ISRCTN11990876 https://doi.org/10.1186/ISRCTN11990876

Impact on recruitment of using an infographic in addition to the participant information sheet.

Submission date
02/05/2024

Recruitment status
Stopped

Registration date
19/06/2024

Overall study status
Stopped

Last Edited
16/04/2025

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Recruitment and retention to trials in a paediatric emergency setting is challenging because there is little or no time for parents/guardians to consider research information and decide about their baby's involvement in a study. Parents can be distressed and understandably focused on their baby, often prioritising verbal information provided by clinicians over written study information. However, brief verbal information provision by practitioners in the emergency setting has been associated with poor parental understanding and poor recall of any aspect of the study presented. Furthermore, practitioner views and preferences may influence how they present the study or lead to misunderstanding by parents/guardians, which may impact trial recruitment and retention.

This study explores the effect of an infographic and collecting information on the consent process in a cluster randomised Study Within a Trial (SWAT; also deposited at: https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/). In a SWAT, different groups of people are randomly chosen to receive different treatments or actions, helping researchers see how well these work in a bigger study. Guidance on how to use the infographic will be provided to those sites allocated to use it during the site initiation visit. The infographic is a simple, brief representation of the information provided in the standard PIS about the two treatments and was developed with input from the Patient and Public Involvement and Engagement (PPIE) group for the EASY study (https://www.isrctn.com/ISRCTN10907780). The intention is to prompt a more structured conversation between the consenting clinician and the parent/guardian of the eligible child and how the randomisation will influence their child's care pathway.

Who can participate?
Adult parents/guardians of participants who are approached to participate in the EASY study.

What does the study involve?
Parents/Guardians will be provided with the EASY study participant information sheet and infographic if the hospital site has been allocated to the SWAT intervention arm. Otherwise, they will receive the standard participant information sheet. Staff will ask each parent/guardian to complete a brief questionnaire. This will include those who were approached but declined

their child's involvement in the trial. The questionnaire will aim to explore satisfaction with and understanding of the EASY study consent process, factors that may have informed decisions to decline participation in the EASY study and the quality of decision-making. The questionnaire will be placed in a stamped self-addressed envelope and returned by post to the Northern Ireland Clinical Trials Unit (NICTU), which is managing the trial. To avoid identifiable data being sent to the NICTU, written consent from the parent/guardian will not be sought for the questionnaire and, instead, consent will be implied by its completion and return.

What are the possible benefits and risks of participating?
A potential benefit is that participants (i.e. parents/guardians) are given the opportunity to influence the consent process in future paediatric trials. There is a potential emotional risk to participants as they complete the questionnaire as it may lead them to worry about their decision to consent / not consent their child to the EASY Study.

Where is the study run from?
The study is being run from paediatric emergency departments across the UK (England, Scotland, Northern Ireland and Wales) and is coordinated by the Northern Ireland Clinical Care

When is the study starting and how long is it expected to run for?
The study started in May 2023 and will run for 42 months.

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme

Who is the main contact?
Ashley Agus, ashley.agus@nictu.hscni.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1008782

Central Portfolio Management System (CPMS)

61097

National Institute for Health and Care Research (NIHR)
152733

Protocol serial number
23012TW-CH

Study information

Scientific Title
A cluster randomised study within a trial (SWAT) embedded within the EASY Study to assess the impact on recruitment of using an infographic in addition to the standard participate information sheet to explain the two treatment arms of the EASY Study to parents/guardians of eligible participants.

Acronym
EASY: SWAT

Study objectives
An infographic in addition to the standard participant information sheet will lead to a higher recruitment rate compared to the standard participant information sheet.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/12/2023, South Central-Hampshire A Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; None provided; hampshirea.rec@hra.nhs.uk), ref: 23/SC/0426

Primary study design
Interventional

Study design
Cluster-randomized study within a trial (SWAT)

Study type(s)
Other

Health condition(s) or problem(s) studied
Impact on recruitment of using an infographic in addition to the participant information sheet in a paediatric emergency setting

Interventions
Intervention 1: EASY study (https://www.isrctn.com/ISRCTN10907780) sites allocated to the SWAT intervention arm will provide parents/guardians with an infographic in addition to the standard participant information sheet during the consent process. The EASY study statistician will generate the randomisation sequence using NQuery Advisor. Sites will be randomised (1:1 using mixed block sizes).

Intervention 2: Sites allocated to the control arm will be given the standard participant information sheet during the consent process.

Intervention Type
Behavioural

Primary outcome(s)
Recruitment rate (%) measured using data collected in study records by counting the number of participants who are recruited at the end of the recruitment period expressed as the percentage of the total sample size

Key secondary outcome(s)
1. Withdrawal rate (%) measured using data collected in study records by counting the number of participants who are withdrawn immediately post-randomisation to the EASY Study expressed as the percentage of the total sample size
2. Retention rate (%) measured using data collected in study records by counting the number of participants who are retained at 28 days post-randomisation to the EASY Study expressed as the percentage of the total sample size
3. Cost per participant recruited and participant retained measured using data collected in study records and calculated by dividing the total costs associated with the infographic by the number of participants recruited (primary outcome) and the number of participants retained (secondary outcome) at 28 days post-randomisation to the EASY Study
4. Parent/Guardian satisfaction with and understanding of the consent process measured using a bespoke questionnaire within 48 hours post-screening for the EASY Study
5. Quality of parent/guardian decision-making measured using a bespoke questionnaire on consent within 48 hours post-screening for the EASY Study

Completion date
12/04/2025

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
Must be a parent or guardian of a participant eligible for the EASY Study (https://www.isrctn.com/ISRCTN10907780).

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
27

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
07/05/2024

Date of final enrolment
12/03/2025

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Alder Hey Childrens Hospital
Eaton Road
West Derby
Liverpool United Kingdom
United Kingdom
L12 2AP

Study participating centre
Birmingham Childrens Hospital
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre

Bristol Royal Hospital for Children
Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ

Study participating centre
Oxford Children's Hospital
John Radcliffe Hospital
Headington
Oxford
United Kingdom
OX3 0AG

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road

Nottingham
United Kingdom
NG7 2UH

Study participating centre
Peterborough City Hospital
Edith Cavell Hospital
Bretton Gate, Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
The Royal Belfast Hospital for Sick Children
274 Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Sheffield Children's Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XN

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
St. Mary's Hospital
Imperial College London, St. Mary's Campus, Medical School, Room 231, Norfolk Place

London
United Kingdom
W2 1PG

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
Belfast Health and Social Care Trust

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes