

A randomised controlled trial of the effectiveness of an education package in reducing baby walker use

Submission date
23/01/2004

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
23/01/2004

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
06/02/2019

Condition category
Injury, Occupational Diseases, Poisoning

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RBK99XX7

Study information

Scientific Title

A randomised controlled trial of the effectiveness of an education package in reducing baby walker use

Study objectives

Is an education package delivered by midwives and health visitors aimed at reducing baby walker use effective?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval as of 06/02/2019:

Queen's Medical Centre, University Hospital NHS Trust Ethics Committee, 13/07/1999, ref. EX029902.

North Nottinghamshire Local Research Ethics Committee, 12/06/2000, ref. NNHA/494.

Previous ethical approval:

Queen's Medical Centre, Nottingham, ref. EX029902.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Pediatric injury

Interventions

i. Evidence based educational package developed to reduce baby walker use. The package will be presented at one ante-natal consultation from 28 weeks (by midwives) and in 2 post-natal

consultations, at the birth review and 3-4 month hip check (by health visitors).
ii. No exposure to package.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The primary outcome measure is prevalence of baby walker possession and use.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1999

Completion date

30/04/2002

Eligibility

Key inclusion criteria

The study population will comprise all pregnant women (of at least 28 weeks gestation) registered with 34 participating practices.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/1999

Date of final enrolment

30/04/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Division of General Practice

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

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+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Trent (UK)

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/03/2003 | | Yes | No |
| Results article | results | 01/03/2003 | | Yes | No |
| Results article | results | 01/09/2003 | | Yes | No |
| Results article | results | 01/12/2003 | | Yes | No |
| Results article | results | 01/08/2005 | | Yes | No |
| Results article | results | 01/09/2006 | | Yes | No |
| Results article | results | 01/06/2018 | | Yes | No |