Do specialist cancer services for teenagers and young adults (TYA) add value?
The 2012 TYA Cancer Cohort Study

Version 11, 24th July 2015
Protocol authorisation

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Protocol approved by:

CHIEF INVESTIGATOR
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24th July 2015

PRINCIPAL INVESTIGATOR

Print name .............................................................
Signature .............................................................
Date .................................................................
## Amendment history

<table>
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<tr>
<th>Version</th>
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<th>Author</th>
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Lay summary

What is the problem? Every year about 2,000 teenagers and young adults aged 13-24 years (TYA) in England are diagnosed with cancer, which is the main cause of deaths in this age group apart from accidents. There is evidence that the results of cancer treatment for TYA are not good enough and that TYA are poorly provided for by current cancer services. In 2005, National Institute for Health and Clinical Excellence issued *Improving Outcomes Guidance for Children and Young People with Cancer* (1). It states that all young people should have access to specialist TYA cancer services. Some but not all parts of England have now established these services, so the care TYA receive varies from place to place. Only about half of TYA are treated in specialist centres. Despite this recommendation for specialist TYA services, there is no definition of ‘specialist care’ or its ‘core’ parts. Professionals and patients say ‘TYA specialist care’ is ‘better’ for TYA, but it is unknown how specialist services affect the success of treatment or if specialist services are cost effective for the NHS.

What are our aims? to identify the most valuable parts of TYA specialist care; to evaluate if specialist TYA care affects outcome; to calculate the costs of specialist TYA care; and to identify the opportunities for organisational and clinical change, which may improve services for TYA with cancer.

How will we do this? TYA aged 13–24 years who are newly diagnosed with cancer in England will be invited to participate. A survey will be administered within 5 months of diagnosis, then at 12, 18, 24 and 36 months after diagnosis. The survey measures quality of life, satisfaction, progress in education and employment as well as details of the quality of treatment given and how long TYA live after a cancer diagnosis. The survey will also measure the costs of cancer both for young people and their families and for the NHS.

What can we learn? This cohort study is part of a larger programme of research designed to tell us if specialist services are better for TYA and if so, in what way and why. This knowledge will help in design and plan services according to patients’ needs and allow us to inform TYA of where they are best treated.
Background

Why do we believe specific consideration should be given to TYA with cancer?

The overall aim of this study is to determine whether specialist cancer care for TYA, as outlined in the *Improving Outcomes Guidance* (1), is associated with improved outcomes during and after treatment compared to other forms of care. Cancer in young people is uncommon, accounting for less than 1% of all new cancer diagnosis in England. ([http://info.cancerresearchuk.org/cancerstats/incidence/age/index.htm](http://info.cancerresearchuk.org/cancerstats/incidence/age/index.htm)). Despite its rarity a number of issues advocate special attention for young people with cancer and a critical need for a robust evidence base to support current and future health care policies. These include:

- A unique spectrum of cancer types occur, which are distinct from those affecting younger children and older adults;
- Cancer is second leading cause of death for young people accounting for 11% of deaths in TYA aged 15-24 (2;3);
- While potentially curable for many patients, there is evidence that outcomes for some cancers have not improved in line with those achieved for children and older adults. However, advantages accrue to society from the successful treatment of more young people with cancer through the prolonged fulfilment of their contribution in employment and other societal impacts (4);
- A cancer diagnosis has an acute and unique impact on a critical and complex stage of life development, disrupting physical health, social and educational goals as well as psychological wellbeing.

The needs of TYA are poorly met by the well-developed cancer services traditionally tailored towards the needs of children and those for older adults with cancer.

Concern has arisen that traditional cancer services are insufficient for TYA. Young people frequently fall between children’s and adult cancer services, into 'the grey zone' (5) or 'no man's land' (6). The consequence of this is realised when lesser improvements in outcomes for young people are observed compared to children and some older adult cancers (7). Delays in cancer diagnosis, unfavourable tumour biology as increasing age, inconsistent use of molecular diagnostics that may be central to optimal care (8); limited access to clinical trials (7;9;10); lack of concordance with treatment protocols (11-13); and a lack of specialist supportive care (7;14) have all been implicated with this short fall in outcome ( survival) improvements.

Young people themselves describe unsatisfactory experiences of care which include: lack of recognition of their autonomy; failure to maintain their need to continue to meet normal life goals during treatment; lack of peer support; care by staff with little experience of young people; and finally, inappropriate care environments (15;16). The failure to meet the unique
psychosocial and healthcare needs of this specific population is increasingly highlighted in the international literature. Place of treatment and cancer care, in terms of both disease and age appropriate specialist settings is increasingly acknowledged as potentially significant to the outcome for TYAs with cancer (7;17).

**How does NHS policy reflect these needs?**

In recent years there has been a rapid expansion in the availability of dedicated services for TYA in the UK. It is now accepted that young people should have access to specialist cancer care (5;14;17). Thirteen principal treatment centres are currently in place. Key components of services include tumour site-specific expertise delivered in conjunction with meeting the broader psychosocial needs of young people to support successful navigation of critical life transitions.

The NICE *Improving Outcomes Guidance* does not direct that care of all 13-24 year olds will take place in specialist centres. Instead, it recommended that all patients aged less than 19 years are referred to principal treatment centres for their treatment. Those 19 years and over should be offered 'unhindered access to age-appropriate care'. This division resulted from: a requirement to be consistent with the National Service Framework for Children and Maternity Services; and in recognition of the heterogeneity of medical and personal need in older young people; and finally, an acknowledgment that there was insufficient persuasive evidence to mandate a greater degree of centralisation of care. Thus, 19-24 year olds should be offered choice of place of care, either referral to principal treatment centres or more local, adult cancer services. Initiatives to support information giving to assist young people to decide on a place of care have begun but their effectiveness is as yet unknown ([www.nhs.uk/young-cancer-care/pages/cancer-care-choices.aspx](www.nhs.uk/young-cancer-care/pages/cancer-care-choices.aspx)). Other settings of non-specialist care include 'shared care centres', usually the closest local hospital to an individual patient’s home, where management of acute complications of treatment, and other aspects of care, may occur either in children’s or adult services (Table 1 shows levels of care and the components expected to be included in this).

**What effect has NHS policy had on TYA experience of care?**

While policy directs patients towards treatment in specialist TYA cancer services there is national variation in access and delivery both in terms of geographic variation and by cancer type. Pilot data obtained by the research team (O’Hara, Moran, Whelan, *unpublished*) suggest that around 50% of individuals aged 15-24 years diagnosed with cancer since 2009 have been referred to a principal treatment centre for discussion by a TYA multidisciplinary team. For 85% of these, the principal treatment centre was their main treating hospital. This corresponds with earlier analyses on TYA patients undertaken using linked cancer registry and Hospital Episode Statistics data, which showed that approximately 50% of TYA patients diagnosed between 2003 and 2005 were admitted for treatment at least once to one of the Trusts that is now a principal treatment centre (Feltbower, Birch, O’Hara *unpublished*).
### Table 1: TYA matrix – the components of different levels of TYA cancer care

<table>
<thead>
<tr>
<th>Care setting</th>
<th>TYA clinical/ service leads at place of care</th>
<th>TYA ward staff</th>
<th>TYA MDT input into treatment and care plan</th>
<th>PTC TYA support team: TYA CNS, and psychosocial support staff</th>
<th>PTC TYA team outreach support/ community care</th>
<th>Model Descriptor</th>
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<tr>
<td>Comprehensive TYA age appropriate cancer unit</td>
<td>TYA lead clinician and lead nurse</td>
<td>Ward staff with TYA focus/training</td>
<td>Yes; TYA MDT in PTC</td>
<td>Yes – at PTC facility</td>
<td>+/- at home</td>
<td>TYA PTC</td>
</tr>
<tr>
<td>Adult ward +/- TYA enhancements (patients &gt; 16/18)</td>
<td>TYA lead clinician and lead nurse sessions</td>
<td>+/- some staff with TYA focus/training</td>
<td>Yes</td>
<td>+/- at local facility</td>
<td>+/- at home</td>
<td>TYA Network care (adult) +/- TYA outreach</td>
</tr>
<tr>
<td>Paediatric ward +/- TYA enhancements or generic adolescent unit (patients &lt; 16)</td>
<td>TYA lead clinician and lead nurse sessions</td>
<td>+/- some staff with TYA focus/training</td>
<td>Yes</td>
<td>+/- at local facility</td>
<td>+/- at home</td>
<td>TYA Network care (paediatric) +/- TYA outreach</td>
</tr>
<tr>
<td>Standard adult ward (patients &gt; 16/18)</td>
<td>No</td>
<td>No</td>
<td>+/-</td>
<td>+/- at local facility</td>
<td>+/- at home</td>
<td>Adult model +/- TYA outreach</td>
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<tr>
<td>Standard paediatric ward (patients &lt; 16)</td>
<td>No</td>
<td>No</td>
<td>+/-</td>
<td>+/- at local facility</td>
<td>+/- at home</td>
<td>Paediatric model +/- TYA outreach</td>
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Blue: all care provided in a specialist centre; Green: care provided by a mix of specialist and non-specialist centres; Yellow: no specialist care unit input

CNS: clinical nurse specialist; MDT: multi-disciplinary team; OP: out-patient; PTC: principal treatment centre; TYA: teenage and young adult

### What evidence exists for the benefits of specialist TYA cancer care?

Despite the implementation of new models and service configurations for the care of young people with cancer, there is limited evidence for the benefit of designated teenage cancer units and specialist services. Studies in North America have examined place of care for young people in terms of the differences between being treated in children’s and adult centres (18-20). In the UK a few studies have explored some elements of adolescent cancer specialist care (21,22). These highlight the importance of TYA cancer specialist units, particularly for being “a good place to be if you are having a bad time” (22) and although limited by study size and design, they strongly emphasise the need for more in-depth evaluation. It is therefore timely to determine how far the delivery of care in specialist TYA cancer services is associated with improved treatment outcomes and influences the quality of survival in comparison to other forms of care. The proposed research is the first prospective, multi-dimensional evaluation of TYA cancer care and will identify benefits associated with different levels of care.
Aims

The overall aim of BRIGHTLIGHT is to evaluate the effectiveness of specialist cancer services for young people aged 13 – 24 years. Specific aims are to:

• Examine three levels of TYA cancer care (based on Table 1) and explore the association with patient outcomes:
  ▪ Relate the level of care received to: quality of life, satisfaction with care, clinical processes and clinical outcomes.
  ▪ Examine young people's experience of the different levels of cancer care.
  ▪ Compare social and educational milestones amongst young people receiving different levels of care.
  ▪ Examine carer’s experience of the different levels of care.

