying attention to problem behaviours, encourage positive discipline practices and strengthen positive communication between themselves and their child.

It is known that parenting programmes, when delivered on a one-to-one basis and in the home, can reduce injuries in preschool children, but it is not known whether a group-based parenting programme delivered outside the home could have similar positive effects. The NIHR Health Technology Assessment (HTA) programme therefore commissioned research to develop a health professional-delivered parenting programme to prevent recurrent injuries in children under 5 years of age and test the feasibility of evaluating this through a cluster randomised controlled trial (RCT). The programme was to be offered to parents of children who had already sustained a significant injury within the previous 12 months.

## Objectives

- (a) To develop a parenting programme to prevent recurrent unintentional home injuries in preschool children.
- (b) To develop a tool for parents to report unintentional home injuries occurring to their preschool children.
- (c) To assess the feasibility of delivering and evaluating the parenting programme through a cluster RCT, specifically.
  - To assess methods for the recruitment and retention of parents.
  - To determine the training, equipment and facilities needed to deliver the programme.
  - To establish appropriate primary and secondary outcome measures and methods for collection.
  - To determine how 'normal care' in a comparison arm should be defined.
  - To determine the resource utilisation and costing data that would need to be collected for the cost-effectiveness component of a main trial.
  - To produce estimates of effect sizes to inform sample size estimation for a main trial.

## Methods

### *Development of the intervention*

We conducted two systematic reviews to inform the development of the parenting intervention. The first was an update of a Cochrane Collaboration review of parenting interventions for the prevention of unintentional injuries in childhood, to determine if new evidence had emerged since the review was originally conducted in 2007. The second review was a synthesis of qualitative evidence on the barriers and facilitators to parental engagement in parenting programmes from parents', deliverers' and researchers' perspectives.

We commissioned a voluntary sector organisation with experience of parenting programme development, Parenting UK (now known as Family Lives), to develop a group-based parenting programme with the potential to prevent injuries. We were concerned that asking parents to attend a parenting course after their child had sustained an injury may cause parents concern that the injury was believed to have been intentional, or could create feelings of stigma or inadequacy. To counter this, we asked Parenting UK to incorporate first aid and home safety advice into the programme, as we know that parents are interested in learning first aid. We worked with Parenting UK to produce the programme together with the resources and training materials necessary to deliver the programme. We called the programme the First-aid Advice and Safety Training (FAST) parent programme.

### *Development of a tool to collect parent-reported child injuries*

Children sustaining injuries in the home may be treated at home with first aid, taken to a community health-care provider (such as their general practitioner or a NHS walk-in centre), or taken to an emergency department. In order to capture outcome information from such a range of different settings, we proposed that parent-reported information on injuries was necessary. We developed a tool in the form of an injury calendar to collect parent-reported information on home-based injuries occurring to all of the preschool children of parents participating in the feasibility study. We developed the tool working with an advisory group of six parents, based at a local children's centre.

### *Feasibility study*

The feasibility study was a multicentre, cluster randomised, unblinded trial comparing the FAST parent programme against usual care, with a sample of 96 parents. Eight children's centres would be randomised to either intervention or control. In intervention children's centres, we planned that local health visitors would deliver the programme to groups of up to 12 parents. Parents were eligible for recruitment if they had a child under 5 years of age who had sustained an unintentional physical injury in the home (or within the boundary of the home and garden/yard) for which they sought medical attention from a health professional at a NHS emergency department, minor injuries unit or walk-in centre during the recruitment period or in the previous 12 months, and were living in the geographical catchment area of a children's centre participating in the study. We proposed to recruit parents via health visitor teams, upon receipt of notification of attendance for an injury at NHS care providers.

The primary outcome measure was parent-reported medically attended injuries in the index child and any preschool siblings sustained during a 6-month period of observation. Secondary outcome measures included parent-reported non-medically attended injuries, parental well-being, parent supervision, child behaviour, first aid knowledge, and home safety equipment and practices. Parent reports of injuries were validated against emergency department, NHS walk-in centre and general practice records. As the feasibility study was not powered to detect differences between groups, planned analyses were limited to completion rates of questionnaires and frequencies.

### *Parameters for a cost-effectiveness study*

A process of formative monitoring and experience of programme development, training and delivery were used to develop a resource use checklist. Costs included were those associated with programme and training-the-trainer development, recruitment, delivery, overheads, equipment and materials.

Costs were categorised using four stages: development of the intervention (stage 0), planning and preparation for delivery (stage 1), delivery (stage 2) and maintenance and reinforcement (stage 3). Resource inputs and cost estimates from a funder perspective were derived based on the timing, quantity and frequency of resource use in 2011–12 prices. We used parent reported data from the injury calendar on NHS provider use to identify medical attention following injuries and thereby potential resource costs or savings to the NHS.

## Results

### *Development of the intervention*

An 8-week programme was produced, designed to be delivered in an acceptable, participant-friendly, incrementally progressive style. Each 90-minute session included parenting skills plus first aid and home safety advice focused around typical parenting situations, illustrated with injury risk scenarios. Parenting skills included understanding child development, parent–child communication, managing attention-seeking behaviour, using praise, setting and maintaining boundaries and having realistic expectations of your child. First aid response and prevention messages were interwoven with scenarios for burns and scalds, cuts and wounds, ingestions, choking, head injuries and managing the unconscious child. A 2-day ‘train the trainer’ programme was developed together with a trainer’s manual, a handbook for parent participants and a set of resources to be used during programme delivery.

