

PROTOCOL

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Contents

LIST OF ABBREVIATIONS/GLOSSARY	6
1. BACKGROUND.....	7
2. STUDY SUMMARY	9
2.1.1 Overall Study Aims	9
2.1.2 Overall Study Objectives.....	9
2.1.3 Study design	10
2.1.4 Study Methods.....	10
3. PLAIN ENGLISH SUMMARY	12
4. RESEARCH GOVERNANCE AND ETHICAL CONSIDERATIONS	13
4.1 Introduction	13
4.2 Informed consent:.....	14
4.3 Confidentiality:.....	17
4.4 Wellbeing and safeguarding.....	17
4.5 Withdrawing from the study.....	20
5. STUDY DESIGN AND METHODS	21
5.1 Design.....	21
5.2 Aims objectives.	21
5.3 Sample	21
5.4 Recruitment	23
5.5 Data Collection and Interview Plan.....	25
5.6 Data analysis.....	25
6. PATIENT AND PUBLIC INVOLVEMENT (PPI)	27
6.1 PPI research team members experience	27
6.2 Involvement in the grant application.....	27
6.3 Involvement in the research	28
6.4 Young Persons Public Advisory Group (YPAG).....	28
6.5 Study Steering Committee.....	29
7. EQUALITY, DIVERSITY AND INCLUSION FOR STUDY PARTICIPANTS.....	29
8. DATA MANAGEMENT PROCEDURES	29
8.1 Data Collection.....	29
8.2 Data Management.....	29

8.3	Data storage.....	31
8.4	Data access and quality assurance.....	31
8.5	Archiving.....	32
8.6	End of the Study.....	32
9.	OUTPUTS, DISSEMINATION AND PUBLICATION	33
9.1	Final Report.....	33
9.2	Dissemination and anticipated Impact	33
10.	STUDY ORGANISATION AND OVERSIGHT	33
10.1	Sponsor and governance arrangements	33
10.2	Regulatory authorities/ethical approval.....	33
10.3	Indemnity.....	34
10.4	Study timetable and milestones.....	35
10.5	Administration.....	36
10.5.1	Essential Documentation.....	36
10.6	Delegation of Sponsorship and study management	36
10.7	Study Management Group (SMG)	36
10.8	Young People's Public Advisory Group (YPAG)	36
10.9	Study Steering Committee (SSC).....	37
11.	MONITORING AND QUALITY ASSURANCE OF STUDY PROCEDURES	38
12.	REFERENCES.....	39
13.	APPENDIX 1 DATA FLOW TABLE.....	43
Figure 1 – Flow diagram study timeline		11
Figure 2 – Study timetable		34
Figure 3 – Data flow diagram.....		42

LIST OF ABBREVIATIONS/GLOSSARY

Abbreviation	Explanation
AED	Automated External Defibrillator
BCPR	Bystander Cardiopulmonary Resuscitation
BLS	Basic Life Support
CAMHS	Child and Adolescent Mental Health Services
CI	Chief Investigator
COSUK	Chain of Survival UK
CPR	Cardiopulmonary Resuscitation
CRN	Clinical Research Network
DBS	Disclosure and Barring Service
EMS	Emergency Medical Services
GCP	Good Clinical Practice
GP	General Practitioner
ISRCTN	International Standard Registered Clinical/social sTudy Number
NHS	National Health Service
NIHR RfPB	National Institute for Health Research, Research for Patient Benefit programme
OHCA	Out of hospital cardiac arrest
PAD	Publicly accessible defibrillator
YPAG	Young People's Public Advisory Group
PIS	Participant Information Sheet
PPI	Patient & Public Involvement
SCAUK	Sudden Cardiac Arrest UK
SMG	Study Management Group
SSC	Study Steering Committee

1. BACKGROUND

Adults report being involved in a resuscitation attempt as distressing.^{1–4} Research is lacking into children's experiences of providing cardiopulmonary resuscitation (CPR). CPR was added to the curriculum for secondary schools in England in 2020⁽⁵⁾ and should be taught in all UK schools from 2022.^{6–8} We found 61% of adults had received some form of CPR training. Just 13% reported training in school.⁹ One aim of introducing CPR training in schools is to increase the number of people providing CPR in an emergency. It is likely to increase the number of children who 'attempt to save a life'.

In 2020, of 31,698 out of hospital cardiac arrests (OHCA) treated by ambulance services just 8.3% patients survived to hospital discharge.¹⁰ CPR performed by a member of the public (bystander) improves chances of survival.¹¹ Approximately 19,300 bystanders performed CPR in England in 2020 (70% of cases).¹⁰ The proportion who were children is unknown, but many would likely benefit from professional support.

CPR training forms part of the 'Relationships, Health and Sex Education' curriculum in English schools, with an emphasis on mental wellbeing.⁵ However, lesson plans for CPR training focus on skills-based training rather than possible psychological impacts.^{12–14} Mental health is a research priority for the NIHR and the Department for Health and Social Care (DHSC). Effectively understanding distress caused to children when they provide CPR may inform changes in CPR training and subsequent support to prevent mental health problems developing. The DHSC identifies this as key in effective mental health care. With the implementation of CPR training in schools, there is an opportunity to prepare children for the experience and signpost them to sources of support.

However, evidence to inform training guidance or support policies is lacking. Exposure to traumatic events during childhood can have lifelong impacts. Children who experience the death of a parent are more likely to develop psychiatric illnesses as an adult.¹⁵ Effective support following distressing childhood events can decrease the psychological harm resulting in long-term benefits and a reduction in healthcare service use.¹⁶ When children

have received CPR training, they have fewer negative emotions towards OHCA written scenarios.¹⁷ However, adults who have been interviewed after providing bystander CPR have criticised their training as not preparing them for the situation.¹⁸

We will explore experiences of children who have performed CPR, to understand the emotional and relationship impacts it had; the support they received including health service use, and whether this was helpful. We will discuss any CPR training they received and how well they feel this prepared them. This project is focused on experiences of psychological distress and steps that can be taken towards its prevention. Child and Adolescent Mental Health Services (CAMHS) in the UK are stretched.¹⁹ A reduction in mental health problems will also reduce the burden on wider health services.²⁰

We conducted three scoping reviews to explore: What are the psychological impacts on child/adolescent bystanders who witness and/or participate in an OHCA? Are there effective psychological interventions for child/adolescent bystanders who witness (+/- participate) at an OHCA? Are psychological impacts of witnessing (+/- participating) at an OHCA addressed in layperson CPR training?