• Examine geographic and socio-demographic inequalities in access to TYA cancer care.

• Evaluate the cost and cost effectiveness of different levels of specialist TYA cancer care to the National Health Services and to young people themselves.

Study design

BRIGHTLIGHT is a cohort survey of 2,012 young people newly diagnosed with cancer. Data will be collected using the BRIGHTLIGHT Survey, a bespoke questionnaire for the purpose of this study. Data will be collected over 3 years at 5 time points: 5 months after diagnosis, then at 12, 18, 24 and 36 months. Comparisons will be made using a metric defining three levels of care. The matrix in Table 1 is forming the basis for the TYA Cancer Specialism Scale. This is being developed using information on all national cancer registrations among 15 – 24 year olds diagnosed with cancer between 2001 and 2007. Validation of the TYA Cancer Specialism Scale is currently being completed (Birch, PhD thesis, University of Leeds).

Theoretical framework

The theoretical framework underpinning this study draws on the phased approach of the Medical Research Council’s (MRC) framework for developing and evaluating complex interventions (23) and theories of evaluating complex social and health programmes (24). The MRC framework is a flexible non-linear process with increased emphasis on development and implementation (Figure 1) as well as evaluation, and has been used successfully in other complex interventions in TYA with cancer (25;26). This study is based on a series of pilot studies to generate the theory and modelling phases of the framework.
This study is the evaluative phase but will also incorporate the development of interventions that will be subsequently piloted and evaluated.

**Figure 1:** Key elements of the development and evaluation process

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**Sample & setting**

BRIGHTLIGHT will include young people aged 13 – 24 years newly diagnosed with cancer (ICD-10 codes C00-C97) in England. The study will examine the care young people receive in a range of clinical settings. Young people with cancer in England may be treated either in a designated Principal Treatment Centre for children (<16 years) or for young people (<19 years) or, if aged 19-24, either in a principal treatment centre or an adult cancer unit in their local hospital. ‘Shared care’ refers to care delivered outside but related to the Principal Treatment Centre.

**Inclusion criteria:**

1. Aged 13 – 24 years at the time of diagnosis;
2. Resident in England at the time of diagnosis and treatment;
3. Recruited within 4 months of diagnosis.

**Exclusion criteria:**

1. Young person is not capable of completing the survey (e.g., unconscious, mental incapacity);
2. Young person does not consent/assent to take part;
3. Recurrence of previous cancer;
4. Death is imminent;
5. Young person is receiving a custodial sentence.

Sample size

The sample size calculation is based on a comparison between the three levels of TYA care drawn from the Cancer Specialism Scale (Table 1) for the primary outcome of PedsQL total score, measured at five time points over the three year follow-up. Previously reported PedsQL data for paediatric cancer patients suggests a standard deviation for this score of 16 (28). To detect a difference in scores of 8 units with 90% power (29) would require a sample of approximately 270 TYA. This calculation has assumed a significance level of 0.01 to allow for multiple comparisons between the three levels of TYA care and has assumed an average of three repeated measurements per patient (intra cluster correlation 0.3 as suggested as a maximum for similar patient outcomes (30)). The calculation has allowed for adjustment for confounding factors using a variance inflation factor with a correlation of 0.5 (31). To ensure adequate power to examine the effect of TYA care on quality of life also within subgroups of age at diagnosis (two levels: 13-18; 19-24 years) and type of tumour (haematological, solid tumour groups), the minimum required sample size has been inflated to 800 (80% power) and 1,000 (90% power). To account for attrition over the 3 year study period and to reflect an approximate yearly total number of new diagnoses, the aim is to recruit between 980 – 1,320 young people.

Using anonymised data from the national TYA database for those patients who choose not to participate, we will evaluate the representativeness of the sample with regard to age, gender, ethnicity, location and diagnosis.

Recruitment procedures

Identifying young people through the registry

Approval has been granted by the National Information Governance Board, from a Research Ethics Committee and through NIHR Coordinated System for gaining NHS Permission from all Trusts where young people are treated (Appendix 2). Young people in BRIGHTLIGHT are identified using the national TYA database developed and maintained by the North West Knowledge and Intelligence Team (NW KIT, formerly known as the North West Cancer Intelligence Service, NWCIS), the National Cancer Intelligence Network lead cancer registry for TYA. The national TYA cancer database is derived by linking data from the National Cancer Data Repository, with data from the national Hospital Episodes Statistics, the Radiotherapy Dataset, Cancer Wait Time data and TYAC registration. A cancer diagnosis in a young person will be evident to NW KIT within 90 days of diagnosis.
The recruitment procedure is depicted in Appendix 3. On a monthly basis, NW KIT will obtain name, date of birth, NHS/hospital number, ICD-10 code and place of care details from the first treatment data in the Cancer Waits dataset. These are the details of all young people who are treated for cancer. A research assistant based at NW KIT will review and email potential participant details to a link researcher in each Trust. Details of the process for handling NW KIT notifications are provided in Appendix 4. The majority of young people present at the 13 Principal Treatment Centres or major children’s/adult oncology units. However, approximately 30 - 40% of young people are cared for in other Trusts, which may only care for 1 or 2 TYA a year.

**Identifying young people locally**

Posters and literature advertising BRIGHTLIGHT are provided to all participating Trusts, to make young people aware of the study. These were developed by the Young Person’s Reference Group, the patient user group attached to the study (detailed later). Literature contains contact details of the study co-ordinating team (referred to from hereon in as BRIGHTLIGHT Study Office) and an information website (www.brightlightstudy.com) so young people have the opportunity to obtain information prior to contact with the NCRN researcher\(^1\)/BRIGHTLIGHT Study Office. Information is also available on [www.Jimmyteens.tv](http://www.Jimmyteens.tv), an internet site used by young people with cancer.

In order to identify young people as soon as possible after diagnosis, participating Trusts will liaise with the TYA MDT (if a Principal Treatment Centre) and the co-ordinators of all MDTs, with the exception of prostate and lung, to be informed if there are any newly diagnosed patients aged less than 25 years.

**Recruitment in participating Trusts**

The link researchers within each Trust will have agreed responsibility for receiving the NW KIT notification file, although recruitment and consent may be delegated to other members of their team. The NCRN researcher will liaise with the clinical team to ensure young people fulfil inclusion criteria. The clinician will gain the young person’s permission for the researcher to approach them about the study. The young person will be given written and verbal information, and will have the opportunity to ask questions. Depending on the young person’s treatment, this will be during an in-patient stay, outpatient visit or when in ambulatory care. In the development work, young people noted a barrier to recruitment was being approached to early and therefore suggested recruitment between 2 – 4 months after diagnosis. However, the researcher/clinical team know their young people so they may

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\(^1\) This is generic term that is being used to refer to all health professionals recruiting and consenting young people to BRIGHTLIGHT.
assess it being appropriate to approach a young person early and therefore consent can be obtained at any time, but recruitment must be before 4 months after diagnosis.

The information sheet

There are separate versions of the patient information sheet available for young people and for parents of young people younger than 16 years. Young people will also be given an executive summary of the information sheet, which contains the key points of the study. Based on data from NW KIT generated in our feasibility project, it is anticipated that the majority of young people [and parents] will understand English; however, to ensure all young people can be included in the survey, the information sheets will be translated into relevant languages and verbal information from the NCRN researcher will be delivered through an interpreter. The necessity of providing information in other languages will be informed by the NCRN researcher during the screening process for eligibility for inclusion. Young people will also be directed to the BRIGHTLIGHT website (www.brightlightstudy.com), which contains the information delivered through video explanations from both members of BRIGHTLIGHT Study Office and the Young Person’s Reference Group about what participation involves.

Young people will be given written and verbal information about the study prior to obtaining consent. A record of consent will be obtained either face-to-face or through the post:

- The NCRN researcher will approach young people to determine whether they would like to participate. This can be on the same day as information is given because consent to participate will be re-confirmed verbally at the time of survey administration. If consent is being sought within 24 hours of information being given then the researcher will check that young people have had sufficient time to read it and consider participation. If this is not confirmed then additional time will be given before re-approaching for consent.
- If the young person is no longer in the Trust after information has been given the NCRN researcher will call the young person to discuss BRIGHTLIGHT and see if they want to take part. If they agree verbally then the consent form will be mailed to young people with a stamped addressed envelope. A follow-up call will be made after a week to confirm this has been received.

The consent process

The consent process is summarised in Figure 2. Young people and parents of those less than 16 years will be asked to sign consent forms. Assent will be sought from young people less than 16 years, subsequent to consent being obtained from parents. The consent/assent states that:
i) They have read the information sheet;

ii) They agree to take part (or to their child taking part) and that their contact details can be forwarded to the BRIGHTLIGHT Study Office;

iii) They agree that the BRIGHTLIGHT Study Office can give young people’s contact details to Ipsos MORI, a commercial research company subcontracted to BRIGHTLIGHT, so they can participate in the survey;

iv) They agree to their main hospital consultant and General Practitioner being informed of their participation;

v) They agree for clinical information to be obtained from medical records and NHS databases;

vi) They have been given the opportunity to ask questions;

vii) Acknowledges that they may withdraw from the study at any time without giving a reason and without adversely affecting their future treatment or care;

viii) That information (and direct quotes) relayed in the survey will be presented and published but this will be anonymous and they will not be identifiable.

ix) That information already collected will be used after they withdraw unless they ask for it to be destroyed.

x) That they agree to being contacted about future studies.

Young people will be asked to provide their preferred contact details (address, telephone number, email address) and those of a friend or family member, who the BRIGHTLIGHT Study Office will be able to contact if communication with the young person is lost throughout the 3 year study period. Change of address/contact detail forms will be available from the website and included in each biannual newsletter. This will be documented on the consent/assent form. The consent/assent forms will be faxed/scanned and emailed through the N3 network to the BRIGHTLIGHT Study Office and the original kept at the NCRN office for collection by a member of the BRIGHTLIGHT research team (site visits will be made throughout the recruitment period). A copy of the consent form will be sent to young people and also to their main clinician to be placed in their medical records (with the young person’s agreement). Written consent will only be obtained once; however, verbal consent will be sought by the BRIGHTLIGHT Study Office prior to each wave of data collection. Young people less than 16 years who assent to participate will be asked to consent when they are 16.
If a young person does not want to participate in the study, the NCRN researcher will ask the young person if they are willing to give a reason for this. In addition, permission to retain the young person’s contact details (email address) will be sought. This will be to enable the BRIGHTLIGHT Study Office to include them in the mailing list for the biannual newsletter, which will contain results from the study and also useful resources. Permission will also be sought for a member of the Young Person’s Reference Group to call or email young people who refuse to participate to explore in more depth why they did not want to take part (script and interview schedule in Appendix 5). Young people will be informed that this will be recorded and transcribed verbatim, when the recording will be deleted. They will also be informed that quotes will be used from these interviews but they will be anonymous. Consent for this and contact details will be recorded on the Patient Refusal Form, which will also be faxed to the study co-ordinating office.