### *Development of a primary outcome measure*

Working with the parent advisory group and a graphic designer, a slimline, month-to-a-view calendar, spiral bound and suitable for hanging on a wall, was designed for parents to record injuries occurring to their preschool children during the feasibility study. The calendar included participant identifiers, a definition of ‘an injury’, examples of how to complete the calendar, space to record the type of injury, the location within the home of the injury event, the action taken by the parent after the injury event (including NHS provider use) and space for free text if the parent wished to describe the injury event.

### *Feasibility study*

Our concerns regarding the ability to recruit parents of children who had sustained an injury appeared valid. Over 10 months, using four different strategies, we recruited 40 parents to the study. With agreement from the HTA we relaxed the eligibility criteria, making the programme available to any parent attending a children’s centre, and engaged a further 11 parents (hereafter referred to as ‘open invite’ participants). Fifteen parents completed the FAST parent programme and provided data at baseline and during follow-up. Completion of the programme was significantly greater (Fisher’s exact test,  $p = 0.002$ ) for participants using the ‘open invite’ approach (85%) rather than those recruited using the original eligibility criteria (31%). Once parents commenced the parenting programme, retention rates were high (80%).

Injury calendars were returned for 21 children offered the intervention and 11 children randomised to control. One hundred and fifty-one injuries were reported by parents over 145 child-months. The rate of any child injuries reported by nine parents who completed the parenting programme and returned injury calendars (either randomised or ‘open invite’ parents) was 1.7 injuries per child-month (69 injuries over 41 child-months), and in the children of six parents in the control arm was 0.5 injuries per child-month (31 injuries over 62 child-months). A high level of reporting of apparently very minor injuries in children of parents attending the programme may indicate some enhanced recall bias. The rate of medically attended injuries reported by nine parents who completed the parenting programme was 0.024 injuries per child-month (one injury requiring one episode of NHS provider use over 41 child-months) and in the children of six parents in the control arm was 0.016 injuries per child-month (one injury requiring four episodes of NHS provider use over 62 child-months). A range of secondary outcome measures was successfully collected.

The FAST parent programme had a largely positive evaluation from participant, deliverer and injury prevention expertise perspectives, and against parenting programme standards. In response to the evaluation, the programme was redeveloped to a 6-week format. Each 2-hour session would open with a discussion about the risk of sustaining a specific type of injury at different ages and stages of development. The session would continue with advice on appropriate first aid response. Discussions on how to prevent that injury would then allow a natural lead into parenting skills development. The redeveloped programme has been prepared ready for further evaluation.

### *Parameters for a cost-effectiveness study*

A resource use checklist was developed. Prototype resource use checklists, unit costs and total costs were developed for phases 0, 1 and 2 of the study. Overall, the average recurrent cost of one FAST parent programme at stages 1 (preparation) and 2 (delivery) was £7297 at 2011–12 prices. Feasibility costing indicates that the average cost per child of repeating the 8-week programme in its mainstream form with eight parents participating would be £912 at 2011–12 prices. The injury calendar records of NHS provider use together with validation records from emergency departments, NHS walk-in centres and general practice would provide information to cost NHS provider use during the follow-up period.

## Conclusions

### *Implications for a future trial*

A parenting programme that combines parenting skills, injury prevention and first aid advice, together with the resources required for delivery, has been developed, tested and refined following evaluation. While conducting this feasibility study a parenting programme for school-aged children [the Families and Schools Together (FAST) programme] has gained prominence in the UK. Therefore, any further evaluation of our parent programme would need to continue under a new name to avoid confusion for parents and practitioners.

A tool to collect parent-reported home injuries in preschool children and associated NHS provider use has been created and shown to be an acceptable method for parents to complete. Parents participating in the intervention arm of the study appear to be at risk of enhanced recall bias due to an increased awareness of injuries. Support to complete the injury diaries correctly would be important in a future trial, for example amendments to the instructions on the calendar and to the way the calendar is introduced to parents to help parents in both arms know when and when not to record an injury. Not all parents will return injury calendars, and therefore accessing records from NHS providers would be required in a main trial so that medical attention for injuries is not missed, and to validate the reports of NHS provider use recorded on injury calendars.

The planned recruitment of parents of children who had sustained an injury within the previous 12 months was not feasible. A faster rate of participant engagement through the 'open invite' route suggests that in a future trial it would be better to target families before the injury event. The social patterning of injury occurrence means that recruitment through children's centres in deprived areas would still target higher-risk families. Participants identified via the 'open invite' route were statistically significantly more likely to complete the course supporting this method of identification. Recruitment through health visitor teams is not feasible for a future trial owing to limited capacity within teams. The setting for delivery of the parenting programme would be dependent on local facilities but needs to be known to parents and easily accessible. First aid courses are very commonly provided in children's centre settings and can be considered to be part of usual care in those settings.

### **Recommendations for research**

1. A multicentre, cluster, randomised, unblinded trial comparing the FAST parent programme against usual care in a community setting is required to determine if the programme is able to reduce injuries in children under 5 years of age.
2. A programme to support intervention fidelity in a future trial should be developed, including revision of the 'train the trainer' event, and sustainable ongoing support for those delivering the programme.
3. A future trial will require the identification of an appropriate measure of child behaviour that will enable behaviour change to be monitored over periods of follow-up during which significant developmental change may occur.
4. The use of a parent advisory group to guide the progress of a future study and assist in solving problems.

### **Trial registration**

The trial was registered as ISRCTN03605270.

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