


BMJ Open Health-related quality of life in adults treated for paediatric acute lymphoblastic leukaemia: a cross-sectional and longitudinal cohort study

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To cite: Aili K, Arvidsson S, Olsson M, *et al.* Health-related quality of life in adults treated for paediatric acute lymphoblastic leukaemia: a cross-sectional and longitudinal cohort study. *BMJ Open* 2022;**12**:e048325. doi:10.1136/bmjopen-2020-048325

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2020-048325>).

Received 28 December 2020
Accepted 22 December 2021



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ABSTRACT

Introduction Acute lymphoblastic leukaemia (ALL) is the most common form of cancer in children. Although treatment methods have improved and resulted in significant improvement of survival and reduction in late effects and late mortality risk, the health-related quality of life (HRQOL) of survivors might be affected. To introduce new interventions in clinical practice with the potential to support positive HRQOL outcomes, more knowledge is needed on how HRQOL in this group is constructed and stimulated. The purpose of this study is to investigate how HRQOL is affected in adults treated for paediatric ALL, in a long-term perspective and possible factors influencing this relationship.

Methods and analysis This cohort of young adult ALL survivors allows for investigations of factors influencing HRQOL outcomes on a national level. Eligible participants are obtained from the Swedish Childhood Cancer quality registry. Data collection includes both a follow-up of data collected in 2012 (n=224) and recruitment of new eligible participants to the cohort (n=601). The cohort will cover survivors of paediatric ALL, diagnosed between 1985 and 2007, at an age between 0 and 15 years. Data will be collected using validated, multidimensional, self-administered instruments, designed to measure HRQOL (SF-36), social support, sense of coherence and resilience.

Ethics and dissemination The study will be carried out in accordance with the ethics permit obtained from the Swedish ethics review authority (Dnr 2019-05181). Dissemination of study results will take place through research articles and reports to the national patient organisation and the national network for consultancy nurses for this target group and to the working group for the Swedish national long-term care programme for childhood cancer. Results will also reach practical application within the follow-up clinic for adult childhood cancer survivors at Sahlgrenska Hospital in Gothenburg.

INTRODUCTION

Acute lymphoblastic leukaemia (ALL) is the most common form of cancer in children with the main incidence occurring between ages 2 and 4 years. In Sweden, there are approximately 100 new cases each year with ALL up to the age of 18 years. The prognosis

Strengths and limitations of this study

- The patient cohorts are recruited on population-based data from the National Childhood Cancer Registry.
- The follow-up of data collected in 2012, opens up for investigating how time (chronologically) influences health outcomes in these groups. Health-related quality of life (HRQOL) changes over time by comparing longitudinal data in cohort 1 and 2 collected in 2012 and 2021.
- The outcomes will also be investigated in relation to data from other healthcare registries including number of days on sick leave and other welfare subsidise.
- The importance of antecedents and health status for the relationships between HRQOL and social support, sense of coherence and resilience will be investigated.
- Findings based on quantitative data will be further explored with interviews to collect and analyse qualitative data on the experiences of factors that have affected HRQOL.
- HRQOL outcomes will be investigated in relation to social support, sense of coherence and resilience, as potential mechanisms of processing the consequences from previous acute lymphoblastic leukaemia treatment.

has improved significantly and continuously since the 1960s, from almost non-existing to a 5-year survival rate to over 90% in the latest Nordic ALL protocol.^{1–3} Over time, treatment methods have improved, and the late mortality risk has decreased.⁴ However, the frequency of late complications is still high, even if the pattern of complications has changed. Large longitudinal studies from the USA have shown that life threatening complications in survivors treated during 1991–2007 have decreased compared with earlier treatment protocols, mainly due to the reduction of cranial irradiation.⁵ Fortunately, the vast

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BMJ Open: first published as 10.1136/bmjopen-2020-048325 on 7 January 2022. Downloaded from <http://bmjopen.bmj.com/> on June 8, 2025 at Agence Bibliographique de l'Enseignement Supérieur (ABES).

majority survivors from standard-risk ALL not treated with cranial irradiation have been shown to have a life that is physically, psychosocially and socioeconomically similar to that of the general population.⁶

However, children treated for ALL and have been in remission for 2–13 years, have been shown a more negative self-image and experience a lower health-related quality of life (HRQOL) than their siblings.⁷ A literature review⁸ shows a large variation in results in research reporting both higher, lower and comparable HRQOL in young and adult survivors of paediatric ALL compared with control groups. Only a few studies have examined the relationship between psychosocial factors, such as coping and resilience, and HRQOL, but the results available indicate that such factors may have protective effects. However, there are no longitudinal studies investigating such relationships possibly providing depth understanding of the determinants of HRQOL and other health outcomes for this group.⁸