To optimise recruitment to BRIGHTLIGHT, two focus groups were conducted with network researchers to explore their views of the study and recruitment methods, explore their anxieties and to identify any perceived challenges they may foresee. The focus groups were through an online-telephone method, which enabled at least one researcher from each network to participate. As participants were only identified through a number, the online
method allowed anonymity and freedom of expression, which was especially important as participants represented a range of professional grades (32). The results of the focus group guided the degree of support the BRIGHTLIGHT team will need to provide in order that recruitment is optimised. An ‘FAQ’ section addressing professionals concerns was added to the website (http://www.brightlightstudy.com/healthcare-professionals/faqs.aspx).

**Recruitment by the BRIGHTLIGHT Study Office**

Young people aged 16 and over, who can consent for themselves, will be recruited by the BRIGHTLIGHT team directly through the study office using two mechanisms. Firstly, through advertising the study on key websites, such as JimmyTeens.tv and teenagecancertrust.org and secondly, by accessing the Twittersphere. Using Twitter to recruit research participants has been shown to be an effective way of increasing recruitment based on snowball sampling techniques (33). Tweets will be sent by the BRIGHTLIGHT Study Office team, on a weekly basis, from the BRIGHTLIGHT Twitter account (@bR1GhTLiGhT) and from accounts of associated charities (e.g. Teenage Cancer Trust, CLIC Sargent) to those who follow the BRIGHTLIGHT study and asked to retweet (RT) the following is an example:

   “Do you have cancer? Age 13-24? Know about BRIGHTLIGHT? Please check at [https://www.survey.bris.ac.uk/lsbu/onlineconsent2014](https://www.survey.bris.ac.uk/lsbu/onlineconsent2014) Please RT to spread the word”

The key information in all tweets will be the Bristol Online Survey (BoS) link containing the information sheets. BoS is an online survey programme that has the benefit of encryption; each survey has a unique secure URL. Access to the BRIGHTLIGHT BoS account is password protected with access limited to the BRIGHTLIGHT Study Office team. The BoS is not a link to the BRIGHTLIGHT Survey but instead allows young people to complete an online eligibility check and to consent to the opportunity to participate in BRIGHTLIGHT (Figure 3).

The tweet with the BoS URL link to the BRIGHTLIGHT consent for contact survey (Appendix 6) will be sent to everyone following BRIGHTLIGHT with the request to RT to try and maximise the number of people who receive it. This will be sent once a week throughout the duration of recruitment. When young people access the survey they are initially asked questions related to the study inclusion criteria to allow potential participants to self-assess whether or not they are eligible to participate. If they are not, they will be told they do not meet the entry requirements of the study but they can still help (they will be directed to Young Advisory Panel). If they are eligible to participate young people are directed to read the patient information sheets, which are accessed in the survey through a hyperlink direct to the BRIGHTLIGHT website. When the young person returns to the survey they are required to agree to each of the statements that are contained in the BRIGHTLIGHT consent form (outlined in the consent process on page 13). This ends by asking young people to
provide their name and contact details and specifies that by doing this they are agreeing that the BRIGHTLIGHT Study Office team and an interviewer from Ipsos MORI will contact them.

**Figure 3** Summary of the process of recruitment by the BRIGHTLIGHT Team

- The tweet with the Survey Monkey URL link is sent to everyone following BRIGHTLIGHT
- Young people access the survey and complete questions checking they are eligible to participate
- If they are eligible they are directed to read the full patient information sheet and executive summary from the website
- If young people are interested in taking part they agree to the conditions outlined in the consent form and provide contact details and information about their healthcare provider
- When young people press ‘finish’ the contents of the survey are available to the BRIGHTLIGHT Team through the secure login, who contact the young person’s healthcare provider to check eligibility
- The BRIGHTLIGHT Team call young people to check they understand what participation involves and answer any questions
- At the time of interview, the consent form is sent to young people, which will be collected and returned to the BRIGHTLIGHT Team by the Ipsos MORI interview

In addition, young people will be asked to give permission for the BRIGHTLIGHT Study Office team to contact their healthcare provider. This is necessary to verify that young people are being treated in the Trust, that they are eligible to take part and to access clinical information. Young people confirm that they fit the inclusion criteria but we need to ensure that they are not very close to end of life, do not have recurrence or they are not currently in custodial care. When all this information is provided young people click on ‘finish’ and their details are stored securely on the BoS until they are removed by the BRIGHTLIGHT Study Office team (accessed through the secure login). This will be removed every weekday and transferred to the BRIGHTLIGHT participant file on an NHS server (see page 35 for data protection arrangements).

Young people will be called by the BRIGHTLIGHT Cohort Manager or Research Assistant to see if the young person has any questions and to confirm that they want to take part. Young
people will be notified that an interviewer from Ipsos MORI will be in touch to arrange a visit. Prior to the interview the BRIGHTLIGHT Study Office team will send a hard copy of the standard BRIGHTLIGHT consent form to the young person to complete and sign, which will be collected by the Ipsos MORI interviewer before the survey is administered. The consent form will be returned to the BRIGHTLIGHT Study Office through Ipsos MORI courier delivery service. A copy of the consent form will be sent to young people and their clinical team to go the medical records (with the young person’s consent).

**Recruitment by Quality Health**

Young people will be identified and recruited using the mechanism employed by Quality Health for the National Cancer Patient Experience Survey (CPES). This method has been approved as an amendment to the existing Section 251 approval (ECC-8-05d-2011) by the Health Research Authority through the Confidentiality Advisory Group and is summarised in Appendix 7.

Young people will be identified centrally by each participating Trust’s IT department based on the criteria of age (16 – 24 years), new cancer diagnosis and ICD10 codes. Data will be transferred to Quality Health via N3/SEFT, where it will be stored under ISO270014/IGSOCV11 protocol. Quality Health will double check young people fulfil the age/ICD10 eligibility criteria and using the DBS method (cross checking other national registries) will check if they are deceased. An information pack containing information leaflet and contact form will be sent to young people with details of Quality Health’s FREEPHONE number if they require further information. Two reminder letters will be sent to prompt young people to return this.

On receipt of the contact form, Quality health will email young people’s details to the BRIGHTLIGHT Study Office via the N3 network to an nhs.net email account. The BRIGHTLIGHT Study Office team will contact the young person’s treating Trust to check the young person does not meet the exclusion criteria and to obtain information about their cancer (diagnosis, date of diagnosis, GP and consultant details).

Details of young people who are confirmed as fulfilling the eligibility criteria will be transferred to Ipsos MORI (as detailed on page 34). Young people will be approached about the survey by Ipsos MORI’s field interviewers, as detailed on page 22; however, prior to administering the survey they will obtain written consent. This adapted consent form only has the Ipsos MORI identifier number and none of the additional contact information. The consent form will be returned to Ipsos MORI’s central field office with all the interviewers contact details. This will be stored and couriered to the BRIGHTLIGHT Study Office quarterly with the paper questionnaires (see page 21).
The BRIGHTLIGHT Study Office will send young people a copy of the consent form with the thank you card and wrist band. A copy will also be sent to the clinical team to be placed in their medical records.

Maintaining the cohort

Following Wave 1, it will be necessary to maintain contact with young people to enable data collection in subsequent waves. Young people will receive a biannual newsletter by email, unless they request a hard copy through the post. This will contain information about the study. The newsletter will also include information about resources available to young people with cancer, upcoming events and any relevant policy information. The study also has a website and Twitter account. The Young Advisory Panel (YAP) will form the editorial team for the newsletter and website. To keep young people engaged with the project we will email young people birthday cards. Young people will also receive a wrist band embossed with the study name and logo as thanks for taking part. These are graded according to the number of times young people have participated (1 = yellow; 2 = orange; 3 = light red; 4 = dark red; and 5 = multi-coloured).

Strategies to maximise accrual

Several steps will be taken to maximise accrual. Beginning before recruitment opens we raised awareness of the study amongst the professional community and amongst young people with cancer. Publicity, developed in conjunction with the Young Person’s Reference Group, will be used in PTCs, through National Cancer Research Institute Clinical Studies Groups, National Cancer Research Network Newsletters, and through TYAC professional and at patient conferences.

Methods

We will assess the extent of specialised TYA care received using the TYA Cancer Specialism Scale (based on Table 1), at the level of the individual patient. There will be 5 waves of data collection:

- Wave 1: 5 months after diagnosis
- Wave 2: 1-year after diagnosis
- Wave 3: 18 months after diagnosis
- Wave 4: 2-years after diagnosis
- Wave 5: 3-years after diagnosis

Data collection will be through young person self-report questionnaire at every wave of data collection using computer-assisted methods. Data for some secondary outcomes will be obtained from the national TYA database and patient records.
Patient completed data
Young people will be asked to complete three questionnaires: the BRIGHTLIGHT Survey, which is interviewer or online self-completed depending on the wave of data collection; the Cost of Care Questionnaire, which is a retrospective health economic evaluation self-report questionnaire; and the Cost Record, which a prospectively completed health economic evaluation. The latter two documents can be completed by the young person or with family/friends.