We found no literature regarding the experience of children who have provided CPR. Across 13 adult studies, negative psychological reactions ranged from 1.4-76% of participants.^{1-4,21-29} CPR is emotionally challenging for all lay responders with some requiring formal psychological support.¹⁻³ One study discussed interventions for psychological support in adult bystanders,¹⁸ reporting short-term benefits of telephone debriefing with an emergency medical dispatcher performed 2-4 days after the resuscitation attempt. Benefits included emotional relief and safety netting in case of severe reactions and a long-term improved ability to cope with their emotional reaction. Three publications highlighted the lack of discussion around the psychological impact of CPR in layperson CPR training sessions. Bystanders reported that 'courses were too superficial and lack preparation for the "unpleasantness of OHCA"'.¹⁸

Exposure to distressing events in childhood can have lifelong impacts³¹ and the impact of these events can be limited using effective psychosocial treatments such as trauma-focused CBT.¹⁶ However, as 82.3% of OHCA occur in the home,¹⁰ children who perform CPR may have the combination of attempting to 'save a life' and experiencing the resulting severe illness or death of a family member. There is no research into the effect this may have.

In preparation for this project, we sought views of members of 'Sudden Cardiac Arrest UK' (SCAUK) – a support group for survivors of sudden cardiac arrest (<https://www.suddencardiacarrestuk.org/>) on the impact that performing CPR may have on children. From 19 responses, four reported experiences of performing CPR as a child, and the associated psychological impact: 'I had PTSD as a result' and 'Unfortunately they didn't survive... I still feel the guilt'. Other responses were from parents who described the substantial impact on children who had witnessed a resuscitation attempt, with some requiring professional psychological support. Although limited, this data suggests a substantial impact on children. There are no ongoing projects with aims that overlap with this study design registered on the International Standard Randomised Controlled Trial Number registry, clinicaltrials.gov and the European Union Clinical Trials register.

2. STUDY SUMMARY

This section presents an overview of the study,

2.1.1 Overall Study Aims

1. What is the experience of a child who has provided CPR to someone who has an OHCA?
2. How does CPR training inform and prepare children for such experiences and how can these findings inform the CPR in schools training programme?

2.1.2 Overall Study Objectives

1. To explore the experiences of children concerning the resuscitation attempt and the impact on their emotional/psychological wellbeing and relationships.

2. To explore the support (formal and informal) received or sought by children following providing resuscitation.
3. To explore the impact of CPR training on the children's experience of resuscitating someone and willingness to help in a future resuscitation attempt.

2.1.3 Study design

A qualitative interview study using reflexive thematic analysis.

2.1.4 Study Methods

Sample

A purposive sample of up to 20 children and young people in England aged 11-23 who took part in an out of hospital cardiac arrest resuscitation attempt by providing chest compressions or rescue breaths or applying defibrillation pads whilst they were aged 11-18. The cardiac arrest will have happened in the UK. Where possible, participants will be purposively selected to include a diversity of participants from different age groups, socioeconomic, ethnic, cultural and religious backgrounds and geographical areas including urban and rural locations.

Data collection

We will interview the young people who took part in a resuscitation attempt at an OHCA by providing chest compressions or rescue breaths or applying defibrillation pads whilst they were aged 11-18.

Analysis

A reflexive thematic analysis of the interview data will be conducted.

The flow diagram (Figure 1) summarises the study and timeline.

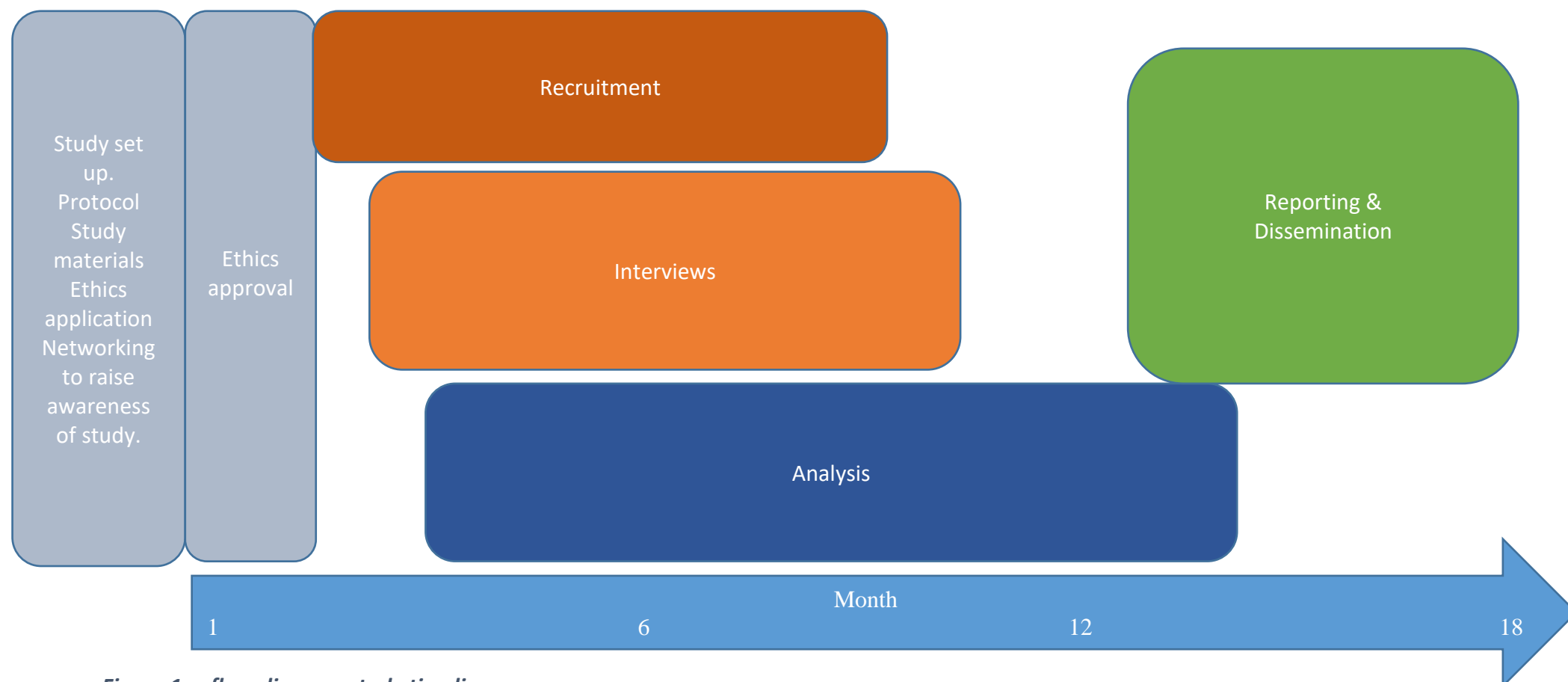


Figure 1 – flow diagram study timeline

3. PLAIN ENGLISH SUMMARY

A cardiac arrest is when someone's heart stops and they collapse. People who are there at the time can improve the person's chance of survival. They can call an ambulance, start cardio-pulmonary resuscitation (CPR) and use a heart restarter. CPR is now taught to students aged 11-18 in many UK schools. This is part of the national curriculum to help increase the number of people who know how to help.

