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# 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

### Study website
https://nictu.hscni.net/service/easy/

# Contact information

### Type(s)
Public, Scientific, Principal Investigator

### Contact name
Dr Ashley Agus

### Contact details
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# Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number
1008782

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
23012TW-CH, IRAS 1008782, NIHR152733, CPMS 61097

## 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

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

### Primary study design
Interventional

### Secondary study design
Cluster randomised trial

### Study setting(s)
Hospital, Medical and other records

### Study type(s)
Other

### Participant information sheet

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

### 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 measure
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

### Secondary outcome measures
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

### Overall study start date
27/11/2023

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
584

### 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
England

Northern Ireland

Scotland

United Kingdom

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

### Sponsor details
Research Office, 2nd Floor King Edward Building, Royal Victoria Hospital, Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA
+44(0)28 961 56057
ResearchSponsor@belfasttrust.hscni.net

### Sponsor type
Hospital/treatment centre

### Website
https://belfasttrust.hscni.net/

### 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

### Publication and dissemination plan

Planned publication in a peer-reviewed journal

## Intention to publish date
30/10/2027

## 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