The BRIGHTLIGHT Survey
The BRIGHTLIGHT Survey is an investigator and patient designed self-report questionnaire administered through computer-assisted methods. The BRIGHTLIGHT Survey has been developed from patient-experience literature (34) and is underpinned by a conceptual framework (figure 4, 35). The primary outcome for BRIGHTLIGHT is quality of life, measured using the PedsQL 4.0™. This is validated for young people aged 4–24 years (36) and contains 23 items covering the core domains of physical, emotional, social and work/school functioning. Total score summarises these domains on a 0-100 scale, with 100 representing the best possible quality of life. We are also using the EQ-5D, which is a standardised measure of health status that will enable quality adjusted life years (QALYs) to be calculated for economic analyses. It comprises of 5 dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) scored on 3 levels (no, some, severe problems). The EQ visual analogue scale records young person’s self-reported health on a vertical scale ranging from ‘best imaginable health state’ to worst imaginable health state’.
The remaining content of the BRIGHTLIGHT Survey has been derived from young people’s experiences as reflected in the conceptual framework. At wave 1, this includes questions related to: pre-diagnostic experience, place of care, experience of health professionals, treatment, clinical trials, adherence, communication & coordination of care, social well-being and employment. The survey also includes validated measures of social support, illness perception and emotional well-being:

- The Multi-dimensional Scale of Perceived Social Support (37;38) contains 12 statements, which are rated as strongly agree to strongly disagree. Scores are calculated for support by friends, family and significant others.
- The Brief Illness Perception Scale (39) is a measure of the emotional and cognitive representations of illness. It contains eight questions with fixed response scale specific for each question, e.g. not at all – extremely helpful.
- Hospital Anxiety and Depression Scale (40) is a measure of the presence and levels of depression and anxiety. It contains 14 items, which are answered on a four-grade verbal scale.

Development of the BRIGHTLIGHT survey is on-going, with questions planned to reflect survivorship, palliative and end of life care, and transition from paediatric/TYA cancer.
services to adult cancer care. In wave 2 questions have been included about fatigue, response to acute treatment toxicity and concerns about recurrence of cancer. These will replace some of the questions specific to pre-diagnosis/diagnosis and early treatment.

Our pilot work revealed that young people often pass through their illness trajectory in a non-linear manner (e.g. relapse and require further treatment or develop unforeseen complications) and this trajectory is unique to each young person. Different questions related to experience will be relevant to each young person at different time points. Accordingly, the BRIGHTLIGHT Survey has complex routing to ensure young people are only asked questions that are relevant to their current situation as well as the specific wave of data collection. For example, questions related to pre-diagnosis and diagnosis will only be asked at Wave 1; responding to a question on completion of treatment will disable all questions related to chemotherapy, radiotherapy, surgery etc. The questions in the BRIGHTLIGHT Survey were developed from: information gathered during our feasibility studies (27); published qualitative studies reporting young people’s cancer experience (34); other research carried out by members of the research team (41;42); and existing work stored within the Data Archive (www.data-archive.ac.uk) and Survey Question Bank (www.surveynet.ac.uk/sqb/). As an interviewer-administered survey to a large cohort of young people, questions within the BRIGHTLIGHT Survey are mainly closed ended using a variety of scales and pre-coded answers, although it concludes with the opportunity for young people to make any additional comments.

The prototype of the BRIGHTLIGHT Survey was confirmed as covering a comprehensive range of experiences by a panel of expert health professionals and initial content validity was confirmed in a workshop conducted with a group of young people who had been treated for cancer. They assessed questions for content and relevance, and reviewed each section for missing questions. The assessment by young people also focused on methods of reducing response bias, including strategies to reduce memory errors (i.e. using a short reference period and focusing on events that are important to young people), social desirability bias (i.e. not including sensitive subjects) and response errors (i.e. ensuring the questions and response options reflect the young person’s experience). Content validity of the BRIGHTLIGHT Survey was also confirmed through cognitive interviews with 23 young people (32). Additional questions will undergo the same testing process with young people.

Cost of Care Questionnaire and Cost Record

The costs incurred by young people and families of different levels of cancer care will be calculated using the Cost of Care Questionnaire and Cost Record. These include the following:

- Travel (car parking, petrol and capital depreciation, public transport);
- Time off work;


- Equipment;
- Prescription drugs;
- Over the counter drugs;
- Accommodation;
- Complementary and alternative medicine;
- Family care.

The Cost of Care Questionnaire is only given at wave 1 and asks young people and their families to reflect back to the time of diagnosis and estimate how much they have spent on the above areas. The Cost Record is given at waves 1 and 2 and asks young people and their families to prospectively record, on a weekly basis the costs incurred as a result of their cancer.

**Carer complete data**

Young people will be asked to nominate a carer to complete the Carer Questionnaire. A carer is defined as an adult who has provided physical and emotional support during their cancer treatment, e.g. parent/guardian, partner or close friend. The Carer Questionnaire is a 30 question, self-completion questionnaire, about their personal experiences of care and support, develop from the unmet needs literature (43-45). Young people will be requested to invite the person they perceive as providing the most care during periods of hospitalisation (if more than one person is thought to provide carer then their combined response will be requested). Completion of the Carer Questionnaire is through Likert-type scales. There are no identifiers on the questionnaire but respondents are able to provide their contact number/email address if they would like to be involved in any future research.

**Procedure**

The BRIGHTLIGHT Survey will be administered through face-to-face, telephone or online interviews depending on the wave of data collection and young person preference. At Wave 1 (5 months after diagnosis) this will be through face-to-face interview and self-report for sensitive sections (preventing social desirability bias). In subsequent waves there will be the option to complete the survey either on-line or through a telephone interview, acknowledging young people will be moving on with their lives. In response to data derived from the 2008 and 2010 Teenage Cancer Trust patient conference, and from our pilot work indicating wide variability in the acceptability of different methods of survey administration, we will maintain flexibility. This will also reduce non-response bias. The use of mixed modes has not been shown to affect data quality but only to improve the rate of response (46). Face-to-face and telephone modes of survey administration will be through computer-assisted devices, which has the benefit of having inbuilt methods for checking for errors (i.e. detecting illogical sequencing). The online survey will be scripted into an online CAWI (Computer Aided Web Design) format and also has similar ability to check for errors.
The time points’ young people will be involved in the study is summarised in Figure 5. Survey administration to young people will be conducted by researchers from a commercial research company, Ipsos MORI, in a location chosen by the young person. On a monthly basis Ipsos MORI will be given young people’s contact details from the BRIGHTLIGHT Study Office. At wave 1 (5 months after diagnosis) following an advance letter and information leaflet being sent to young people, and their carer, the researcher will contact young people by phone to introduce themselves and arrange a date and time to complete the BRIGHTLIGHT Survey. Prior to completing the survey, for young people recruited through the CPES method, the interviewer will obtain written consent. Young people will complete the survey with the researcher through computer-assisted administration. A carer, who has been nominated by young people and agree to participate, will be given the Carer Questionnaire to complete while the young person completes the BRIGHTLIGHT Survey. If more than one carer is present they will be asked to complete it through discussion. This will be returned either to the interviewer in a sealed envelope or a FREEPOST envelope will be left with carers to return the questionnaire when it is completed. Finally, the researcher will explain how to complete the Costs of Care Questionnaire and Cost Record and leave these with young people at the end of the interview with FREEPOST return envelopes. It will be stressed to young people and families/carers that completion of these documents can be done together. They will be requested to return the Cost of Care Questionnaire within the week. The BRIGHTLIGHT Study Office will co-ordinate the return of the Cost Record through phone and email contact with young people and their families. After administering the survey, the research company will destroy all the young person’s details following their standard quality checks. Data collected on the computer-assisted administration systems will be stored solely as the unique study number.

The survey is being administered by researchers who have experience in interviewing young people. As with other centrally managed cohort studies, a telephone hotline number will be given to young people at the end of the survey in case they become distressed following the survey or have questions related to questions contained within it (47). The hotline will not in itself provide help but will facilitate provision of support by others. A comprehensive list of resources has been developed, from local and national cancer contacts to general resources related to TYA issues (e.g. sexual health). This has been developed based on existing supportive resources for young people (48). The hotline will be manned by the BRIGHTLIGHT Study Office during working hours. These resources are also available on the study website for supporting young people outside of office hours. Young people will also be provided with a card containing helpline numbers at the end of the interview should they have any concerns and wish to access support directly. Finally, the Senior Research Manager and Cohort Manager will contact young people a week after participating in each survey to ensure there are no subsequent concerns. If the interviewer has concerns after administering the survey the BRIGHTLIGHT Study Office will be informed at the earliest time and young people will be contacted as soon as possible.
**Procedure at follow-up**

It will be important to track mortality in the cohort to ensure no undue distress to young people’s friends and family when they are contacted for Waves 2 to 5. This will be through two routes: first, NWcis will inform the BRIGHTLIGHT Study Office of any notifications they have received from the principal treatment centres; and second, the young person’s healthcare team will be contacted a fortnight before data collection is scheduled. Before data collection at Waves 2 to 4, young people will be contacted by the BRIGHTLIGHT Study Office to confirm that they would still like to participate and to identify their preferred mode of survey administration. When this has been confirmed, young people’s contact details will be sent to Ipsos MORI. Data collection for Waves 2 – 5 will either be via an online survey or telephone interview. For the online survey respondents will receive an email/text message inviting them to participate in the study. The email/text will contain instructions and a secure link to the survey website. Each link is unique to each participant, and the survey can be completed in stages if the respondent requires. Those who do not respond to the online survey will be sent up to two reminder emails/texts, with each again containing their unique link. Those who do not respond to the online survey, or who express a wish to be contacted by telephone for Waves 2-5 will be contacted directly by one of Ipsos MORI’s telephone interviewers. If a young person is palliative (as informed in the follow-up check with the health care team), then the Senior Research Manager will call the young person to get their permission for Ipsos MORI to call them. Respondents can book a convenient time to complete the interview or do so immediately if this is convenient. Several attempts will be made to try and make contact with the respondent if the initial attempt is unsuccessful.
Data transfers and storage for Waves 2 – 5 will follow the same procedures as Wave 1, with contact details being destroyed when data collection and quality checks are complete.

**Researcher collated data**

The BRIGHTLIGHT Case Report Form (CRF) contains key measurable clinical process and outcome variables. These have been to sample medical outcomes through the pathway of diagnosis, treatment delivery, treatment efficacy and supportive care. Where possible, data will be obtained from the national TYA database. The focus is on the most measurable variables, considering data that is required to be collected for governance (e.g. radiotherapy delivered), NHS peer review (e.g. diagnosis) and Good Clinical Practice for UK clinical trials, which is often electronically stored (e.g. chemotherapy prescription data). Additional data collected manually will only be those that are essential to understanding the value which may be provided by TYA services.