Adults are emotionally affected by helping but we don't know how children are affected. We want to find out how children experience helping with resuscitation. This will help develop training and support for children.

We will interview people who were aged 11-18 when they helped in a cardiac arrest. We want to ask them about their experience and how it affected them, their families, friends and school life. We will also ask them about their resuscitation training. To find volunteers for interviews, we will let children and their families know about the study in different ways. We will ask schools to help us, so teachers might ask children and their parents or guardians if they would like to talk to a researcher. We will post information on groups that support people and their families who have experienced a cardiac arrest and use other social media. We will ask them to contact the study team if they are interested. We will talk to schools to make sure there is good support for those who take part. If the young person is no longer at school, we will make sure they know how to get support.

Our research team contains people who have had experience of cardiac arrest, including a young person who witnessed a cardiac arrest. We also have someone who had a cardiac arrest and started a support group for others who have survived a cardiac arrest. Another team member has experience teaching, running schools, and doing research with children. These team members will give the other members of the team advice about running the study throughout. We will look at the information in the interviews to find out what

experiences mattered to the children, how it affected them and what support helped or didn't help. We want to find out if this is like what is already known about helping children through other difficult experiences. We will look for any improvements needed and where more research is needed. This will include possible changes to CPR training.

To inform the relevant groups of our results we will write a scientific paper and a plain English summary, have an animation/video of findings and also hold an online event announcing our results.

4. RESEARCH GOVERNANCE AND ETHICAL CONSIDERATIONS

4.1 Introduction

The study will be conducted in accordance with the NHS Research Governance Framework and the principles of Good Clinical Practice (GCP). The study will comply with relevant King's College London policies and guidance. All data will be stored securely and held in accordance with the Data Protection Act (2018). Ethical approval for the study will be sought from King's College London College Research Ethics Committee. We will work with schools involved to follow their governance processes for research conduct.

The ethical issues for the study are that participants, and for participants that are aged under 16, their parents, that their autonomy is respected. To do this we intend to gain informed consent from adult participants. We will gain informed consent from the parents/those with parental responsibility for the participants under 16. We will gain verbal assent to participate from those under 16 as well. We will also make sure participants and their parents/those with parental responsibility are aware of how to withdraw from the study.

Ensuring confidentiality of the data subjects share in interviews and their contact details required for organising participation is an important consideration.

Wellbeing of the participants is an important consideration for this study. The study participants will be healthy volunteers, however the topic of cardiac arrest and recounting

experiences of being involved in a resuscitation attempt has the potential to cause distress to participants. We will therefore ensure support is in place within the school setting for participants still at school and for adult participants we will provide information about sources of support.

The research team will have access to sources of support as the topic could also be upsetting for them.

4.2 Informed consent:

Adult participants and young people aged 16 and 17: All participants aged 16 or over will provide their own informed consent to be involved in the study. A researcher will contact them by phone, online call or by email after they have expressed interest in being involved in the study and provide them with the participant information sheet and informed consent form. The researcher will arrange a convenient time, at least 24 hours after the information has been sent to the potential participant to talk to them about the study and answer any questions. The information will likely be sent by email, but we will be able to send them by post should the potential participant request it. If this is the case the researcher will leave sufficient time for the post to arrive when arranging the follow up conversation.

If the potential participant decides to take part the researcher will ask them to sign and return the consent form. The researcher will then sign the consent form and ensure the participant has a copy and that a copy is retained for the study records. For participants no longer in school/college (i.e. aged over 18), the researcher will arrange a convenient time and place with the participant to conduct the interview. This is likely to be face to face, but an interview via the internet (e.g. Microsoft Teams) will be an option should the participant prefer. For the young person aged 16 or 17, the researcher will make arrangements, where possible, to interview the participant at school/college, although it will be possible for interviews for all young people still in the school system to have an interview elsewhere.

It will be possible for the participant and researcher to sign the consent form at the face-to-face interview, should that be more suitable for the participant.

Before the interview starts the researcher will again check that the participant is content to proceed, giving them a further chance to ask any questions.

Participants under 16: Consent will be sought from the parents/those with parental responsibility for participants under 16. All participants themselves will be given the opportunity to discuss participation and provide their verbal assent as well, which will be recorded before the interview starts.

Once parents or those with parental responsibility for the child have indicated an interest in their child taking part in the study, the researcher will provide them with an information sheet (if they need another copy) and a consent form and they will be given the opportunity to ask the study researcher questions. They will be encouraged to discuss participation with their child and if they decide they want their child to take part both they and the child will be given the opportunity to ask the researcher more questions, before the researcher asks the parent to sign the consent form. This can be done via telephone or online discussion and information can be sent to the parent by email or post. The signed consent form can be returned by email or post.

For all participants under 18 who are still attending school, whether identified by the school/college or through another route, the study team will explain to the young person and their parent that we would prefer the interview take place at the young person's school. The researcher will explain the reasons for this and seek their verbal consent to contact the school to arrange this. If they agree, the researcher will then contact the school to gain agreement for a suitable room in the school to be made available for the interview. We will also need agreement that the school will be able to provide suitable emotional and safeguarding support for the participant before we go ahead with the interview. For pupils who are not introduced to us by the school themselves, we will ask the child's parent for the

school's contact details and, if necessary, a supporting email or phone call. The study team will then contact the school to explain what is involved and gain appropriate permissions. Once the school has agreed a suitable time for the child, parent and school will be arranged for the interview.

If the school does not give permission for interviews to be conducted on school premises, and the young person is still in the school system, we will establish if the school would be prepared to support the child should we interview them elsewhere and, if so, how. If the school is able to provide support if needed, we will then discuss with the parent and decide a suitable location for the interview. This location may be at one of the collaborator's universities (if the child lives near enough that travel would be easy), or at the child's home with the parent's/person with parental responsibility's permission. If the interview takes place in the home, a parent must be present in the home at the time of the interview. The child will be able to choose whether they want their parent to be in the same room with them during the interview. The researcher will give the parent and the child/young person information about sources of support such as child line, the Samaritans and their GP should they want support after the interview.

