University College London Hospitals NHS
NHS Foundation Trust

Title of project: When cure is not likely: What do young adults with cancer and their families need and how can it best be delivered? A BRIGHTLIGHT companion study

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UCL

Protocol Authorisation

PRINCIPAL INVESTIGATOR

Print name ………………………………………………………..

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Date ………………………………………………………..

Amendment History

Version	Date	Author	Application reference	Notes

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Lay Abstract

Background

This study will help increase our knowledge to understand better the needs of 16-40 year olds ("young adults") when cure from cancer becomes unlikely. The younger members of this group are on the borders of paediatric care and as cancer is relatively uncommon in this age group, patients are less often encountered in adult cancer and palliative care services. Overall cancer is relatively uncommon in people in early to mid-adulthood. Nevertheless, one quarter of deaths in 16-40 year olds are due to cancer. The impact of incurable cancer on patients and families is strongly influenced by age but for adults in early to mid-life, very little is known about their experiences as death approaches or how care is best delivered. Professionals consistently acknowledge many specific challenges of managing end of life care in this age group.

From this study we aim to understand;

a) The most important parts of care in the last year of life for people with cancer aged 16-40 years.
b) Whether differences exist between the experiences of people with cancer who are aged 16-24 and those aged 25-40 years.
c) How young adults and their families can be supported in the last year of life to achieve their preferences for care.
d) The challenges that exist for health and social care professionals providing care.

Methods

There are five distinct parts to our research.

I. **Analysing available information:** we will look at all available literature and information about end of life care in young adults including the information that is now collected routinely in the NHS about preferences and place of death.
II. **Interviews with patients, families and professionals**. We will work closely with health care professionals from four study sites (University College London Hospitals, Southampton University Hospitals, Leeds Teaching Hospitals, and St. Joseph's Hospice) to identify patients for interview about their care when cure is no longer likely. Fifteen 16-24 year olds taking part in the BRIGHTLIGHT study (a study already underway in the UK) and thirty 16-40 year olds from the four study sites will be invited to participate. We will ask them to propose a family member or carer and their key worker to be interviewed as well.
III. **Workshops with patients and professionals.** We will conduct nine workshops for interactive discussion and to increase our understanding of the range of perspectives, opinions and experience. Three workshops will be with family members and carers, three with professionals and three bringing together family members and carers and professionals.
IV. **Hold professional panels.** We will present our findings and recommendations to a panel of professional experts for further refinement.
V. **Make recommendations for practice.** We will have a good understanding of the core components and pathways of end of life care for young adults and make recommendations for practice and further evaluation to assist policy makers, commissioners and other stakeholders.

How the results of this study will be used

The findings will add evidence to inform national standards, pathways of care and core competencies for training staff. We will identify areas for change or further exploration. We will make public our findings widely to both lay and professional audiences.

1. Purpose of the study

This research will illuminate the core issues affecting end of life care[1] in young adults with cancer (aged 16-40 years), gathering evidence from the perspectives of the young people themselves, their families and the multidisciplinary team.

Using a national, multiple method realistic evaluation, we shall use an iterative approach guided by the MRC framework for evaluating complex interventions. [1,2] The aim is to define, describe and understand the core components for excellent practice in the delivery of end of life care for young people with cancer, to inform policy and practice and to set priorities for further evaluation studies.

In the United Kingdom (UK), health policy on specialist cancer services has bracketed young adults up to 24 years with teenagers (teenagers and young adults, TYA). [3] In the United States, Canada and Australia, strategies for improving cancer outcomes have most often focussed on 15-40 year olds (‘adolescents and young adults’, ‘AYA’). [4] Notably, Douglas House, a unique hospice for young adults in Oxford serves an age range of 16-35 years. [5] This age group has attracted little attention in other European countries where there has been less consistency in the age range studied. We aim to explore comparisons between those aged 16-24 years and those aged 25-40 years to highlight key issues and differences that may be influenced by age.