A common instrument for self-assessment of HRQOL is SF-36, whose validity and reliability have been specifically examined among adult survivors of paediatric cancer.⁹ The instrument covers eight different dimensions of HRQOL: physical functioning, social functioning, role limitations due to physical functioning (role functioning—physical), bodily pain, general mental health, role limitations due to emotional functioning (role functioning—emotional), vitality (energy and fatigue) and general health perception. One reason for the wide variety of results from studies examining HRQOL may be the complexity of the measure. When a person is diagnosed with a life-threatening illness such as ALL, an adaptation process begins that alters the person's perception of their HRQOL. This process can explain how the HRQOL experience changes over time in connection with illness and how it is affected by antecedents (eg, gender, education, personality, self-esteem) and various influencing factors (eg, resilience, social support).¹⁰ The adaptation process involves a change in the understanding of what HRQOL is, a so-called, response-shift, which in turn has an effect the individual's perception of their own HRQOL. This means that the behavioural, cognitive and affective processes that occur in connection with changes in an individual's health status can have an indirect effect on that persons own HRQOL.¹⁰ This iterative and dynamic process begins with the onset of the disease and continues both during and long after treatment has ended. Since most patients with ALL are treated in early childhood this process is even more complex involving parents and sibling. The process is important to understand in order to target adequate supportive resources tailored to individual needs and conditions to promote as favourable HRQOL outcomes as possible. To achieve this, longitudinal studies of changes in HRQOL and the importance of antecedents and influence factors are required.

The prevalence of mental illness among adults who survived cancer as a child has only been investigated to a

limited extent. The studies available shows an increased prevalence, which indicates the need for more research in the field.¹¹ The importance of fatigue and lower vitality may in itself be a relevant factor to study more closely among those who survived paediatric ALL. Fatigue is common in both mental illness as well as complex pain disorders (eg, chronic widespread pain) and lower vitality (estimated by SF-36) have been shown to predict the onset of chronic widespread pain even in previously pain-free individuals.¹² Qualitative studies based on interviews with adults who have survived ALL can supplement quantitative data from questionnaires and give an experience-based understanding of the adaptation process in relation to the HRQOL; how it changes over time and how it can be supported in different ways. It has been found that some adults who survived paediatric ALL describe that they as children wanted to be more involved in their care and also receive more continuous support to be able to manage and process the physical, mental and social consequences of the disease, to continue life after the disease.¹³ To increase the possibility of introducing new supportive interventions in clinical practice, more knowledge is needed on how the HRQOL among adults who have survived cancer is affected and positively stimulated.

Objectives

The main purpose of this study is (1) to describe the development of HRQOL over time and (2) to investigate factors of importance for HRQOL in adults treated for paediatric ALL.

This will be studied by investigating HRQOL in adult survivors of paediatric ALL based on the hypothesis that HRQOL in adult paediatric ALL survivors is associated with (1) time for treatment and age at follow-up and (2) background factors. (1) *The significance of age and time* will be investigated by describing the changes of HRQOL over time from young adulthood to 10 years later, and by investigating differences in HRQOL between young adults treated for paediatric ALL in 1985–1997 and young adults treated in 1997–2007. (2) *Factors of importance for HRQOL* in adult survivors of paediatric ALL will be studied by investigating associations between HRQOL and several potentially buffering background factors such as socio-demographic factors, lifestyle, social support, sense of coherence and resilience, as well as associations with care consumption and sickness absence. For a holistic perspective, factors of importance for HRQOL will also be investigated by qualitative studies describing experiences from adult survivors of paediatric ALL.

METHODS

Design

The study is a cross-sectional and longitudinal cohort study based on questionnaire data that will be collected in 2021 as part of a long-term follow-up of a cohort consisting of adult survivors of paediatric ALL, established in 2012. Analysis of baseline data from the cohort

established in 2012 has shown significant differences in comparison to norm values. Survivors of paediatric ALL estimated a lower vitality (56.9 ± 2.9) than the norm (68.8 ± 1.1), and a lower mental health (71.3 ± 2.6) than the norm (80.9 ± 0.9).¹⁴ At the planned follow-up in 2021, participants will be around 37 years old, and will have reached an age where they are expected to take responsibility for work and their own family. Therefore, in order to get an idea of the long-term effects of paediatric ALL, it is important to follow the group during this time when they are increasingly exposed to external risk factors, and when they have reached an age which in itself entails an increased risk of ill health. The data collection in 2021 will also include a cross-sectional study of adult survivors of paediatric ALL treated 1985–2007 and explorative interviews with a selection of participants.