During the consent process the researcher will ask the participant or their parent/person with parental responsibility (as age appropriate) for consent to contact them approximately two weeks after the interview to check on the participant's wellbeing and if necessary direct them to sources of support.

For all participants: Once the interview is organised at the school, or other venue the researcher will check at the start of the interview with all participants they understand, have any questions and whether they want to continue. Those aged 16 or over that give their verbal assent will continue and those that do not will be withdrawn from the study. Young people <16 years will be asked to verbally agree (or disagree) with assent statements read out by the researcher, and this verbal assent will be audio recorded and stored safely with

their parent's signed consent form. These assent statements will have been emailed to them in advance to give them the opportunity to discuss with their parent(s) and to contact the researcher with any questions prior to the interview. If the child doesn't not want to continue with the interview they can withdraw at this point.

4.3 Confidentiality:

All results and findings reported will be anonymised, to ensure no individuals can be identified in the study. Participant and parental information will be obtained, used and stored in compliance with the 2018 Data protection act. Further details are given in section 8.

4.4 Wellbeing and safeguarding

The study participants will be healthy volunteers, however the topic of cardiac arrest and using resuscitation techniques has the potential to cause distress to participants.

We intend to hold interviews with young people who are still in fulltime education at their school or college and therefore we will follow safeguarding procedures in line with local policy. The team will develop study specific guidance on safeguarding.

During the interview, the researcher will provide a time-out or stop the interview if the participant becomes distressed. Participants will be directed to appropriate support as per a developed protocol including school councillors, Chain of Survival UK (COSUK), GP services, CAMHS and Improving Access to Psychological Therapies. Should an urgent mental health issue arise the researcher will be able to call 999 or 111 as appropriate, involving the school, parent or adult participant themselves as appropriate.

We will work closely with the schools to ensure an adult member of staff familiar with safeguarding policies and procedures for the school is available at the time of the interviews

so the researcher conducting the interview is able to work with the school representative should any safeguarding issues be raised during the interview. This process will be the same if the child becomes distressed and needs support. Where a child is clearly upset the researcher will stop the interview and seek support from the designated school member of staff. The schools' procedures will be followed, and a record made of what happened and what action was taken and who at the school took the issue forward for the research team's records. The researcher will have appropriate checks (DBS) for working with young people and undertake safeguarding training appropriate to the age group and setting where they will be working. King's College London has safeguarding policies and support which will inform the study guidance. For adult participants we will provide information on sources of support. All participants will be able to request that the interview is stopped at any point and will not have to answer any questions they do not want to. The researcher will check in with participants at different points of the interview to see if they want to continue.

If the school does not give permission for interviews to be conducted on school premises or the parent/young person over 16 refuses to have the interview at the school, and the young person is still in the school system, we will establish if the school would be prepared to support the child should we interview them elsewhere and, if so, how. If the school is able to provide support if needed, we will then discuss with the parent and decide a suitable location for the interview. This location may be at one of the collaborator's universities (if the child lives near enough that travel would be easy), or at the child's home with the parent's/person with parental responsibility's permission. If the interview takes place in the home, a parent must be present in the home at the time of the interview. The child will be able to choose whether they want their parent to be in the same room with them during the interview. The researcher will give the parent and the child/young person information about sources of support such as child line, the Samaritans and their GP should they want support after the interview. See Section D1e(iii) for further details.

For participants or their parent/person with parental responsibility (as age appropriate) who have provided consent, the researchers will contact them approximately two weeks after the interview to check on the participant's wellbeing and if necessary direct them to sources of support.

The researcher will ensure they have details of the local Multi-Agency Safeguarding Hub (MASH) service (or equivalent) in the area and how to make a referral in case there are any safeguarding issues that the child raises in the interview. If the researcher does have safeguarding concerns and it is safe for them to do so, they will inform the parent of their concerns and that they are contacting the MASH. As soon as feasible, the researcher will inform the CI or another member of the study team about what has happened. Once the researcher returns to work, they will record their concerns and actions in the study records and any subsequent information that arises. The researcher will be able to talk to the CI and, if they prefer, to the staff support services at the University about the impact of the incident on them.

In the unlikely event that an adult participant raises an issue of current safeguarding concern the researcher will discuss the situation with the study leads and team who will make a decision on what action to take based on their responsibilities as researchers in this situation.

Study team support: We will develop a support structure for members of the study team. Exploring the topic and hearing about people's experiences has the potential to be distressing or concerning to the researchers and other members of the team. We will consider a buddying system, where a member of the team has an identified buddy they can talk to following data collection. The CI will be available to members of the research team to debrief after data collection, should they wish, and the King's College London has welfare support available to all members of staff should team members need or prefer such confidential support.

We will develop proportionate approaches with our research partners on how researchers will respond to sensitive disclosures made by study participants.

We will follow King's College London guidance and risk assessment templates with regards to lone working for the study team.

4.5 Withdrawing from the study

We will inform all participants that they can take a break from participation in research activities or withdraw completely from the study at any point. We will include any recorded data in the analysis, even for partially completed interviews, unless the child or their parent or the adult participant requests that it is withdrawn when asked by the researcher at the time the interview is stopped. If it is not possible to ask the participant about keeping the partial data in the study at that time, the data will be withdrawn from the study.

All participants, and for those aged under 18, their parent/guardian, will be provided with a contact email for the study. They will have the opportunity to withdraw from the study at any time prior to their interview, during their interview, or after their interview, until their data has been anonymised and incorporated into the set for analysis, as at this stage it will no longer be feasible to identify and remove their data. As we will be completing analysis alongside data collection, participants will be given at date, 1 month after the date of their interview and will be able to request withdrawal up to that date, before the data is anonymised and incorporated into the analysis. If a participant withdraws from the study, all data relating to them will be destroyed.

A Withdrawal Form will be completed by the study team to record the details and level of withdrawal.

5. STUDY DESIGN AND METHODS

5.1 Design

A qualitative interview study using reflexive thematic analysis.

5.2 Aims objectives.

Aims

What is the experience of a child who has provided CPR to someone who has an OHCA?
How does CPR training inform and prepare children for such experiences and how can these findings inform the CPR in schools training programme?

Objectives

1. To explore the experiences of children concerning the resuscitation attempt and the impact on their emotional/psychological wellbeing and relationships.
2. To explore the support (formal and informal) received or sought by children following providing resuscitation.
3. To explore the impact of CPR training on the children's experience of resuscitating someone and willingness to help in a future resuscitation attempt.