In devising this research study, our underlying theories are:

1. That end of life care for young adults with cancer aged 16-40 years could be improved by increased understanding of (a) current care pathways for people with different types of cancer (b) the effects of age (above and below 25 years) (c) the need for accurate information (d) how active participation by young adults in decision making can impact on current and future care (e) the importance of respect for individual autonomy and family interactions.

2. That outcomes would be improved by an approach to end of life care that is (a) more aware of individual patient need and autonomy (b) supports professionals to recognise and respond to patient need (c) takes account of family interactions and relationships with patient and staff (d) enables patients to receive active and palliative treatments in a place of their choice to achieve their preferences for end of life care.

Thus, our objectives are to understand:
a) The core components in the pathways of care in the last year of life for people with cancer aged 16-40 years.
b) Any differences between the experiences of people with cancer from the age ranges 16-24 and 25-40 years.
c) How young adults and their families can be supported in the last year of life to achieve their preferences for care.
d) The challenges that exist for health and social care professionals providing care.

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[1] End of life care is defined as ‘care that helps all those with advanced, progressive, incurable illness to live as well as possible until they die’. [6]

2. Background

One quarter of deaths in 16-40 year olds are related to cancer.[7] Overall survival rates have improved less than those of younger children and older adults.[8] Despite descriptions of the specific needs of teenagers and young adults for specialist cancer care, there is a dearth of empirical research, policy and expert practice related to their End of Life care. This is also true for young adults up to 40 years.

There are gaps in policy for this age group. Better care: Better Lives [9] makes no distinction between the needs of children and teenagers and young adults and deals exclusively with children's palliative services. Similarly the End of Life Care Strategy, Promoting High Quality Care For All Adults At The End Of Life makes no specific reference to young adults.[10]

Published literature about End of Life for teenagers and young adults has been confined to summaries of good practice or, where studies have been undertaken, data has been sourced from parents rather than young people themselves.[11-13] Others have undertaken retrospective analysis of medical notes [14] or produced comment and review papers.[15-18] Notably, just one study interviewed young people and explored their views on decision making as End of Life approached.[19]

Equally, work on the older young adult cancer population is limited. The few studies that have collected data from adults of all ages, either through interviews or questionnaires (EORTC QLQ-C30) have identified differences between ages at end of life including varying preferences for active treatment and greater symptom burden or lower quality of life.[20-22]

For those aged below 40 years, boundaries between curative and palliative treatment are often blurred; decisions may be influenced by cancer type, age and family circumstances. There is a lack of standardized models, approaches and communication aids for this age group; the management of symptoms and psychosocial concerns may be neglected if the challenges to communication are not overcome. Avoidance and delaying of discussions about End of Life decisions are common resulting in consequences for the quality of care.[15]

The challenges in delivering care to young people are as relevant to the delivery of end of life care as to intensive curative chemotherapy.[23-24] National policy in England and Wales directs that TYA have access to specialist services to meet specific challenges faced by young people in accessing services responsive to needs associated with the physical, educational, psychological and social developmental stages that are disrupted by the diagnosis and treatment of cancer.[4] This policy is being evaluated in the BRIGHTLIGHT study, (NIHR RP-PG-1209-10013; Appendix 3, study synopsis).

BRIGHTLIGHT will provide: a cohort of participants of all those aged 13-24 diagnosed with cancer in England in one year; the contexts and pathways of cancer care for young adults in England; sources of contributors to workshops and expert panels; prospectively collected patient outcome data and extensive analysis of the national cancer and end of life data sets. This takes into account information already available in the national cancer data repository (NCDR) and from the National End of Life Care intelligence network (Nend of lifeCIN) for those aged 16-40 years. BRIGHTLIGHT and this proposal are closely linked to the remit of the National Cancer Research Institute Teenage and Young Adult Clinical Studies Group.[25]

This study will provide the much-needed evidence to underpin quality of care and the enablers that will assist in addressing current barriers:

	Barriers to excellent end of life care	**Enablers of excellent end of life care**

We can influence	Evidence base: Poor understanding of (a) disease trajectory; (b) unmet health and social care needs; (c) variations between cancers; (d) variations between age, groups, gender, ethnicity	Data from BRIGHTLIGHT, NCDR and Nend of lifeIN
	Service factors: Support needs of staff , patients and families in decision making	Data from workshops and interviews
	Attitudes and barriers to care of young people: structural; cultural; financial. Individual factors: personal and disease specific, education	Training and support health and social care professionals
	Costs of care	Understanding of the costs of components of end of life care components
What will influence our project	Recognition of last year of life and end stage disease Interaction between active and palliative treatments Family dynamics Attitudes of health care professionals	Integrated care pathways
	National factors in healthcare environment; costs of care (perceived and actual), commissioning	Strategic documents; DH and voluntary sector pressures; new service providers; public opinion; epidemiological trends
	Regional variation in policy, service configuration and provision; cultural and economic factors	Assessing transferability of intervention in regional sites Engagement of clinical champions; multi-disciplinary team approach to care
	Training and support needs of health and social care professionals	Training and support for health and social care professionals

3. Study Design and Methods

Research will be undertaken in 5 discrete but inter-related phases.

(i) Preparatory phase;
(ii) Interviews with young adults, families and professionals;
(iii) Scenario workshops with families and professionals;
(iv) Analysis and interpretation of these data including synthesis with a literature review and quantitative data available through NCDR, Nend of lifeCIN and BRIGHTLIGHT then refinement through discussion with a panel of experts;
(v) Development of recommendations for practice and further evaluation.

See Appendix 1 for diagram of these phases.

(i) Preparatory phase

This will be undertaken at UCLH and includes a detailed synthesis of the literature relevant to end of life for young adults with particular emphasis on identification and understanding of the mechanisms potentially causing the desired outcomes. Additionally, patterns of care described by National Cancer Data Repository and National End of Life Care Intelligence Network will be used to give further characterisation by definition of tumour types responsible for deaths, place of death and variations within our age range. This phase will inform the semi-structured realist interviews with young adults and scenario development.

(ii) Interviews

Several groups including patients, families and professionals will be interviewed as described below. Four sites will be involved in this part of the study.

We will conduct interviews with 45 young adults aged 16-40 years of age, purposively sampled to reflect a range of diagnoses (relevant groupings include leukaemia, lymphoma and solid tumours including brain, testis, sarcoma, carcinomas). Recruitment will be from the two sources outlined below (Appendix 2 illustrates recruitment, consent and data collection processes).

Sample 1 will be 15 teenagers and young adults aged 16-24 years participating in the BRIGHTLIGHT[2] cohort who will 'self-identify' through responses to trigger questions in the BRIGHTLIGHT survey indicating that a) no more treatment is possible, b) they have been offered/received care from the symptom control team or palliative care team or c) giving a response to the question asking what they had been told about their cancer suggesting that they are aware that cure is no longer likely. The BRIGHTLIGHT Senior Research Manager (SRM) or Cohort Manager (CM) will confirm with the young person's healthcare team that they are receiving end-of-life care (if this was not confirmed on the pre-survey check) and make sure that it is suitable to approach them to take part in the study. When this is assured they will call the young person, briefly describe the study and gain verbal consent to forward the information sheet. After approximately a week, the young person will be contacted via an appropriate means (e.g. 'phone, text) by the same person (SRM or CM) to see if they have received the information sheet and asked if they would like to take part in the study. For those who agree they will be asked for verbal consent to pass their contact details onto the RA who will then contact the young person.

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[2] See www.brightlightstudy.com for details of BRIGHTLIGHT and appendix 3 for a synopsis.

If a young person verbally consents to participate the RA will arrange a time and place to meet them for the interview. On the day before the interview the RA will call to confirm the young person would still like to participate; if they do then the RA will visit the young person as planned but before commencing the interview, s/he will confirm the young person understands what they are agreeing to and get written consent. For a detailed description of this recruitment process, refer to Appendix 4.