Participants

All participants included in the data collection in 2012 will be invited to participate in the follow-up study. All individuals registered in the Swedish Childhood Cancer quality registry in 2012, diagnosed with ALL between 1985 and 1997, were eligible for inclusion ($n=416$). In 42 cases, the presence of mental health disorders or disabilities (downs syndrome), emigration or longer stays abroad was confided by relatives and prevented their participation. Out of the remaining 374 individuals 224 (60%) completed the questionnaire after up to two reminders. In this follow-up of the 2012 data collection, additional participants will be recruited from the same registry among those diagnosed between 1998 and 2007 ($n=601$). In total, the cohort, through the new recruitment, will cover people who survived paediatric ALL, diagnosed between 1985 and 2007, at an age between 0 and 15 years. The follow-up of data collected in 2012 opens up for investigating how time (chronologically) influences health outcomes in these groups.

Data collection

Data will be collected with a questionnaire and interviews from March to December 2021. The questionnaire will be based on the variables used in 2012 which included validated instruments for HRQOL (SF-36)¹⁵ and a number of variables with potential influence on HRQOL, such as sociodemographics (family, education, employment, income), life style (physical activity, sleep, alcohol and tobacco), general self-efficacy (General Self-Efficacy Scale),^{16 17} social support (Social Support-13),¹⁸ resilience (Resilience Scale),^{19 20} sense of coherence (Sense of Coherence scale),²¹ mental health (Depression Anxiety Stress Scale 21),²² physical health (Charlson Comorbidity Index),²³ musculoskeletal pain (prevalence),²⁴ fatigue (Multidimensional Fatigue Inventory-20),²⁵ and sick leave and health consumption (based on self-report and national registry data). The questionnaire will be digital and invitations to participate with the link to the digital questionnaire and informed consent forms will be sent out by ordinary mail. Reminders will be sent out with

2-week intervals and with the second reminder, a paper version of the questionnaire will be sent along and will be followed by final reminder. Data collection will end 2 weeks after the final reminder and thereby close the 2-month data collection period. This process, combining a digital questionnaire, several reminders and a final reminder with a paper version of the questionnaire, will increase the probability of getting as high a response rate as possible by inviting to participate both digitally and on paper and also reduce missing data both in terms of participants failing to answer all questions in the questionnaire and dropouts of participants. To supplement the self-report data several objective clinical parameters for the participants will be collected from the Swedish Childhood Cancer quality registry, such as the treatment protocol used, risk classification, chemotherapy, radiation, bone-marrow transplantation, relapse, secondary malignancy. On submission of the questionnaire, there will also be an invitation to participate in a semistructured telephone interview ($n=40$) performed by a researcher who is experienced in qualitative methodology and interviews with informants in sensitive contexts (SA). In order to obtain a maximum variety of experiences, the selection of participants for the interviews will be made strategically, based on the responses from the questionnaire. This means that the selection will be made by participants being deliberately selected to achieve variation regarding, for example, intensity of treatment, gender, age, work experience and experience of HRQOL. The interviews have an exploratory approach with open-ended questions. The interview guide begins with a question about the informant's experiences of being treated for leukaemia as a child. This is followed by questions related to health, quality of life and lifestyle, where the informants are allowed to describe what it means to them, how it is for them today and how it has been affected by having been treated for leukaemia as a child. Finally, the recommendations that the informant would like to give to healthcare professionals who currently care for children with leukaemia are touched on. In order to gain an increased understanding of what the informants express, follow-up questions will be asked, such as: Can you describe it in a little more detail? How do you mean?

Analysis

Data analysis will be carried out during the end of 2021 to end of 2022. Quantitative data will be analysed using different statistical methods depending on the research questions to be answered. In a first step, HRQOL will be described by presenting mean values and SD. The aspect of changes in HRQOL during adulthood will be investigated by using data from the cohort providing data in 2012 and 2021. For analyses when investigating the association between time for treatment and HRQOL, a comparison and test for difference in mean HRQOL between the two groups (one entering the study in 2012, the other group entering the study in 2021) will be made. When investigating factors of importance for HRQOL

univariate and multiple regression analyses will be used. The size of the study population and an assumed response rate of 60%–70% should allow for a sample size sufficient for evaluations of small differences in HRQOL outcomes between groups, using the SF-36 instrument.²⁶

The qualitative interviews will be analysed according to phenomenographic methodology as it allows to focus on how the informants perceive a certain phenomenon or aspect of the world. In the analysis, attention is directed to 'how' the phenomenon is perceived and describing the variation in perceptions.²⁷ The analysis will be performed by two experienced researchers in qualitative methodology (SA and MO). After transcription, each interview will be listened to and transcripts read several times for familiarisation and to get an overall impression of the data material. Each interview will be processed by searching for statements that correspond to the purpose of the study (condensation), which will then be analysed to find similarities and differences (comparison). The condensed statements will then be grouped based on their characteristic features (grouping) and similarities between the groups will be described (articulation) and then referred to as categories (labelling). The final step in the analysis is to compare the different categories in terms of similarities and differences to ensure that the categories has unique characteristics and are on the same level of description (contrasting). Throughout the analysis, there is a constant interaction between the different stages and continuous discussion and confirmation of the process and developed results between the researchers performing the analysis and the rest of the research team. The team include a broad range of competence backgrounds both in qualitative research methodology and the clinical context and research field.