5.3 Sample

We will interview up to 20 people who took part in a resuscitation attempt at an OHCA by providing chest compressions or rescue breaths or applying defibrillation pads whilst they were aged 11-18. For a moderate size interview study, previous work has suggested a sample size requirement of between 10 and 20 participants.³² This should generate sufficient data, considering the study's scope and topic, to fully analyse participants' experiences.³³

We will use a purposively sample of both urban and rural schools across different geographical regions of England, informed by known differences in CPR provision across England.³⁴ We will purposively sample participants to cover a range of characteristics: school year group (years 7-8, 9-10 and 11-13), gender, religious/cultural backgrounds, socio-economic status and ethnicity. While, as with all qualitative research, we are not aiming for a generalizable sample, we do aim to obtain views of people from varied backgrounds including underserved populations. By recruiting through schools, we have the opportunity to potentially recruit children from all backgrounds.

Inclusion criteria

We will include those who are between 3 months and 5 years from the time of the OHCA. This is to avoid interviewing in the immediate aftermath before any acute intervention has taken place. A maximum period of 5 years allows time to assess whether there are ongoing problems, whilst allowing recollection of the details of the training and support they had received around the event. This is a similar approach as taken by Dainty et al³⁵ their study of survivorship. We found that in our limited exploration with people from the support group, recall of events remained vivid years after the event. The OHCA will have taken place in the UK, in order to keep the focus on experiences of support provided through the UK schools and healthcare systems. Participants will be proficient in English to take part in an interview. As resources for the study will be limited, we do not anticipate there would be many potential participants who do not speak English because the OHCA they will talk about needs to have happened in the UK and they will currently be accessing their education through English. We will monitor our recruitment and report if these assumptions prove inaccurate and include it in the limitations of the study.

Exclusion criteria

We will exclude experiences where intervening in the cardiac arrest was part of a health-related work or training role. In this case, participants may process the incident differently including having different support available. We will also exclude those who were not

resident in England at the time of the event as their post-event experiences potentially occurred within a different culture with different support mechanisms available.

5.4 Recruitment

We will recruit participants through; 1) the school system, 2) CPR training providers and organisations who may have contacts with children who provided CPR, 3) CPR bystander support groups and 4) research team networks.

- 1) *The school system:* We will present the plan for our project at headteacher conferences and ask schools to contact us if they are aware of students at their school who have performed bystander CPR. We will also utilise our existing networks from delivering CPR education in schools to contact CPR training coordinators in schools. We will ask a member of school administrative staff to first approach the parents/guardians of any potential participants to give them information about the study and contact details for the study team, and to advise them to contact the study team should they be interested in their child taking part. Schools will approach parents of all eligible students (including those 16-18yrs), but written consent will be obtained from all ≥ 16 years rather than their parents. If the parents and young person agree, they will be invited to take part.
- 2) *Training providers and organisations:* We will use our existing contacts at St Johns Ambulance (SJA), the Resuscitation Council UK (RCUK) and British Heart Foundation (BHF) whether they know of any potential participants they could approach on our behalf.
- 3) *Support groups:* We will contact members of CPR bystander support groups such as Chain of Survival UK (COSUK) to appeal for volunteers.
- 4) *Research team networks:* Members of the research team have significant involvement in cardiac arrest research and resuscitation education. Through their networks, they are aware of children who have performed CPR. If the young person is interested in

participating in the study, then they will be put in contact with the study team to allow questions to be answered and for the interview to be arranged.

For 2, 3 and 4 - If potential participants are identified from outside the school system, then if the participant is aged under 18 at the time of recruitment, first contact will be made by an adult who is trusted by the young person.

Once a young person, or the parent of a young person <16 years has contacted the research team to express an interest in the study, the researcher will arrange a time to discuss the study further with them, either via telephone or MS Teams. If the young person is <16 years, this discussion will take place with both the young person and their parent. The researcher will explain the study further and ensure that the young person (and their parent if they are <16 years) has plenty of opportunity to ask questions. If the young person (and their parent if they are <16 years) agrees to take part, the researcher will discuss the next steps with them.

For all participants under the age of 16 at the time of the interview, we will require a signed parental/guardian consent form. Those who are 16 or above will complete their own written consent form. At the time of the interview, all participants will be asked to give verbal confirmation that they agree to take part and to their interview being audio-recorded. Young people <16 years will be asked to verbally agree (or disagree) with assent statements read out by the researcher, and this verbal assent will be audio recorded and stored safely with their parent's signed consent form. These assent statements will have been emailed to them in advance to give them the opportunity to discuss with their parent(s) and to contact the researcher with any questions prior to the interview.

Please see section 4.2 above for more details of the consent processes

5.5 Data Collection and Interview Plan

Semi-structured interviews, developed by the research team, using a conversational approach to encourage dialogue will take place in person in a private room. Participants will be given the option of having a parent/guardian or trusted adult from the school present for the interview. Before commencing, the aim of the study and ethical considerations will be discussed and questions answered. It is anticipated that interviews will last for up to an hour. Interviews will be recorded (audio or via a secure online platform such as Microsoft Teams).

5.6 Data analysis

The interviews will be transcribed and analysed using reflexive thematic analysis.^{37,38} This will involve familiarisation with the dataset through reading and rereading transcripts to gain an initial sense of the content. This will allow the researcher to immerse themselves in the data so that they become familiar with depth and breadth of content. Reading and rereading will be an active process whereby the researcher will start to notice meanings and patterns and what is interesting about them, taking notes or marking ideas for coding that can be returned to in subsequent phases.

Next the researcher will formally code features of the data relevant to the aim of the study across interviews. Working systematically across the data set, the researcher will code as many data items as deemed relevant, in an inclusive and equal manner. The aim here will be to identify/highlight aspects of the data that may form a basis of repeated patterns. Codes will be loosely arranged into potential themes, which will be reviewed in relation to the coded extracts and the entire dataset. At this stage, all relevant coded data extracts are collated and sorted into the potential themes, here the researcher is starting to analyse codes and consider how they might combine to form an overarching theme.

This is followed by the refinement of potential themes, for example some themes may be lost where sufficient data to support is lacking or data are too diverse, while others might

merge. The remaining themes will contain data that coheres in a meaningful way, but there should be a clear distinction between themes.