After a first interview, this group will be invited to participate in a second interview between 2 and 4 months later. At the time when the young person is recruited, they will be asked to nominate a key worker who will be in charge of providing support during the study. This key worker will be in contact with the researchers and will follow up with the young person after the interview to see if they need additional support.

Sample 2 will be interviews to include thirty patients aged 16-40 years. Recruitment will be facilitated by clinical staff at six study sites: University College London Hospitals, Southampton University Hospitals, Leeds Teaching Hospitals, St Gemma's Hospice, Wheatfields Hospice and St. Joseph's Hospice. These research sites were selected because they all have established palliative care teams and services, they actively participate in research, and the staff are skilled at recruiting patients in End of Life for research.

A poster will be displayed in appropriate spaces with contact details of the site PI and potential participants asked to talk to their clinician if they are interested. Once members of the clinical team have identified potential participants, they will make sure their details can be shared with the researchers. If the participant agrees, the researchers will contact them with more information about the study. Whenever possible, this will be done through a face to face conversation about the study, but if this is not possible, the information will be sent via post and questions will be answered over the telephone. The participants will then be given time to look at the information sheets and ask questions about the study. If the participant agrees to take part in the study, they will be asked to sign a consent form.

The young people in sample 2 will be asked to identify a family member, and a professional directly involved in their care such as the key worker who can be approached to be interviewed in addition (total 90 interviews). The young people will be asked to check with the family member to see if they agree that their details be passed to the researchers so that they can contact them with more information about the study. If the family member agrees, the researchers will contact them to talk about the study and provide them with the information sheet. The researchers will also approach the nominated healthcare professionals to provide them with more information about the study and to see if they are interested in taking part.

This second sample will allow targeting of patients identified by their key workers as being directly aware that cure is no longer likely and currently in the end of life phase. Ten will be aged 16-24, and 20 between 25-40 years. The sample size and distribution has been selected to add additional interviews to complement sample 1, to reflect the clinical heterogeneity present across this age range and in anticipation of saturation of themes during analysis (refer to Appendix 5 for the sampling matrix).

Using an investigator designed template (see Appendix 6), medical notes of interviewees will be reviewed to analyse written communication and documentation about discussions related to end of life in order to seek illustrations of best practice. Records of key discussions will be sought including communication between health professionals; record of advance care planning, do not resuscitate orders; communication about preferred place of death; insight of patient and family; information given and received; and evidence to show if limits of desired levels of information had been elicited. We will pilot the review of the notes at the beginning of the period of data collection and adjust the template to suit the content found in the medical notes.

All semi-structured realist interviews will be conducted by a researcher experienced in working with young adults and discussing sensitive issues. It is anticipated they will last for approximately one hour, will be digitally recorded, and transcribed verbatim prior to qualitative analysis of transcripts. Interviews will occur in the place of choice of participants, usually during clinic visits or in their own homes.

(iii) Workshops

Scenario development: end of life trajectories for young adults with cancer will be derived from an initial scenario development workshop attended by palliative care consultants, palliative care and cancer clinical nurse specialists, allied health professionals, oncologists and haematologists. Findings from the literature review, analysis of National Cancer Data Repository and National End of Life Care Intelligence Network data and emerging findings from the interview data will be presented. Scenarios will be co-constructed to precipitate discussion around key influencing variants such as diagnosis, different ages within the range being studied, symptom constellations and patterns of information disclosure and communication (for examples refer to Appendix 7).