The BRIGHTLIGHT CRF is completed online through the Bristol Online Survey. This is an encrypted online survey, with data held on a UK academic server. This platform has been reviewed by the Information Governance Manager at University College London Hospitals NHS Foundation Trust who confirmed this complies with the Data Protection Act (1998). Data collected in the CRF is pseudo-anonymous (NHS number and date of birth as the only identifying data). Additional identifiable data is also required to be submitted:

1. Histology report
2. Evidence of molecular diagnosis or classification
3. Full MDT outcome record proforma
4. Correspondence stating the aim of treatment (curative/palliative etc.)
5. Correspondence outlining the treatment plan (curative/chemotherapy/radiotherapy/other or a specified combination)

This information will be sent either to the BRIGHTLIGHT NHS.NET email account, faxed to the safe haven fax or through the post to the BRIGHTLIGHT office.

To further maximise quality, clinical measurements from clinical notes will be piloted in 50 sets of case notes from 3 centres, in collaboration between clinical (Stark, Whelan), cancer registry epidemiologists (Feltbower) and methodological (Barber) team members. Inter-rater protocols and training will be developed to identify and minimise any difference in interpretation. If ambiguous clinical terminology is identified, these will be defined. Members of the NCRN who will be involved with data collection will receive a brief from the project team prior to data collection. Variables extracted from clinical notes will be examined for both test-retest reliability and migration due to ‘learning curve’, in 48 randomly selected sets of notes from 6 centres, using time intervals between ratings of
either 6 or 12 months. Re-rating will conducted by researchers from other centres, blinded for previous scores.

**BRIGHTLIGHT Team collated data**

We will collect information from primary care prior to and after diagnosis. This will allow us to determine whether specialist care influences engagement with primary care health services following treatment for cancer and subsequent cost difference related to this.

To develop the TYA CSS and inform health economics analysis, HES data will be obtained from the Health and Social Care Information Centre (HSCIC). Each BRIGHTLIGHT participant will have linked in-patient (including day case), outpatient, A&E and mental health HES admissions data recording their unique ID (NHS number, cohort ID), HES_ID, episode start and end dates, episode order, consultant code, and provider code. The application for this data will be made either directly from the BRIGHTLIGHT office or a linkage will be made by the North West Knowledge Intelligence Team.

**Data analysis**

Data from the BRIGHTLIGHT Survey collected through computer-assisted devices will be coded and cleaned by Ipsos MORI before returning to the research team in a statistical software package. Paper self-report versions and health economics data will be entered manually into the same software at the BRIGHTLIGHT Study Office.

The influence of missing data in all analyses will be considered. Initially missing data will be examined descriptively focusing on the extent of missing data, reasons for this (where available) and through comparing the characteristics of patients with and without missing values. Regression models will be used to identify predictors of missing outcome and important predictors will be adjusted for in primary regression analyses. Where questionnaire items are incomplete, preventing calculation of final scores for analysis (e.g. quality of life scores), a sensitivity analysis will be conducted using multiple imputation methods (53;54). Further sensitivity analyses using multiple imputation methods will be considered for missing explanatory variables. Imputation methods in both cases will incorporate correlations due to repeated measurements (54). Detailed plans for all analyses (including handling of missing data) will be prepared in advance of the final analysis of the data.

The primary analysis will investigate the influence of level of TYA care on PedsQL total score. Adjustments will be made for confounding factors including age at diagnosis, gender, diagnostic group, stage, socioeconomic status and ethnicity. A full set of confounders for adjustment will be identified a priori, using Direct Acyclic Graphs approach. Analysis will use
multiple regressions allowing for repeated measurements within patients. The assumptions of the model will be checked and alternative models will be used as appropriate.

A similar approach will be taken in examining the relationship with level of TYA care for patient satisfaction and patient care outcomes. Time from referral to tumour progression, one and three year survival will be considered in a Cox regression model (or similar if assumptions are not met). Outcomes evaluating process of care will be considered descriptively. In all models interaction terms will be included to examine the differential effect of the level of care on outcome by broad categories of age at diagnosis and tumour type. The impact on results of allowing for possible sources of clustering at higher levels (e.g. by cancer network, PTCs or Trust) will also be explored using multi-level models.

The patient experience data will be analysed according to predefined key questions. Associations of interest (for example between progress in education/employment and level of TYA care) will be examined using appropriate statistical models with consideration of predefined confounding factors. Other data will be examined purely descriptively using summary statistics and tabulations. Data from open ended comments will be analysed using qualitative content analysis.

The proportion of individuals receiving high levels of specialist care according to the Cancer Specialism Scale aggregated to cancer network or Strategic Health Authority will be mapped using GIS software. Associations between levels of TYA care will be investigated with geographic and socio-demographic inequality measures using ordered logistic regression. First, the Cancer Specialism Scale will be examined against cancer network and primary care trust. Use of TYA services will be regressed against individual, small area, practice and primary care trust characteristics from the assembled data. Inequalities in use of TYA services will be quantified using individual and small area socioeconomic status, and ethnicity measures. Inequalities will be investigated by comparing outcomes according to deprivation quintiles whilst adjusting for the level of TYA specialist care and other confounders (gender, age, diagnostic group and stage of disease). Consistency of the results will be investigated using cross-section time series (i.e. panel data) techniques to identify changes in inequalities over time (e.g. a difference-in-difference approach).

Health economic analysis

Care pathways will be constructed for young people receiving the different levels of specialist TYA cancer care, based on the TYA Cancer Specialism Scale (Table 1, page 5) and published studies of treatment pathways for specific cancers, including the Map of Medicine [http://www.mapofmedicine.com/]. These will vary by type of cancer and patient age. The pathways will be populated using patient level data from the patient cost questionnaires, clinical notes and administrative data sources e.g. national TYA database. Pathways will be costed using national published sources. Costs per patient will then be compared between
these levels of care. The pathways that will be constructed will vary depending on the type of cancer and the age of the patient, but will include the following cost components:

- Patient with symptoms contacting their General Practitioner (including diagnosis in secondary care, outpatient clinic attendances and diagnostic tests and procedures);
- Management in secondary care (including, as an inpatient, further diagnostic tests, surgical procedures, chemotherapy, radiotherapy, and as an outpatient, chemotherapy, radiotherapy and follow-up management);
- Management in community (including on-going treatment such as drug and diet management, and physical rehabilitation and psychosocial support such as counselling);
- Palliative care (including palliative care provided in the hospital, hospice or at home).

Pathways will be constructed for different types of cancer. Cancers with similar pathways will be grouped together. Based on the epidemiology of cancer in young people, the six main groups will be: acute leukaemias; lymphomas; brain tumours; bone sarcomas; carcinomas; other solid tumours including germ cell, soft tissue sarcoma and melanoma. Once the care pathways for different types of cancer and patient ages have been developed they will be populated with researcher collated data to give the proportion of patients following particular treatment pathways and the volume of resources used (e.g. numbers of tests and surgical procedures, length of stay, number of outpatient visits). In addition, infrastructure costs will be considered, arising from possible reorganisation of services. These will include costs of training specialists and capital costs of centres. This will be through standard methodologies (55). Costs per patient will then be compared between these pathways, stratifying by the type of cancer. The time horizon for this analysis will be three years (the duration of follow-up in the programme of the cohort). Once individual costs per patient have been assembled patients will be categorised by type of care received and costs per patient will be compared between these groups using regression analysis controlling for potential confounding factors, such as type and severity of cancer and age. The analysis will be incorporated into the cost-effectiveness modelling (see below).

The analysis of costs to young people and families from the patient cost questionnaires will be calculated by applying unit costs from published sources to calculate the mean monthly out-of-pocket cost per TYA patient. Travel costs for private car travel, including parking costs, will be calculated using published motoring costs. Distances travelled between home and place of treatment postcodes will be calculated using GIS software. Costs of public transport will be collected directly in the survey. The opportunity cost of time lost from work will be estimated based on the prevailing wage rate, adjusted for employment. The costs of all other items will be recorded directly in the survey. As with the analysis of NHS/personal social services costs, costs per patient will be categorised by type of care and compared between these groups using regression analysis controlling for potential confounding factors, such as type and severity of cancer and age. These analyses will also be incorporated into the cost-effectiveness modelling (see below).
Cost-effectiveness models will be constructed to assess the short- and long-run cost-effectiveness of specialist TYA care versus standard care. The analysis will conform to accepted economic evaluation methods (56). Cost and cost-effectiveness for the ‘within-study’ period, over the duration of the programme, (three years/short-run model) will be estimated, and also over the expected lifetime of the patient (lifetime/long-run model). As with the analysis of costs, cost-effectiveness will be assessed separately for different types of cancer (acute leukaemia; lymphoma; brain tumours; bone sarcomas; carcinomas; other solid tumours including germ cell, soft tissue sarcoma and melanoma). Cost-effectiveness in the short-run model will be measured using the patient-reported outcome measures; as well QALYs calculated by combining the EQ-5D and mortality data. In the lifetime model cost-effectiveness will be calculated in terms of the incremental cost per QALY gained. De novo cost-effectiveness models will be developed that will be populated based on available evidence, supplemented with published data to extrapolate beyond the duration of follow-up in the cohort study. Following decisions about model structure, a list of parameter estimates required for the model will be developed. The specific details of the data to be used to populate the model will be determined following the development of the structure and the systematic searches of the literature to identify existing data to model long term costs and outcomes.

In both the short-run and the long-run models incremental analyses will be undertaken comparing levels of care, applying standard rules for decision making in cost-effectiveness analysis based on dominance and extended dominance. In all analyses extensive deterministic (one-, two- and multi-way) and probabilistic sensitivity analysis will be undertaken, the latter assuming appropriate distributions and parameter values [79]. We will use these analyses to construct cost-effectiveness acceptability curves, which will show the probability that specialist care is cost-effective for different values of the NHS willingness to pay for an additional QALY.

**Collaboration with Ipsos MORI**

Ipsos MORI Social Research Institute were awarded the tender to provide research services for BRIGHTLIGHT after a formal tendering process was conducted through the Official Journal of the European Union. The selection of Ipsos MORI was based on not only their ability to provide a national network of skilled interviewers but also that they fulfilled essential criteria fulfilling our ethics and data protection arrangement. Ipsos MORI are contracted to University College London Hospitals NHS Foundation Trusts and therefore assume responsibility for Ipsos MORI interviewers.
All the Ipsos MORI interviewers are highly experienced at face-to-face survey administration. The interviewers who are working on BRIGHTLIGHT also have extensive experience of working with children and other vulnerable groups (such as patients with cancer, young offenders and rape victims) so are well equipped to administer surveys to young people with cancer. Interviewers all have health clearance through Ipsos MORI Occupational Health providers and all interviewers speaking with TYAs aged 13-15 also have Basic Disclosures. The procedure for administering the BRIGHTLIGHT Survey to young people less than 18 years, demands that there is another adult in the house throughout the time the interviewer is in the young person’s home. Interviewers will not be accessing young people on any participating Trusts property unless express permission has been granted by the Trust.