Lastly, themes will be defined so that they identify the essence of what they are about and what aspect of the data they capture. Themes should present a coherent and internally consistent account facilitating a clear narrative. A theme will be characterised where data items are displayed on several occasions across the entire dataset. A higher frequency, however, will not denote importance, rather a theme will be determined by whether it conveys something important and meaningful regarding the overall aim of the study.^{37,38} Themes will therefore be closely linked to the data.

Justification of Analysis Plan

Reflexive thematic analysis emphasises reflexive engagement with data, considering subjectivity and interpretation of the researcher. It will enable us to identify and report themes across our dataset to gain a rich description of children's experiences of administering CPR.

A realist (essentialist), inductive and semantic approach to analysis will be adopted. This assumes a simple, largely unidirectional relationship between meaning experience and language.³⁷ It will allow the analysis to remain rooted in participants' responses, but to move beyond description, theorising the significance of the patterns and their broader meanings/implications.³⁶ Codes and themes will be audited within the research team to ensure credibility and protect against researcher bias.³⁹ This will involve coding by an independent researcher and review and discussion with the research team throughout the analytic process, to ensure themes are accurate and grounded in the data. In order to acknowledge the reflexive nature of thematic analysis, use of a reflexive log and reflexive discussion will also be employed to identify researcher impact and manage risk of researcher bias.

6. PATIENT AND PUBLIC INVOLVEMENT (PPI)

6.1 PPI research team members experience

Our team of co-applicants has three members who are key to ensuring that our study is sensitive to the vulnerable population we are interviewing and in ensuring our results are representative of participants data and presented in ways that are understandable to the general public and relevant for stakeholder groups. They have been involved throughout the development of the project and are integral to the research team. Our team members have relevant expertise and experience for the study. The team include: a survivor of cardiac arrest themselves, who founded the support groups Sudden Cardiac Arrest UK (SCAUK) and Chain of Survival UK (COSUK); an experienced educator with knowledge of the secondary school system, effective ways of providing support and safeguarding children and who championed the introduction of CPR training on the national curriculum; and a young adult who witnessed CPR being as a 15 year old, has experience of trauma counselling, and has experience working with a national first aid organization and providing CPR training to young people.

6.2 Involvement in the grant application

At the outline stage one of our PPI members facilitated asking members of the SCAUK group about relevant experiences and their inputs are included in the background to the study. The PPI team members contributed to discussions providing information about how children and families can be affected by the experience of witnessing and being involved in a CPR attempt, impacts if the OHCA patient is a family member or a stranger, support available and the challenges and variable experiences of accessing support, information and contacts with a voluntary organisation providing CPR training and first aid at events, training and supporting young people through the school system, advising on the recruitment strategy through schools and first aid and CPR training providers. Stage 2 At stage 2 the PPI team members have provided further information and advice to explain our safeguarding approach highlighting the importance of having an adult member of staff available for the

interview time and to work closely with the school for them to take any safeguarding issues forward. They reviewed and contributed to revised drafts.

6.3 Involvement in the research

Our PPI contributors provide essential expertise to guide and inform our research using their expertise and experience of cardiac arrest, support and education both for resuscitation skills and the national education system and the provision of support to young people with in it. This expertise is essential to guide and inform our research. PPI research team members will participate in monthly Study Management Group (SMG) advising on all aspects of the study. The PPI members of the research study team will help to further develop the dissemination plan to ensure that the results are passed onto members of the affected communities. We have included costs for time, travel expenses for all PPI contributors involved. Researchers will work with PPI members to assess training and support needs. Training resources we can draw on include Warwick Clinical Trials Unit or King's College health related PPI training, the NIHR Centre for Engagement and Dissemination resources.

6.4 Young Persons Public Advisory Group (YPAG)

IA will lead the PPI Young Person's Public Advisory Group (YPAG) with support from the researcher and PPI Lead (CH). The YPAG will meet four times to review the study materials and progress and provide advice to the study team from the young persons' perspectives. Training for the young people's PAG will be integrated into the meetings throughout the project. The PPI members and the YPAG will also review all outputs from the study to ensure that young people's views are at the centre of our results and ensure that the language utilised is understandable, respectful and inclusive. The PPI members and YPAG will also advise on the further research they believe is required to best support those affected.

We will keep records our meetings in order to capture and report the contribution public contributors make to the study using the GRiPP2 checklist.

6.5 Study Steering Committee

The Study Steering Committee (SSC) will have adult PPI members who will be able to advise the research study team and monitor the inclusion of PPI views in the study.

7. EQUALITY, DIVERSITY AND INCLUSION FOR STUDY PARTICIPANTS

We aim to obtain views of people from varied backgrounds including underserved populations. By recruiting through schools, we have the opportunity to potentially recruit children from all backgrounds.

8. DATA MANAGEMENT PROCEDURES

8.1 Data Collection

Data will be collected through interviews with participants as detailed in the methods section.

8.2 Data Management

Data collected during the study will be handled and stored in accordance with the UK Data Protections Act (2018) and General Data Protection Regulations (GDPR) and King's College London policies. King's College London will be the Data Controller for this study. Please see appendix 1 for data flow table.

Personal data (contact details) will be held to organise the interviews with the appropriate written or verbal consent. Written informed consent will allow for the continued use of interview data. The data will be kept securely and stored on a study SharePoint site with

access restricted to staff working on the study. Study team members will check that consent forms are completed correctly at the time of consent.

We will need to collect personal information such as name and contact details of research participants, their parents and contact details of staff at the schools supporting participants to provide details of where interviews will take place and to keep a record of participation. We will also be collecting demographic data on participants including age, gender, religion, ethnic group, and socioeconomic status from participants to create a descriptive summary of these characteristics in the study and to assess whether there are any particular patterns in the data associated with the different characteristics. We will keep personal identifiable details separate from data in electronic and paper records, using separate files. Participants will be allocated a unique study ID which will be used on data sources. A file linking participants names and study ID, for university and regulatory audit purposes will be kept separately from data and other identifiable information. All electronic files will be password protected where possible and saved on a secure study SharePoint site provided by King's College London. Paper copies will be kept in lockable filing cabinets in locked offices King's College London where all rooms are protected by a secure access control system that are only accessible to authorised personnel.

The Pseudonymised demographic data and any handwritten field notes will be stored with the Informed Consent Form (ICF) at the time of collection, both of which will be brought back to King's College London after the interviews. ICF forms and demographic data will be stored separately and will be stored securely in a lockable filing cabinet in a locked office when it is unattended. All rooms in the Faculty of Nursing and Midwifery Building (JCMB) are protected by a secure access control system that are only accessible to authorised personnel. There is a reception desk before the secure access doors which provides additional security when attended. Participant and parent contact details will be destroyed at the end of the study.