Nine scenario workshops: A series of three workshops will be held in the study sites used in (ii) above using the scenarios to encourage interactive discussions and generate new thinking and potential solutions to problems raised. The use of different sites will support comparisons across contexts and address issues of generalisability and transferability of findings across different UK settings. Workshops at each site will be held with:

1. Families and carers of young adults with cancer; patient representatives and regional stakeholder organisation representatives (workshop maximum size 15)
2. All members of the multiprofessional team involved in delivery of treatment for cancer and end of life care (workshop maximum size 15)
3. Mixed participants representing groups (1) and (2) (workshop maximum size 20)

The family members and healthcare professionals will be recruited using two routes. First, from the participants who were interviewed as part of sample 2. The consent forms for the interviews explained in (ii) will include a section where the family members and healthcare professionals can indicate if they would like to be contacted to participate in the workshops. Second, additional family members and healthcare professionals will be recruited in the study sites by the researchers and members of the clinical team. Close contact with the clinical team will facilitate recruitment.

Consensus will not be sought, rather perspectives, opinions and experiences elicited allowing scenario ‘mapping’. This will be done in small groups using mapping aids to identify key ideas and hypotheses arising on how end of life care could be improved.

All workshops will be moderated by members of the research team who have experience of these methods as well as end of life/cancer care. Workshop teams will be developed to ensure consistency across this aspect of data collection.

(iv) Expert panel review

A panel of experts will be convened to include palliative care professionals, general practitioners, oncologists, haematologists, allied health professionals, policy makers, ethicists, charities and commissioners. Participants will not have been involved in previous workshops or interviews. Professionals will be identified by previous participants and members of the research team. Professional organisations such as the NCRI Palliative and Supportive Care Clinical Studies Group will be consulted. These will be purposively selected based on their experience working with young people who are receiving end of life care, knowledge of policy issues and agree to participate.

A distillation of knowledge and understanding gained from realist interviews and workshops combined with quantitative data, will be presented to the expert panel describing ideal pathways with an explanatory account of key components of care. The panel will be asked to comment on areas of agreement and disagreement, provide alternative or additive explanations and to test and retest experientially the fit of mechanisms to potentially achievable outcomes as described in the pathways.

(v) Development of recommendations

The analysis and interpretation by an expert panel will lead to the writing and refining of an overarching explanatory account for end of life care for young adults with cancer. We shall present data to inform our objectives stated in section 1.

Emerging national standards, pathways of care and core competencies are anticipated and will be considered within the document. We shall circulate our draft to participants in the realist interviews and workshops, policy makers, commissioners and other stakeholders and take account of their comments in producing a final version. Identification of areas for potential intervention will be included and recommendations for future empirical evaluation and testing of the effect on outcomes will be suggested. Such empirical work would be the subject of the next phase in testing the feasibility and acceptability of the core components of delivering improved end of life care in a pilot observational study or exploratory randomised trial in the future. This would include consideration of the economic aspects of these approaches to care.

4. Data analysis

Methodological approach

We will use realistic evaluation, derived from critical realism. Its strengths are an emphasis on understanding the causal mechanisms which generate outcomes, consideration of context and a desire to improve practice and service delivery.[26] It supports a mixed method, iterative approach to capture multidimensional aspects of the evaluation of end of life care, which can be viewed as a complex, multi-component intervention. Realist research explores the links between context, mechanism and potential outcome. It increases our understanding of ‘what works, for whom, in what circumstances, in what respects and why?’ It seeks to penetrate beneath the observable inputs and outputs of an intervention. We shall initially untangle the influence of context in the care of young adults in age groups 16-24 and 25-40 years, with a range of cancer diagnoses, experiences and expectations of care. We shall use workshops to generate hypotheses on mechanisms by which care in the last year of life for people aged 16-40 years might be improved. Using qualitative data and quantitative data we shall assess which components of an intervention or approach to end of life care might lead to improvements in patient and family centred outcomes.

Analysis of interviews

Sample 1: Transcripts of the interviews will be analysed using a grounded theory approach. This provides a systematic and inductive approach for the collection of data, sampling and the building of theoretical frameworks.[27] Analysis will occur simultaneously with data collection. After reading and re-reading the transcripts, memoing and selective focused coding, constant comparison between codes will take place leading to development of categories. Software such as Atlas.Ti will support this. The second interviews facilitated by theoretical sampling will ensure completion of any conceptual gaps in the emerging theoretical framework with an understanding of individual experiences over time.