The patient and public involvement

The cohort was initially established based on interaction with children with ALL and their parents as well as with healthcare practitioners involved in the medical and social care of patients with paediatric ALL and with a local patient organisation for this group of patients. This interaction took place within the boundaries of a research-based design project aiming to develop social support for young survivors of ALL. It demonstrated the need to monitor long-term HRQOL and specific influencing factors within this target group. The establishment of the cohort took place in consultation with clinicians at a regional paediatric cancer centre and the Swedish Childhood Cancer Registry. There is and will continue to be target group influence over the data created in the cohort since; (1) the collected variables are based on HRQOL issues established in interaction with the target group and relevant stakeholders and (2) as data in the cohort are based on the participants' self-reported experiences.

Ethics and dissemination

The study will be carried out in accordance with the ethics permit obtained from the Swedish ethics review authority

(Dnr 2019-05181), All collected data will be treated confidentially and the participants will not be able to be identified due to coding of all data material. The results in the study will only be presented at group level without the possibility of identifying individuals. Participation in the study is voluntary and based on informed consent. Each participant will be able to withdraw their participation at any time without having to justify why. The project will contribute to development of knowledge that is of benefit to a group with increased risk of HRQOL problems later in life and investigating such risks can contribute to improving care both to children who are currently undergoing treatment for ALL and to children and adults who have undergone treatment earlier in life. Dissemination of study results will take place through reports to the national patient organisation for this target group, the national network for consultancy nurses for this target group and to the working group for the Swedish national long-term care programme for childhood cancer. Results will also reach practical application within the follow-up clinic for adults after childhood cancer at Sahlgrenska Hospital in Gothenburg.

STRENGTHS AND LIMITATIONS

A few strengths and limitations should be mentioned in relation to this study. A strength of the study is that it focuses on a well-defined patient group that corresponds to about a third of all childhood cancer cases annually in Sweden. The advantage of this is that variations that are specific to different types of cancer diagnoses and their treatment protocols do not occur in the study and therefore do not have an impact on the study results. The disadvantage is that the number of eligible informants is reduced. In the data collection in 2012, a portion of the eligible participants did not complete the survey. We do not have ample data on these non-responders allowing for interpretations on how representative the participants were in relation to the total number of eligible participants; however, we could see that the non-responders were evenly distributed between men and women, were of similar age as the participants and had similar geographical distribution nationally as the participants.

It should be highlighted that although the response shift process is underlined in this study, as important to understand how HRQOL develops over time following treatment for paediatric ALL, the actual response shift effect itself will not be investigated as part of the study. Rather, the focus is on the importance of several factors that might influence HRQOL outcomes on individual level. These will be investigated to increase knowledge on what factors that might be relevant for response shift processes for this particular group and that should be further researched.

A strength of the study is that it is based on a collaboration between academic researchers at Halmstad University and clinically active researchers at the paediatric cancer long-term follow-up unit at the Sahlgrenska

University Hospital in Gothenburg. Previous research from the research group has studied the long-term effects of cancer illness and treatment on young people's health outcomes and how follow-up care, social support and increased participation during care can be provided to the target group. The research has resulted in both development of care processes and practice and the design of digital support services tested in clinical practice. Members of the research group are part of national and Nordic clinical networks for late effects among paediatric cancer survivors and participate in the development and follow-up of the Swedish national long-term follow-up care programme for childhood cancer allowing for feasible dissemination.

As treatment outcomes for ALL have improved, the importance of long-term follow-up and handling of late effects have increased, both during childhood and in adulthood. This is the main purpose of the Swedish national Guidelines for long-term follow-up after paediatric cancer treatment. A prerequisite for the work on the national guidelines is research that follows this target group long-term and maps trends and relationships around risk factors and protective factors. The current cohort is based on national recruitment of participants and has a relatively good response rate. Studies based on the cohort and long-term follow-up of outcomes can therefore be considered generalisable in a national context. Such studies can also supplement the clinical experience and provide guidance for continuous improvement work on long-term follow-up after childhood cancer.

Contributors All authors participated in the conception and design of the study, planned the data collection and analysis, and participated in writing the article.

Funding The 2012 data collection was funded by the Swedish Research council grants to JN and the follow-up data collection has received funding from Halmstad University to JN, KA and SA.

Competing interests The authors have no competing interests to declare.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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