8.3 Data storage

All essential documentation and study records will be stored by King's College London in conformance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel. Any paper data forms, field notes, meeting notes, or other documents will be stored in a lockable filing cabinet in a secure room, to which access is restricted to authorised personnel. Electronic data will be stored in a secure area of the University computer system (SharePoint) with access restricted to staff working on the study with access managed by the study researcher and Chief Investigator. Interview data may be audio recorded on audio devices or audio/video recorded on a secure online platform such as Microsoft Teams. Recordings will be downloaded as soon as possible to encrypted university laptops and subsequently to the secure study area on SharePoint. Any data that are transferred out of the secure environment (for example audio files of interviews for transcription) will adhere King's College London's guidance. Any transcription service used will be subjected to the King's College London approved supplier review processes/Data sharing agreements.

Data sharing agreements for sharing pseudonymised data between King's College London and study team members at other universities involved in data analysis will be included in collaboration agreements or data sharing agreements.

8.4 Data access and quality assurance

Study participants will be assigned a unique study identifier (Study ID). The study team will maintain a separate confidential and secure list of patient identifiable information (name, date of birth, identification number and contact details/parent contact details) for the purposes of research (e.g. organising interviews), audit / quality assurance. This will be securely held on the secure study SharePoint site. It will be destroyed at the end of the study and not archived.

Once the study has been completed the records will be destroyed according to King's College Data Retention Schedule. The CI or staff they delegate this role to at King's College London for administration and storage purposes will have access to the final study data set. Access requests from co-investigators will be considered by the CI. A formal process will be developed by the study team to facilitate such requests and decisions in line with King's College London processes. There are challenges with sharing qualitative data that will inform decisions. For example, it may be possible to identify participants or participating organisations through contextual data contained in the transcripts, even after names and places have been removed or pseudonyms have been removed. This means that data will not be shared beyond the study team. Any data shared will be anonymised and transferred as per King's College London policies.

8.5 Archiving

Study documentation, including consent forms, and data, in a pseudonymised form, will be archived in the KCL Digital Records Management System for ten years according to the King's College London Data Retention Schedule. This states that children's data should be kept for three years after they are 18. We are assuming that the youngest participant could be 11 and so by the time they reach 21 it will be 10 years from the end of the study.

8.6 End of the Study

The study will officially end on the last day of funding, although dissemination of results will continue beyond that date.

Since this study is not implementing any intervention, it is unlikely to be stopped prematurely, unless funding is ended early. The independent Study Steering Committee will oversee the progress of the study and will advise the funder of any serious concerns that could lead to a premature end to the study. King's College London College Ethics Committee will be notified in writing if the study has been concluded or terminated early.

9. OUTPUTS, DISSEMINATION AND PUBLICATION

The overall outputs of the study will include:

9.1 Final Report

The main report will be drafted by the study co-ordinating team, and the final version will be agreed by the Study Steering Committee before submission to the NIHR RfPB programme (the funder).

9.2 Dissemination and anticipated Impact

We intend to hold an online event to present and discuss findings with stakeholders. A written summary of findings and stakeholder event materials will be available on our website and will include a video animation of key findings.

Through the research teams networks, we anticipate the findings could influence content of CPR training courses in schools, and inform future research, service provision and campaigns, should they be needed, for the support needed by young people who are involved in out of hospital cardiac arrest resuscitation attempts.

10. STUDY ORGANISATION AND OVERSIGHT

10.1 Sponsor and governance arrangements

King's College London is the research sponsor.

King's College London will manage the financial aspects of the grant.

10.2 Regulatory authorities/ethical approval

King's College London requires all research with human subjects to be reviewed either through national health and social care processes or through its own research ethics committees. All participants in this study are healthy volunteers and there are no medical/health service interventions or use of NHS facilities involved, so we will seek approval sponsorship and ethical approvals from the King's College London College Research Ethics Committee prior to any study activities commencing. Should any

amendments be required, these will be submitted for consideration by King's College London College Ethics Committee following consideration by the Study Management Group.

The study will be eligible for inclusion on the CRN Portfolio and will be registered on the ISRCTN.

10.3 Indemnity

King' College London provides indemnity for any harm caused to participants by the design of the research protocol.

10.4 Study timetable and milestones

Year		Pre study activity		1				2	
Quarter		-1	-2	1	2	3	4	1	2
Activity	Write protocol and develop study materials								
	Ethics approval (CREC)								
	Recruitment								
	Data collection								
	Data analysis								
	Report writing and dissemination								
	Study management group meetings			xxx	xxx	xxx	xxx	xxx	xxx
	Young Person's Advisory Group (YPAG)			x		x	x		x
	Study steering committee				x		x		x

Figure 2 Study timetable

Milestones:

1. Ethics approvals in place by end of month 1.
2. Interviews complete by end of year 1.
3. Funder report submitted at the end of the study.

10.5 Administration

The study will be based at the Florence Nightingale Faculty of Nursing Midwifery and Palliative Care (NMPC), King's College London.

10.5.1 Essential Documentation

A Study Master File will be set up held securely on a college SharePoint site.

10.6 Delegation of Sponsorship and study management

University Hospitals Coventry and Warwickshire (UHCW) who were awarded the grant as lead applicants have delegated responsibility for sponsorship, management of the study and any resulting intellectual property (IP) to King's College London.

10.7 Study Management Group (SMG)

The Study Management Group, consisting of the CI (CH), MS, and other co-applicants and the study researcher will meet regularly (approximately monthly). The purpose of this group is to coordinate work and monitor progress with project, deal with operational and research issues and report to the Young Persons Public Advisory Group meetings on progress. Significant issues arising from management meetings will be referred to the Study Steering Committee.

10.8 Young People's Public Advisory Group (YPAG)

The Young People's Advisory Group (YPAG) will meet flexibly as determined by the need for their input. They will provide the research team with insights and advice such as the accessibility of study materials and study outputs for young people. They will meet 4 times over the study period. IA will lead the YPAG with support from the researcher and other team members. The group will consist of six children from a community-based organisation such as a school or the Scouts, and attempts will be made to include young people of various different ages between 11-23 years of age to reflect the study population.

They will meet approximately every six months. They will receive study progress reports, advise on participant recruitment, interview design and content, analysis, and the dissemination plan and associated outputs. The research team will ensure that the community organisation from which YPAG members are recruited has established processes for offering pastoral support and safeguarding young people, and will work with the organisation to support YPAG members if needed. Training will be integrated into the meetings. It will include establishing the purpose and role of the group, getting to know each other, establishing ground rules and ways of working, understanding what research is, what the study aims to do and how what they provide fits in to the study. The research team will be receptive to their ideas for doing things in the group.

10.9 Study Steering Committee (SSC)

An independent steering committee will be set up to oversee the study on behalf of the funder and to provide the study team with advice and guidance. They will meet approximately every six months at points they agree are of most benefit to their role and the delivery of the project, but at least once a year.

The SSC will have an independent Chairperson. It will have members with relevant experience such as in research in cardiac arrest and bystander involvement, training young people in resuscitation techniques, knowledge of providing CPR training and wellbeing support in the education system, trauma in young people and support and treatment provision. We will have 2 PPI steering group members who, along with other committee members, will be able to advise the research study team. They will have insight into impacts of witnessing cardiac arrest on young people, their families, and their school and social networks. Their role will be ensuring that the study is following the proposed plan and ensure that the views of the PPI members of the research team and the study's Young Person's Advisory Group (YPAG) are being assimilated into all aspects of the study. Routine business will be conducted by email, post or online meetings/teleconferencing. Members of the Steering Committee will complete and adhere to a Steering Committee Charter.

The Steering Committee, working on behalf of the funder will:

- Inform and advise on all aspects of the study.
- Review, advise on and agree major decisions such as a major change in the protocol.
- Monitor the progress of the study and make progress related recommendations to the study team and the funder where necessary.
- Review relevant information from other sources that could impact on or inform the study.

11. MONITORING AND QUALITY ASSURANCE OF STUDY PROCEDURES

All research team staff involved in data collection will have had GCP training as part of their role.

The researcher with support from the SMG will develop a system to check the quality of participant records (e.g. completion of consent forms and storage of study documentation and data). They will ensure secure transfer processes of data from interview locations to the University (e.g. encryption of laptop where qualitative data may be temporarily stored, secure transfer of audio files to the transcription company). They will periodically check paper documentation matches electronic records and personal identifiable data is not stored with research data.

A King's College London approved risk assessment will be conducted for this study.

Quality assurance qualitative data: The process of analysis will be supported by CF in line with reflexive thematic analysis processes to ensure a high-quality analysis.

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13. APPENDIX 1 DATA FLOW TABLE

<u>Originating Site(s)</u>	<u>Type of data</u>	<u>Means Paper/Electronic</u>	<u>Format Identifiable/pseudonymised/anonymised</u>	<u>Transferred to</u>	<u>Stored</u>	<u>Who will have access</u>	<u>How long will these be stored for</u>
Parent/adult participant /young person aged 16-18 participant location	Consent form	Paper	Identifiable during data collection, analysis and study write up. The paper will be destroyed at the end of the study, but an electronic scan taken for archiving. This will remain identifiable.	KCL	Locked cabinet at KCL, JCMB during the study. See How long will these be stored for in column for archiving.	KCL researchers only	These will be scanned for archiving at the end of the study and paper versions destroyed. The electronic versions will be archived electronically in the KCL Digital Records Management Service. Presuming the youngest participant is 11 at the time of the interview we will archive for 3 years after they have reached the age of 18. 7 years +3years =10 years according to KCL data retention policy
Parent/adult participant/young person aged 16-18 participant location	Consent form	electronic	Identifiable during data collection, analysis and study write up and archiving.	KCL via email	KCL SharePoint during the study. Archived in the KCL Digital Records	KCL researchers only during the study. KCL archive staff as necessary during archiving	10 years

<u>Originating Site(s)</u>	<u>Type of data</u>	<u>Means Paper/Electronic</u>	<u>Format Identifiable/pseudonymised/anonymised</u>	<u>Transferred to</u>	<u>Stored</u>	<u>Who will have access</u>	<u>How long will these be stored for</u>
					Management Service		
Research participant's location (e.g. school, other place arranged for interview local to the participant)	Interview recordings	Electronic (encrypted recording device) or Microsoft Teams Microsoft Teams recording	Identifiable during data collection and transcription. Will not be archived.	KCL to be downloaded as and audio/teams recording file and saved onto the study SharePoint site	KCL SharePoint	KCL Researchers only	Deleted from audio recording or computer/laptop as soon as possible after safely downloaded to KCL study SharePoint site. Recordings will be kept until they have been transcribed and transcriptions checked for accuracy.
KCL	Interview recordings	Electronic audio file	Identifiable during data collection and transcription. Will not be used for analysis nor will they be archived.	Approved KCL transcription company under an appropriate data sharing agreement	Stored for transcription purposes by company in accordance with data sharing agreement	Minimum number of people at the transcription company needed to fulfil the data sharing agreement to transcribe recordings	Deleted once transcribed
Approved KCL transcription company	Interview transcripts	electronic	Identifiable, but pseudonymised as part of the transcription and checking process. Pseudonymised during, analysis	KCL	KCL SharePoint during the study and archived on KCL Digital Records	KCL researchers will check transcripts are pseudonymised and then allow access for study team researchers from	Pseudonymised transcriptions. archived on KCL Digital Records Management System 10 years after the end of the study

<u>Originating Site(s)</u>	<u>Type of data</u>	<u>Means Paper/Electronic</u>	<u>Format Identifiable/pseudonymised/anonymised</u>	<u>Transferred to</u>	<u>Stored</u>	<u>Who will have access</u>	<u>How long will these be stored for</u>
			and archiving. Any data examples used in publications and outputs will be anonymised.		Management system after the study ends	University of Warwick and University of Oxford for assistance with analysis if necessary KCL archive staff as necessary during archiving	
Potential research participant or their parent/person with parental responsibility	Participant and if a child participant, participant's parent/person with parental responsibility's name and contact details	electronic	Identifiable during the study. Will not be archived	KCL	KCL SharePoint	KCL researchers only	Deleted at end of study
Child participant's parent or person with parental responsibility	Child participant's school contact details	electronic	Identifiable during the study (but should be professional information). Will not be archived.	KCL	KCL SharePoint	KCL researchers only	Deleted at the end of the study

<u>Originating Site(s)</u>	<u>Type of data</u>	<u>Means Paper/Electronic</u>	<u>Format Identifiable/ pseudonymised/ anonymised</u>	<u>Transferred to</u>	<u>Stored</u>	<u>Who will have access</u>	<u>How long will these be stored for</u>
KCL	Pseudonymisation break sheet containing participant name, parent/person with parental responsibility name and unique study ID number	Electronic	Identifiable during recruitment, data collection analysis and write up (i.e. during the study). Will not be archived	N/A	KCL SharePoint	KCL researchers only	Deleted at the end of the study