Sample 2: Grounded theory methods of analysis will also be used. The development of codes and constant comparison of codes in the development of categories will occur across the sources of data for each young adult. For example data will be triangulated using the interview data from the young person, their family member, nominated health professional and analysis of the medical notes. When a conceptual understanding has been developed for each case, analysis will occur across the sources of data as a whole.

Analysis of workshops

Detailed field notes will be taken, memos and post-it notes collected and workshop discussions will be audio-taped and transcribed verbatim as discussion around scenarios is as crucial as the 'mapping'.[28] Data will be entered into Atlas. ti. The research team will create a preliminary analysis from initial observations of the scenario maps developed and the transcripts of discussions from workshops (1) and (2) to generate a series of hypotheses of how end of life care can be improved. This initial analysis will be used to inform discussions in workshop (3).

After the data from the workshops is analysed, a short report will be distributed among the participants in order to share the findings as near to the time as data collection as possible.

Analysis for expert panel review

Analysis of data collected in an iterative process, a key aspect of realist methods, will be the focus. Preliminary thematic summaries of findings from the interviews and workshops will be combined with emerging quantitative data. Hypotheses on mechanisms of how end of life care could be improved will be carefully defined and prioritised. These will be refined further through discussion within the research team and with a panel of experts. This phase will allow a reconsideration of understanding of the interrelationships between the context and mechanisms generated by the experience of end of life care derived from all aspects of data collection, testing assumptions and exploring further remaining uncertainties.

5. Ethical considerations

We recognise that this is a sensitive area of research and we will be working with vulnerable participants. We anticipate the fact that the questions included in our interview could pose potential emotional and psychological burden for those involved. We are sensitive to this fact. The clinical members of our research team have significant experience in this area that we can draw upon. In addition we will make use of the now growing body of evidence of published studies on this topic.[29,30]

Therefore, we have taken the following measures in order to minimise the risks and burden for the research participants. The researchers to be appointed will have extensive experience of gaining consent and interviewing vulnerable participants. The researchers will ensure the protection and well-being of the participants throughout the entire duration of the study. The participants will be informed that they can ask questions or express their concerns about the study throughout its entire duration and can withdraw at any point. The researchers will also search for signs of discomfort or distress among the participants and will address them individually by talking to the participants and letting them know their options for withdrawal. During the discussion, the participants will be informed that they can refuse to answer questions. The information sheets contain the contact information of all of the members of the research team. The participants will be informed that they are free to contact the researchers with questions and concerns even after the study has ended.

Inbuilt support will be embedded in liaison with key members of the clinical team for recruitment, consent and support mechanisms for the participants if the interviews give rise to issues that need to be followed up (see Appendix 2). The researchers and the members of the clinical team will have ongoing communication about recruitment and data collection. The members of the clinical team will play an instrumental role during the screening and selection process with the purpose of identifying potential participants and guaranteeing their protection. The key worker will be in charge of following up with the participant after the interview to see if any issues need to be discussed and provide appropriate guidance and assistance. This is important as the research may lead specific patients to face and discuss issues that had previously not been raised.

Considerable researcher burden is also possible. Having two researchers will ensure mutual support. There will also be extensive support from the research team, where expertise in methods and cancer care will be closely matched with researcher need and support. Monthly clinical supervision has been costed into our study.

6. User involvement

This aspect presents specific challenges and has been approached as follows: young adults and their families will be involved in data collection, feedback and analysis as an intrinsic aspect of our study; the NCRN Consumer Liaison Group has been approached to determine specific interest amongst members; the proposal will be read and commented on by family members of two young adults who died of cancer; input into patient information sheets and other patient information will be sought from the Young Peoples Reference Group associated with BRIGHTLIGHT (approximately 20 members - young people diagnosed with cancer between the ages of 14 and 25 (current age 18-29), some of whom have worked with us for over three years on various studies); additional input into patient and subject information sheets will be sought from an additional PPI group, the Cancer Partnership Research Group of the Surrey, Sussex and West Hampshire Clinical Research Network; presentations will be made from January 2013 to ‘Kayleigh’s workshop – terminally talkative’ at the annual young people’s conference, Find Your Sense of Tumour. This was first held in 2011 for those receiving end of life. Facilitated by two psychologists, it is now a regular event at the conference. The attendees from 2011 have also set up their own site on ‘Facebook’, moderated by psychologists, and which we can access if more immediate consultation on the study is needed. Through contact with the NCRN Consumer Liaison Group we have identified patients and patient representatives who will comment on the evolving study and contribute to workshops and panels.

We expect there will be very hard to reach participants consequent on limited awareness of End of Life, high levels of family and professional protection or exaggerated denial. Close relationships between researchers and key workers will be developed to improve chances of access. This will be enhanced by the clinical credibility and national profile of the research team.

7. Data sharing plan

BRIGHTLIGHT is approved by the National Information Governance Board reference ECC 8-05(d)/2011. Electronic data from the study will be stored on an NHS server supported by University College London Hospitals NHS Foundation Trust (UCLH). Paper documents will be stored in a locked filing cabinet in the cancer trials research facility at UCLH. Access will be limited to research associates and chief investigator. All digital recordings will be deleted once a written transcript has been produced. The interview and workshop transcripts will be anonymised and password protected. These will be archived, and available for further analysis after publication of the findings of BRIGHTLIGHT on End of Life.

8. Management of the study

The study is sponsored by UCL.
The core project team led by the CI work in close proximity and will meet regularly.
An advisory group will be established to regularly review and advise on study progress.

Timescales – total period 24 months

Month 1-4	Researchers start employment Detailed review of the literature and analysis of National Cancer Data Repository and National End of Life Care Intelligence Network Detailed protocol development
Month 5-17	Workshops and interviews
Month 18-21	Analysis
Month 21	Expert Panel
Month 22-24	Circulation of account to participants, policy makers, commissioners and other stakeholders. Completion of final account, dissemination through local meetings and writing of peer reviewed publications.

References

[1] Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ (Clinical research ed. 2008;337:a1655.

[2] MRC. Complex Interventions Guidance. 2008 [cited March 28th 2012]; Available from: (http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871)

[3] National Institute of Health and Clinical Excellence. Improving Outcomes in Children and Young People with Cancer. 2005.

[4] Geiger AM, Castellino SM. Delineating the age ranges used to define adolescents and young adults. J Clin Oncol. 2011 Jun 1;29(16):e492-3.

[5] Helen and Douglas House. [cited 28th March 2012]; Available from: www.helenanddouglas.org.uk

[6] Department of Health. End of life care strategy. Promoting high quality care for all adults at the end of life. 2008.

[7] Office for National Statistics. Mortality Statisitics. 2010 [cited 28th March 2012]; Available from: http://www.ons.gov.uk/ons/publications/re-referencetables. html?edition=tcm%3A77-230730

[8] Barr RD. Adolescents, young adults, and cancer--the international challenge. Cancer. 2011 May 15;117(10 Suppl):2245-9.

[9] Department of Health. Better care: better lives. Improving outcomes and experiences for children, young people and their families living with life-limiting and life-threatening conditions 2008.

[10] Department of Health. End of life care strategy. Promoting high quality care for all adults at the end of life. 2008.

[11] Grinyer A, Thomas C. The importance of place of death in young adults with cancer. Mortality. 2004;9(2):114-31.

[12] Kars MC, Grypdonck MH, de Korte-Verhoef MC, Kamps WA, Meijer-van den Bergh EM, Verkerk MA, et al. Parental experience at the end-of-life in children with cancer: 'preservation' and 'letting go' in relation to loss. Support Care Cancer. 2009 Jan;19(1):27-35.