Ipsos MORI are corporate members of the Market Research Society (www.mrs.org.uk), abiding by their Code of Conduct. For more details about Ipsos MORI Social Research Institute, please look on their website:

Ethical considerations

The current study design takes into consideration a number of ethical issues:

1. Methods of recruitment
The rationale underpinning this is as a cohort study, it is essential that we have a robust strategy to approach every young person fulfilling our inclusion criteria. Through using the cancer waits dataset we have a mechanism to identify all young people; however we require a process of approaching young people that respects their privacy. The North West Cancer Intelligence Service (NWCIS) is the cancer registry responsible for the TYA dataset; however, they are forbidden to contact patients directly. One mechanism would be to inform the BRIGHTLIGHT Study Office every month of new diagnoses but they are unable to filter confirmed from suspected cancer diagnoses and therefore we would be receipt of a lot of patient data unrelated to the study. The National Cancer Research Networks are uniquely placed to mediate between the registry and the BRIGHTLIGHT Study Office so we are only informed of young people who fulfil our inclusion/exclusion criteria and who have consented to participate. All the details of those without cancer and do not consent will be deleted.

2. Informed consent
Any research can be perceived as being burdensome for young people and their families when they are dealing with the day to day realities of cancer and its treatment. It is essential that as researchers we are confident that the young person, and where relevant, the family, has given informed consent to participate, and that this consent is an on-going process (57).
Most young people aged 13 – 24 years will be undergoing cancer treatment when they are approached to participate in Wave 1, some will still be receiving treatment in subsequent waves and some unfortunately, will be receiving end of life care. It is essential that consent/assent is informed at Wave 1. Details of the consent/assent process are outlined earlier. Age appropriate information will be given to young people less than 16 years, and their parents. As the study involves young people participating in a survey about their experiences, it is important that they want to take part so their willingness to participate will be paramount. To ensure young people understand what participation involves, written consent/assent will only be sought when the researcher is confident the young person understands the study.

3. Longitudinal study-related issues

As noted earlier in the procedure for administering the survey, a major ethical issue in conducting longitudinal research in young people with cancer is ensuring young people who have died are identified prior to being approached for the next wave of data collection. This is to prevent undue distress to their families. We will receive notifications from NWCIS, who will obtain this information from the death registries. However, to account for potential time lag in the registry being informed we will contact young people’s health care team prior to each wave of data collection.

Participation in the study is for 3 years, young people will only be requested to sign a consent form at the beginning; however, prior to Waves 2 to 5 young people will be given the opportunity to withdraw (58). If young people withdraw from the study, we will confirm that they are willing for us to continue using previously collected data. The exception to this will be young people <16 years at Wave 1 who sign assent forms. When they turn 16, young people will be sent a consent form and stamped addressed envelope and a follow-up call will be made by the senior researcher to ensure young people understand what continued participation means and what it will involve. Young people will be removed from further data collection until consent has been received, although their contact details will be retained so they can receive the newsletter.

Prior to each wave of data collection (2 to 5), young people will be contacted by the BRIGHTLIGHT Study Office to confirm a suitable time/place/mode of survey administration, and given the opportunity to withdraw. If young people decide to withdraw, they will be asked if they can be contacted for subsequent waves. They will also be asked if they would be willing to complete just the PedsQL (primary outcome measure) and if so, it can either be completed over the phone by the BRIGHTLIGHT Study Office or a paper version will be [e]mailed. Young people who did not consent to participate in Wave 1 will have the opportunity to participate in subsequent waves if they are receiving the newsletter. A standard inclusion in the newsletter will be a reminder to keep the study office informed for changes of address and the following statement:
“If you did not take part in BRIGHTLIGHT when you were diagnosed, but think you might like to complete future questionnaires, please contact Rachel or Anita on 07415 557668, email: Brightlight@uclh.nhs.uk.”

If a young person contacts the study office, they will be given verbal information about the study over the phone and sent written information through email. They will be contacted the following week to determine that they have received the information and to answer any questions. If they would like to take part, a consent form will be sent to the young person with a stamped addressed envelope to return it to the study office. Data collection will only commence when the study office has received the consent form.

4. Involving young people less than 16 years
It is important that young people less than 16 years have the opportunity to be involved in the study as this is an evaluation of TYA services aimed at 13 – 24 years the whole of this age range needs to be represented. The BRIGHTLIGHT Study Office includes experienced children’s health care professionals and researchers who respect the rights of privacy and confidentiality of children and adolescents to the same degree as adults. Informed assent will be obtained from all those less than 16 years after gaining consent from parents, with consent obtained as the young person reaches 16. The appropriateness of questions will be determined by a review from young people and an independent review from parents.

5. Potential sensitive subjects
Prior to a study it is difficult to anticipate participant’s responses to questions, as we know individuals will respond differently. The questions in the BRIGHTLIGHT Survey have been developed based on qualitative research of young people’s reported experiences of cancer. Young people have also been involved in the development of the BRIGHTLIGHT Survey. Despite this we have taken a number of steps to ensure that we respond quickly and appropriately to young people’s worries or concerns related to our data collection.

   a. The research team is made up of experienced researchers and practitioners in TYA care and this has influenced the suitability of the questions included.
   b. The researchers from Ipsos MORI are experienced researchers who have undertaken data collection with young people previously and will pick up on cues and any signs of distress that may result from questioning.
   c. At the end of survey administration, young people will be asked if there is anything from the questions that is worrying them or any area that made them think about their own care which they are unsure about. For example, we ask about future employment and this may be the first time a young person has thought about this in relation to their own diagnosis and treatment. The young person will be advised to contact their clinical team and will be given details of the telephone hotline number and website.
   d. The study has a telephone hotline number that will be given to young people at the end of the survey in case they become distressed following the survey or have
questions related to questions contained within it (47). The hotline will not in itself provide help but will facilitate provision by others through a comprehensive list of resources related to TYA issues (e.g. sexual health). The hotline will be manned by the BRIGHTLIGHT Study Office during working hours. These resources will also be available on the study website for supporting young people outside of office hours. The BRIGHTLIGHT Team will also make a follow-up phone call to the young person a week after each survey has been completed to ensure there are no subsequent concerns.

e. Hospital policies for reporting and supporting persons who disclose potentially harmful information will be adhered to.

f. We will contact young people a week after participating in each survey to ensure there are no subsequent concerns.

6. Use of a contract research company

We made the decision to collaborate with a research company based on their extensive established resources (e.g. nationwide network of skilled survey interviewers who can work to a protocol). However, a number of other benefits have emerged:

- Researchers have broad experience working with both young people and in clinical settings;
- Independent researchers, who are not involved in clinical care, reduce the risk of bias during data collection;
- Stringent measures exist to minimise missing data (questionnaire design and interviewer administered);
- There are robust methods for ensuring data safety and quality.

Ipsos MORI were the successful organisation who was awarded the tender following a formal procurement procedure by University College London Procurement Services through the Official Journal of the European Union (OJEU). Researchers employed by Ipsos MORI undergo intense training to administer surveys in a uniform manner. They work according to the Market Research Society (www.mrs.org.uk) Code of Conduct (2010); following the guidance for conducting research with children and young people (2006); and adhere to the Privacy and Electronic Communication Regulations (2003).

User involvement

Patient involvement has been central to our pilot work, which we plan to develop during this study. We worked with the National Cancer Research Institute’s (NCRI) TYA Clinical Studies Group (CSG) consumer group, called the Core Consumer Group (CCG). This was a group of four cancer survivors who had a remit to reflect on and disseminate the research streams of the TYA CSG and gain consensus from a wider TYA patient audience. Consultation was done by the CCG through presentations and an interactive survey at Teenage Cancer
Trust’s annual patient conference ‘Find Your Sense of Tumour’ (FYSOT), which was attended by over 300 young people who had experienced cancer. The CCG was facilitated by Dr Fern and CCG member, Hannah Millington, is a co-applicant and continues to represent young people.

In the pilot studies, the CCG designed invitations for patient workshops; worked as co-researchers; co-facilitated workshops; assisted with data analysis and are co-authors on publications. They presented proposed research annually at the Teenage Cancer Trust patient conference which included TYA diagnosed 13-24 yrs. This consultation was facilitated by an electronic interactive survey. The proposal for the 2012 TYA Cancer Cohort study (BRIGHTLIGHT) was presented in March 2010 to 93 TYA diagnosed aged 13-17 and 43 aged 18-24. Overall, 67% would have been willing to participate shortly after diagnosis, with a preference for a face-to-face interview (64%). We have also tested the acceptability of the proposed quality of life questionnaires with patients currently undergoing treatment. The CCG have presented posters and gave oral presentations at the NCRI and INVOLVE conferences in 2010. Two manuscripts are under review with the CCG as co-authors (e.g. http://www.ncri.org.uk/ncriconference/2009abstracts/abstracts/C3.htm).

The 2012 TYA Cancer Cohort has been renamed BRIGHTLIGHT following the initial workshop with the Young Person’s Reference Group, a dedicated user group providing advice, guidance and critique of the methods and conduct of the study. After a further workshop operationalising the study, members will be consulted using options such as Facebook discussion rather than face-to-face meetings, recognising the range of life stage commitments of TYA. The CCG and the Young Persons Reference Group will have an advisory role throughout and will be pivotal in interpreting results and dissemination. The Reference Group have refined the information sheets, are developing the website, and will be editors for the biannual newsletter. We will draw on the experience of the Young Persons Reference Group to advise us how to target patient groups who may be underrepresented in our cohort.

Furthermore, we are capturing the views of families, siblings and significant others through established family support networks in Leeds, Manchester, Cambridge and London. Groups in Manchester, Cambridge and London meet regularly and two members of the research team will attend one of these meetings in each region annually to present the study and capture views. Recognising that the views expressed in these forums are likely to reflect those who receive most of their care in a principal treatment centre we have gained permission to utilise the ‘Realshare’ website, which is a secure website for patients being treated in the South West, providing a virtual platform for patients who are dispersed over a large geographical region. Members must have an NHS number to register. We will use this forum to place advertisements for young people to invite their parents to a coffee morning.
which we will hold once a year. Two members of the research team will present the study and capture views.

