Helping children's centres to enhance home safety

Submission date 06/12/2012	Recruitment status No longer recruiting	Prospectively registered	
	5 5	[X] Protocol [_] Statistical analysis plan	
Registration date 06/12/2012	-	[X] Results	
Last Edited 06/02/2019	Condition category Other	Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Study website http://www.nottingham.ac.uk/injuryresearch/projects/kcs/index.aspx

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT01452191

Secondary identifying numbers 10583

Study information

Scientific Title

Keeping children safe at home: cluster randomised controlled trial of the implementation of an injury prevention briefing in children's centres for the prevention of specific types of injuries

Study objectives

Many children have accidents, some are very serious and they are a major cause of death in children aged 1-4 years. Many accidents are preventable This study aims to find out the best way to help Children's Centres to provide home safety information about preventing fires to parents and carers of young children.

36 Children's Centres in four study centres (Nottingham, Bristol, Norwich, Newcastle) will be recruited to the study. 30 families will be recruited from each Children's Centre. Children's Centres serving the most deprived populations will be eligible to take part . Families will be eligible to take part if they have attended a participating Children's Centre in the previous three months, have parents who are 16 years or older, have a child under three years old and live within the catchment area of that Children's Centre. When 30 families have been recruited that Centre will be allocated, at random, to one of three groups. Children's Centres in group one will be provided with guidance about preventing fire-related injuries (an Injury Prevention Briefing (IPB))and help and support to implement the IPB, the second group will be sent the IPB and the third group will not be provided with the IPB ("usual care"). Children's Centres will devise their own programmes of safety advice for parents based on the IPB.

At recruitment and 12 months later, families and Children's Centres will complete questionnaires about fire safety practices. Children's Centres will also complete a paper-based tool about the implementation process at 12 months. Information about barriers and facilitators to implementing the IPB will be collected through interviews with Children's Centre staff.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Current ethics approval as of 06/02/2019: Derbyshire Research Ethics Committee, 18/03/2011, ref. 11/EM/0011. University of the West of England, Bristol, Research Ethics Committee, 22/07/2011, ref. HSC/11 /06/61.

Previous ethics approval: First MREC, 18/03/2011, ref: 11/EM/0011

Study design

Randomised interventional prevention process of care study

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Primary Care Research Network for England

Interventions

Injury Prevention Briefing This arm will be sent the IPB to use, but will not receive facilitation to implement it.

Injury Prevention Briefing + Children's Centres allocated to the Injury Prevention Briefing (IPB): Facilitation will be provided with an IPB (developed by the study team) that documents evidence based interventions known to reduce injuries, and strategies to get these into practice. The research team will facilitate the use of the IPB in this group.

Usual care group: Will receive usual care delivered by Children's Centres.

Follow Up Length: 12 months

Intervention Type Other

Phase Not Applicable

Primary outcome measure

The proportion of families who have a fire escape plan (ascertained from self-completion questionnaire measured at 12 months

Secondary outcome measures No secondary outcome measures

Overall study start date 01/06/2011

Completion date

31/03/2014

Eligibility

Key inclusion criteria

There are two levels of participation:

- 1. Children's Centres as participants, who will be delivering the intervention
- 2. Families as participants, who will be receiving the intervention

Children's Centres:

Phase 1 Children's Centres in the four study areas (Nottingham, Newcastle, Bristol and Norwich) Phase 2 Children's Centres in more disadvantaged areas (defined as those who have more than 50% of under 5 year-old children in their Centre catchment area who live in one of the 30% most disadvantaged Super Output Areas).

Families:

Any family who has attended the participating Children's Centre in the previous three months, who have a child under three years old, and lives within the catchment area of that Children's Centres.

Male or female participants, aged over 16 years.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 1080; UK Sample Size: 1080; Description: 36 Children's Centres 30 parents from each Children's centre = 1080

Key exclusion criteria

Children's Centres: Phase 2 Children's Centres that are not in more disadvantaged areas as defined above and phase 3 or subsequent wave Children's Centres.

Families 1. Families who attend a participating Children's Centre who do not have any children under the age of 3 years 2. Any parent who is under-16 years of age

Date of first enrolment 01/06/2011

Date of final enrolment 31/03/2014

Locations

Countries of recruitment England

United Kingdom

Study participating centre University of Nottingham Nottingham United Kingdom NG7 2RD

Sponsor information

Organisation University of Nottingham (UK)

Sponsor details Research Innovation Services Kings Meadow Campus Lenton Lane Nottingham England

United Kingdom NG7 2NR

Sponsor type University/education

Website http://www.nottingham.ac.uk/

ROR https://ror.org/01ee9ar58

Funder(s)

Funder type Government

Funder Name

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs				
Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	22/01/2014	Yes	No
<u>Results article</u>	qualitative study results	10/12/2014	Yes	No
Other publications	recruitment and retention strategies	07/03/2015	Yes	No
Results article	results	15/12/2015	Yes	No
<u>Results article</u>	results	24/03/2017	Yes	No
<u>Results article</u>	results	01/07/2017	Yes	No