[13] Grinyer A. Palliative and End of Life Care for Children and Young People: Home, Hospice, Hospital. Oxford: John Wiley and Sons 2012.

[14] Cohen-Gogo S, Marioni G, Laurent S, Gaspar N, Semeraro M, Gabolde M, et al. End of life care in adolescents and young adults with cancer: experience of the adolescent unit of the Institut Gustave Roussy. Eur J Cancer. 2011 Dec;47(18):2735-41.

[15] Baker JN, Hinds PS, Spunt SL, Barfield RC, Allen C, Powell BC, et al. Integration of palliative care practices into the ongoing care of children with cancer: individualized care planning and coordination. Pediatric clinics of North America. 2008 Feb;55(1):223-50, xii.

[16] Christenson K, Lybrand SA, Hubbard CR, Hubble RA, Ahsens L, Black P. Including the perspective of the adolescent in palliative care preferences. J Pediatr Health Care. 2010 Sep-Oct;24(5):286-91.

[17] Pritchard S, Cuvelier G, Harlos M, Barr R. Palliative care in adolescents and young adults with cancer. Cancer. 2011 May 15;117(10 Suppl):2323-8.

[18] Wein S, Pery S, Zer A. Role of palliative care in adolescent and young adult oncology. J Clin Oncol. 2010 Nov 10;28(32):4819-24.

[19] Hinds PS, Oakes LL, Hicks J, Anghelescu DL. End-of-life care for children and adolescents. Seminars in oncology nursing. 2005 Feb;21(1):53-62.

[20] Lundh Hagelin C, Seiger A, Furst CJ. Quality of life in terminal care—with special reference to age, gender and marital status. Support Care Cancer. 2006 Apr;14(4):320-8.

[21] Parr JD, Zhang B, Nilsson ME, Wright A, Balboni T, Duthie E, et al. The influence of age on the likelihood of receiving end-of-life care consistent with patient treatment preferences. Journal of palliative medicine. 2010 Jun;13(6):719-26.

[22] Trevino KM, Maciejewski PK, Fasciano K, Greer JA, Partridge A, Kacel EL, et al. Coping and psychological distress in young adults with advanced cancer. Journal of Supportive

Oncology. 2011;http://www.supportiveoncology.net/single-view/aipcoping-and-psychological-distress-in-young-adults-with-advancedcancer/8ea0588008.html.
[23] Hollis R, Morgan S. The adolescent with cancer--at the edge of no-man's land. The lancet oncology. 2001 Jan;2(1):43-8.
[24] Whelan J. Where should teenagers with cancer be treated? Eur J Cancer. 2003 Dec;39(18):2573-8.
[25] National Cancer Research Network.
[26] Pawson R, Tilley N. Realistic Evaluation. London: Sage 1997.
[27] Charmaz K. Grounded Theory: objectivist and constructivist methods In: Denzin N, Lincoln Y, eds. The Handbook of Qualitative Research. 2nd ed. Thousand Oaks: Sage 2000:509-36.
[28] Oreszcyzn S, Carr S. Improving the link between policy research and practice: using a scenario workshop as a qualitative research toll in the case of genetically modified crops. Qualitative Research. 2008;8:473-97.
[29] Hinds PS, Burghen EA, Pritchard M. Conducting End-of-Life Studies in Pediatric Oncology. WJNR 29(4):448-465; 2007.
[30] Walshe CE, Caress AL, Chew-Graham C, Todd C. Case Studies: A Research Strategy Appropriate for Palliative Care? Palliative Medicine 18(8):677-684; 2004.

Appendices

Appendix 1: Phases of research
Appendix 2: Recruitment and data collection
Appendix 3: BRIGHTLIGHT study synopsis
Appendix 4: Sample 1 recruitment
Appendix 5: Sampling
Appendix 6: Review of medical notes
Appendix 7: Hypothetical scenarios