**Data protection**

The flow of data is depicted in Figure 6. Data protection is of utmost importance in the study because of the need to retain patient identifiable data. This is to enable follow-up surveys over 5 time points in 3 years. BRIGHTLIGHT is underpinned by a National System Level Security Policy agreed by the NIHR Cancer Research Network Coordinating Centre, which has been approved by the National Information Governance Board. The transfer of patient details from NWCIS to the NCRN and the BRIGHTLIGHT Study Office, and from the NCRN to the BRIGHTLIGHT Study Office, is through NHS encrypted email and is only stored on NHS servers with user unique login details. The BRIGHTLIGHT Study Office only has patient details stored from those who have consented to participate or consent to retain details. Details include name, address, phone number; email address and similar information for a second contact (see recruitment above). Access to this information is limited to the Senior Research Manager and Cohort Manager and is password protected. If either of these team members changes, the password will also be changed. All patient data from survey and registries is stored in a separate file under a unique study number, independent to the patient details. This data is pseudoanonymised to include only date of birth and postcode.

**Figure 6:** Flow of young person’s data

NWCIS: North West Cancer Intelligence Service; NCRN: National cancer Research Network; UCLH: University College London Hospitals; UCL University College London. Bold lines = passage of patient identifiable information; dotted lines = passage of pseudoanonymised data.
1 All names extracted from the cancer waits dataset (approx. 700 per month of young people suspected for cancer).
2 After screening for eligibility, inform all those young people who do not have cancer.
3 Consent to pass patient details to UCLH Study Office.
4 Details passed to the contract research company, with young person’s consent.
5 UCLH request additional information from the young person’s medical notes, with the young person’s consent

The passage of patients’ details to survey researchers at Ipsos MORI who are working in the field will be by: secure transfer from Ipsos MORI CAPI (computer assisted personal interview) Servers direct to CAPI laptops (whole disk encrypted); and printed on hard copy survey contact sheets sent by post to the survey researchers working in the field. Following completion of survey quality control checks, updating of sample data with updates collected from patients during the survey interviews and confirmed successful secure transfer of the data to the research team at UCL, patients’ details will be securely deleted, leaving only anonymous survey data on completion of every wave of the survey fieldwork.

Patient identifiable details transferred between the BRIGHTLIGHT Study Office to the research company will also be through encrypted email, preferably the N3 network. Data transferred back to the BRIGHTLIGHT Study Office will be through the same network but it will be anonymised (unique study number only). The research company will receive the names of patients who have consented on a monthly basis. As soon as data collection is complete at each wave, these details will be deleted. The terms of tendering a research company include confirmation that policies ISO 27002 and ISO 27001 have been adopted.

Management of the study

BRIGHTLIGHT is led by the Chief Investigator, Professor Whelan, with support from the co-applicants (listed at the beginning). An overview of the management of the study is shown in Figure 7. The BRIGHTLIGHT Study Office comprises of a Senior Research Manager, Lead for Patient and Public Involvement, Cohort Manager and Research Assistant, who meet weekly. The core team (BRIGHTLIGHT Study Office, Chief Investigator, workstream 1 lead and one co-applicant) meets monthly. The Executive Team (all the co-applicants and BRIGHTLIGHT Study Office) meet biannually. A Steering Committee with an independent Chair has been convened to provide clinical, methodological and ethical guidance. This committee met prior to the start of recruitment of patients and will meet approximately 6 monthly thereafter. A charter defining the role and operation of the steering committee was provided for signature to all members. In particular we recognise that young people with cancer are a potentially vulnerable population and we will ensure a rapid response to any ethical concerns which arise, through the co-applicant team and with escalation to the steering committee as required.
“University College London holds insurance against claims from participants for injury caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital’s duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

Hospitals selected to participate in this clinical study must provide clinical negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary can be provided on request.”

Figure 7  Management of the study and levels of monitoring

Incident reporting

For any event that is a deviation, violation or serious breach of the protocol the process outlined in the standard operating procedures of UCLH and Joint Research Office at UCL
(https://www.ucl.ac.uk/jro/standingoperatingprocedures) will be followed. This includes reporting through DATIX in the hospital and the on-line report form at UCL (https://opinio.ucl.ac.uk/s?s=17671). A reportable incident is EITHER something which should have happened in the study but did not OR happened but should NOT have happened which significantly effects;
   a. the rights or wellbeing of the research subject
   b. the scientific value of the study
   c. the compliance of the study with relevant legal rules or ethics guidance including the Data Protection Act or the Human Tissue Act
   d. UCL’s or the Trust’s reputation

Any incident defined as serious will be reported within 24 hours of first becoming aware of the incident through these mechanisms. The corrective and preventative actions will be implemented as a priority. As well as reporting to UCLH/UCL, the Confidentiality Advisory Group at the HRA will be informed of any incident involving processes covered by the s251 approval. The Research Ethics Committee and BRIGHTLIGHT Steering Committee will also be informed.
References


implementation of a randomised controlled trial. J RES NURS 2010;DOI:
10.1177/1744987110380803.


## APPENDIX 1: Substantial amendment summary

<table>
<thead>
<tr>
<th>Amendment number</th>
<th>Date of approval</th>
<th>Change</th>
</tr>
</thead>
</table>
| 1                | 03/08/12         | 1. Change the name of the study to BRIGHTLIGHT.  
2. Change the name of the survey to the BRIGHTLIGHT Survey.  
3. Adding the name of the website to documents (www.brightlightstudy.com).  
4. Specifying the name of the commercial research organisation (Ipsos MORI).  
5. Increasing the sample size to 2,012.  
6. Change the time young people can be approached to participate (2 – 4 months after diagnosis).  
7. Adding the option of the BRIGHTLIGHT team gaining consent.  
8. Changes to the format of the consent form.  
9. Changes to how young people are approached by Ipsos MORI.  
10. Change in the time point of data collection (5 and 8 months).  
11. Option of online survey completion.  
12. Reducing the length of the survey (40 minutes).  
15. Formatting changes to the protocol.  
16. Conducting focus groups with NCRN researchers. |
| 2                | 21/12/12         | 1. Approval of the final versions of the outcome measures.  
2. Addition of a Carer Questionnaire.  
3. Adding details about Ipsos MORI interviewers to the protocol.  
4. Clarifying who has a duty of care in the information sheets.  
5. Approval for a poster advertising the study.  
6. Approval for the final versions of the invite letters and information from Ipsos MORI.  
7. Amending the time period for gaining consent.  
8. Adding the option of young people joining the study at waves 2/3.  
9. Addition of the policy for transferring data from NWCIS to trust to the protocol.  
10. Approval for the helpline card. |
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<tbody>
<tr>
<td>11.</td>
<td>Change to the procedure if a young person is in palliative care.</td>
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<tr>
<td>12.</td>
<td>Addition of the Steering Committee to the protocol.</td>
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<tr>
<td>13.</td>
<td>Approval to send young people BRIGHTLIGHT wrist bands.</td>
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<tr>
<td>14.</td>
<td>Approval to send GPs cancer awareness literature.</td>
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<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Change the time of data collection from 5, 8, 12, 24 and 36 months to 5, 12, 18, 24 and 36 months.</td>
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<td>2.</td>
<td>Reducing the time between giving information and getting consent.</td>
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<td>3.</td>
<td>Replaced some of the questions from wave 1 related to pre-diagnosis and diagnosis with questions on fatigue, impact of acute treatment toxicity and concerns about cancer recurrence.</td>
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<td>4.</td>
<td>Adding additional contact information on the consent form: specifying the postcode and requesting mobile and landline numbers.</td>
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<td>5.</td>
<td>Changing one of the members of the Steering Committee in the protocol.</td>
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<td>4</td>
<td>20/06/13</td>
<td>Conduct a related study on participants in the cohort to test feasibility for an additional study and to cross check the content of the survey.</td>
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<tr>
<td>5</td>
<td>06/09/13</td>
<td>Use of the twittersphere to recruit young people.</td>
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<tr>
<td>6</td>
<td>06/05/14</td>
<td>To interview the CCG and YAP as part of BRIGHTLIGHT PPI evaluation.</td>
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<tr>
<td>7</td>
<td>29/05/14</td>
<td>Content of the BRIGHTLIGHT Case Report Form (CRF) and administration through the Bristol Online Survey.</td>
</tr>
<tr>
<td>8</td>
<td>16/06/14</td>
<td>Additional questions to the wave 4 questionnaire.</td>
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<tr>
<td>9</td>
<td>18/07/14</td>
<td>Obtain digitally recorded verbal consent from participants in the user group evaluation interviews.</td>
</tr>
<tr>
<td>10</td>
<td>29/08/14</td>
<td>Change the sample size and age/diagnosis stratification for the sub analysis.</td>
</tr>
<tr>
<td>11</td>
<td>16/09/14</td>
<td>1. Use the Cancer Patient Experience Survey method of direct recruitment through Trust IT for recruitment.</td>
</tr>
<tr>
<td>12</td>
<td>10/07/15</td>
<td>Approve additional questions to be asked at wave 5.</td>
</tr>
<tr>
<td>13</td>
<td>Pending</td>
<td>1. Approval to keep young people’s details until the end of the study.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Approval for a letter to send prior to Ipsos MORI contacting young people at wave 5.</td>
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<tr>
<td></td>
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<td>3. Approval of a certificate to send to young people at</td>
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<td></td>
<td>wave 3 thanking them for participating. 4. Approval for a process of incident reporting in the protocol.</td>
<td></td>
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<tr>
<td>14</td>
<td>Current</td>
<td>Amendment to the protocol to specify all the data sources, including those coming from primary care and the Health and Social Care Informatics Centre (HSCIC).</td>
</tr>
</tbody>
</table>
APPENDIX 2: A list of acute NHS Trusts in England treating young people with cancer

This is based on data extracted from the national TYA cancer registry for young people treated for cancer aged 15 – 24 years between October 2010 and March 2011.

<table>
<thead>
<tr>
<th>NHS Trust</th>
<th>Number of young people</th>
</tr>
</thead>
<tbody>
<tr>
<td>University College London Hospitals NHS Foundation Trust</td>
<td>65</td>
</tr>
<tr>
<td>Leeds Teaching Hospitals NHS Trust</td>
<td>55</td>
</tr>
<tr>
<td>Nottingham University Hospitals NHS Trust</td>
<td>52</td>
</tr>
<tr>
<td>Sheffield Teaching Hospitals NHS Foundation Trust</td>
<td>46</td>
</tr>
<tr>
<td>The Christie NHS Foundation Trust</td>
<td>45</td>
</tr>
<tr>
<td>University Hospital Birmingham NHS Foundation Trust</td>
<td>42</td>
</tr>
<tr>
<td>Imperial College Healthcare NHS Trust</td>
<td>38</td>
</tr>
<tr>
<td>The Royal Marsden NHS Foundation Trust</td>
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APPENDIX 3: Schematic representation of the identification and recruitment procedure for young people in the 2012 TYA Cancer Cohort Study

CWT: cancer wait time dataset; NCRN: National Institute for Health Cancer Research network; NWCIS: North West Cancer Intelligence Service (the cancer registry responsible for the national teenage and young adult (TYA) data set)
1. All electronic communication will be through the NHS N3 network.

2. The NCRN researcher will confirm with a member of the clinical team managing the young person’s care that they have a confirmed diagnosis of cancer, the date of diagnosis and that they are capable of participation, e.g. unconscious. No medical records will be accessed to gain this information.

3. Location is defined as the cancer network not acute Trust/hospital. This is for monitoring purposes only (i.e. if one network has a higher rate of refusal than others then more training from the BRIGHTLIGHT Study Office may be required).

4. Diagnosis will be summarised as broad categories, e.g. leukaemia, germ cell tumour, so young people with rare cancer types are not identifiable.

5. The protocol for gaining consent/assent is in line with national guidelines (Royal College of Nursing 2011).

6. Young people’s consent includes agreement that: they have read the information sheet; agree to take part (or to their child taking part); for their contact details can be forwarded to the BRIGHTLIGHT Study Office; that the Study Team can give their contact details to a contract research company so they can participate in the survey; agreement for their consultant oncologist/haematologist and General Practitioner being informed of their participation; agreement for clinical information to be obtained from their medical records and NHS databases; affirms they have been given the opportunity to ask questions; and acknowledges that they may withdraw from the study at any time without giving a reason and without adversely affecting their future treatment or care.

7. Faxes will be received in a ‘safe haven’ fax at University College London Hospitals.

8. Contact details will be stored in a file on the server with access restricted to the Senior Research Manager and Cohort Manager. The file will be password protected, which will be changed if members of staff change. Participants will be allocated a unique study number. Data collected through the survey and clinical data from the registries will be stored in a different location on the server under the unique study number only. Access to the file will be restricted to the Chief Investigator and Senior Research Manager. Transfer of data to the statistician/co-applicants conducting analysis will be through the N3 network in a password protected file.

9. A condition of procurement of the contract research company will be that they are part of the N3 network or can provide equivalent secure electronic access/encryption.

10. As data is collected from young people, the contract research company will delete their details from their records. As data collection occurs at 5 time points over 3 years, the BRIGHTLIGHT Study Office will contact young people prior to each wave of data collection. Only the details of those who verbally agree to continue participation will be passed on to the research company.
APPENDIX 4: Protocol for transferring data to and from NWCIS to NHS Trusts

[Approximately] 18th of the month NWCIS receive CWT data

Extract 1st treatment data
Limit data to ages 13 – 25 years

Between the 18th and 25th of the month NWCIS emails names to the BRIGHTLIGHT contact in the relevant Trust via an NHS.NET email address. This will be in an Excel file containing name, NHS number, hospital number, date of birth, hospital of first treatment and ICD-10 code. This will be linked to a BRIGHTLIGHT specific study number, which will be generated by NWCIS.

Each Trust follows their agreed recruitment pathway. If identifying young people locally, CWT data will be used to cross check that all young people have been captured.

The BRIGHTLIGHT contact completes the ‘Outcome’ column in the Excel file.

The Trusts returns the Excel file monthly to NWCIS on 15th of the month (+/- 3 days). A reminder message will be sent to remind them of this.

The file must have all identifiable information (name, date of birth, NHS number and ICD-10 code) removed from the file before returning it to NWCIS

NWCIS checks the returned file(s) against the latest CWT data. All ‘no contact’ patients will be added as a query to the next month’s list of names. If outcome is ‘no longer at this Trust’, NWCIS will check other hospitals to identify where the young person has been transferred to.

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2 Recruiting until the day before the 25th birthday so this will ensure we capture those diagnosed at 24.99 years but started treatment aged 25.

3 This is a drop down menu with a number of options: Excluded (please specify), recruited, refused [+/- agree to contact details being retained], referred to another Trust, no longer treated at this Trust, no contact with the Trust this month, other (please specify)

4 If the Excel is not returned then ALL the previous month’s names will be added to the next month’s list as a query. If the Excel continues not to be returned, after 2 months NWCIS will inform BRIGHTLIGHT Senior Research Manager to contact the Principal Investigator for this Trust.
APPENDIX 5: Script and interview schedule for the telephone interview to explore why young people do not participate in research

Hello, is this [name]?
Hi, I’m Matther part of BRIGHTLIGHT; you said you would be willing to talk to me about not taking part in the BRIGHTLIGHT study. Is it still okay to talk about this?
Is this a good time to talk?
Okay, you know that I will record this conversation? Are you OK with that? I will let you know when I start recording and when I stop. If you want me to stop it at any time just let me know.
Before I start, do you have any questions?

Questions for the interview:
Can you tell me something about how you were approached to take part in this study?
  • Do you remember when were you approached?
  • What information were you given?
  • Were there any parts of the information about the study, which didn’t make sense to you?
  • If so, which ones?
At the time did you think the study was relevant to you?
  • If not, can you talk about why not please?
Are you able to tell me the main reasons why you didn’t want to take part?
Is there anything you can suggest that would have made it more likely for you to participate?
Is there anything else that would have been helpful for you to know at the time?
Is there anything else that you think it would be helpful for the research team to know about deciding to take part in a study or not?
APPENDIX 6: BRIGHTLIGHT Consent to Contact Survey

BRIGHTLIGHT CONSENT FOR CONTACT

Introduction

BRIGHTLIGHT is a national study of young people, aged 15-24 years, with cancer. Every young person in England who has a new diagnosis of cancer is being invited to take part in the BRIGHTLIGHT study. BRIGHTLIGHT is a collaboration between researchers from London, Manchester, Leeds, Birmingham and Southampton, supported by the National Cancer Research Institute Teenage and Young Adults Clinical Studies Group. The BRIGHTLIGHT core research team are based at University College Hospital London.

BRIGHTLIGHT is following the lives of young people for three years after their diagnosis to find out what it is like to be treated for cancer as a young person. We are asking:

- How does having cancer affect your life?
- What do you think of the cancer services you are receiving?
- What are the costs to you and your family, of receiving treatment and care?

Young people who take part fill in a survey 5 months after their diagnosis. Not all the questions are about your cancer, most are about you as young people. After the first survey you will be contacted 4 more times over 3 years to see if you want to give us an update about how you are getting on. If you don't want to take part, you just say so and we will wait for the next time point.

If you think you might be interested you can find out more details on our website: www.brightlightstudy.com

1. To register to take part we need to know a little bit about you so please complete the question below:

Are you aged 15 – 24 years?  
Yes  ☐  No  ☐

Are you diagnosed with cancer in the last 4 months?  
Yes  ☐  No  ☐

Are you being treated in a hospital in England?  
Yes  ☐  No  ☐

If you said no to any of question 1 you are not eligible to take part in the BRIGHTLIGHT study but you can be part of the team by joining YAP (Young Advisory Panel). Please email Anita at team BRIGHTLIGHT to find out more (brightlight@uclh.nhs.uk)

If you said yes to all the questions above you might be eligible to take part. Please take time to read our information sheets about what taking part would involve. For a summary of what taking part involves please click here. For the full, detailed information about what taking part involves please click here.

Usually when you are being asked to take part in a study, a researcher would talk to you about it before asking you to sign a consent form. We are doing this backwards to give you more of a choice about taking part. If you think you might like to take part, please confirm the points in question 2 and provide contact details. When these are submitted, Anita or Natasha from Team BRIGHTLIGHT will give you a call.
BRIGHTLIGHT consent for contact

*2. You need to agree to the following in be able to take part:

1. I confirm that I have read and understood the information sheet dated 17th April 2013 (version 4) for taking part in BRIGHTLIGHT.

2. I know that I will have the opportunity to ask questions and have these answered satisfactorily before taking part in the first interview.

3. I confirm that I have had sufficient time to consider whether or not I want to be included in the study.

4. I understand that participation is voluntary and that I am free to withdraw at any time, without giving any reason, without any medical care or legal rights being affected.

5. I agree to my contact details being kept by being kept by the BRIGHTLIGHT Study Office for the 3 year duration of the study.

6. I agree that the BRIGHTLIGHT Study Office can pass my contact details to Ipsos MORI, the contract research company who are conducting the interviews, so they can give me the survey.

7. I agree that clinical information can be obtained from my medical records and NHS databases.

8. I understand that any information/direct quotations used from the surveys in a report or publication will be completely anonymous, and I will not be able to be identified.

9. I understand that if I decide to stop taking part, information that has already been collected will still be used unless I ask for it to be deleted.

10. I confirm that I know that by submitting this response I am agreeing that the personal information I provide will only be used for the purposes of this project and not transferred to an organisation outside of UCL, other than to Ipsos MORI. The information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.

By providing your name and contact details you are agreeing that the BRIGHTLIGHT team will contact you so we can get an interviewer from Ipsos MORI to give you the survey.

3. What is your first name?

4. What is your last name?

5. What is your street address?

6. At what email address would you like to be contacted?

7. What is your telephone number?

8. Please let us know the name of the main hospital you are receiving treatment, name of your consultant and the name of your nurse specialist (we need this information to confirm that you are eligible to take part).
APPENDIX 7: Schematic representation of the proposed CPES\textsuperscript{5}-based method for recruitment

- Patient identifiable data stored on NHS server
- Guidance manual for identifying eligible young people
- Data transfer according to section 251 approval via N3/SEFT
- QUALITY HEALTH
  - Stored under ISO270014 IGSOCV11 protocol
  - Check if deceased Using DBS method
- Eligible patients
  - Mailed an information pack to the address supplied by the NHS Trust
  - Two reminders sent by QUALITY HEALTH
  - Contact forms returned to QUALITY HEALTH
  - Contact forms sent to the BRIGHTLIGHT Office by nhs.net email
  - BRIGHTLIGHT Team contact Trust to confirm eligibility
  - Written consent obtained at interview
  - Study continues as current protocol

\textsuperscript{5} CPES: Cancer Patient Experience Survey