ABSTRACT

Introduction More than 10% of adolescents live with a chronic disease or disability that requires regular medical follow-up as they mature into adulthood. During the first 2 years after adolescents with chronic conditions are transferred to adult hospitals, non-adherence rates approach 70% and emergency visits and hospitalisation rates significantly increase. The purpose of the Bridge study is to prospectively examine associations of transition readiness and care experiences with transition success: young patients’ health, health-related quality of life (HRQoL) and adherence to medical appointments as well as costs of care. In addition, we will track patients’ growing independence and educational and employment pathways during the transition process.

Methods and analysis Bridge is an international, prospective, observational cohort study. Study participants are adolescents with a chronic health condition or disability and their parents/guardians who attended the New Children’s Hospital in Helsinki, Finland, or the Royal Children’s Hospital (RCH) in Melbourne, Australia. Baseline assessment took place approximately 6 months prior to the transfer of care and follow-up data will be collected 1 year and 2 years after the transfer of care. Data will be collected from patients’ hospital records and from questionnaires completed by the patient and their parent/guardian at each time point. The primary outcomes of this study are adherence to medical appointments, clinical health status and HRQoL and costs of care. Secondary outcome measures are educational and employment outcomes.

Ethics and dissemination The Ethics Committee for Women’s and Children’s Health and Psychiatry at the Helsinki University Hospital (HUS/1547/2017) and the RCH Human Research Ethics Committee (38035) have approved the Bridge study protocol. Results will be published in international peer-reviewed journals and summaries will be provided to the funders of the study as well as patients and their parents/guardians.

Trial registration number NCT04631965.

INTRODUCTION

One measure of the success of contemporary paediatric practice is the extent to which children with severe chronic health conditions...
The concept of transition, the planned process of transferring healthcare from specialist paediatric to adult services, was introduced almost 30 years ago. Since then, recommendations for how to support the process of transition have been developed, commonly in reference to specific diagnoses but also within generic national guidelines. Commonalities within these recommendations include the importance of transition planning starting early, support for adolescents’ self-efficacy and self-management and the need to consider individual circumstances.

Adolescence, and the transitions of care that accompany it, can be a challenging time for young people, their families and health professionals. Adolescents leaving their familiar child health professionals can find involvement with new professionals difficult and parents can struggle with expectations that they are less directly engaged in adult services. Professionals who are used to treating adult patients may lack knowledge about childhood onset conditions, resources and training required to work with adolescents and young adults. During the first years after adolescents with chronic health conditions are transferred to adult hospitals, adherence to treatment and follow-up regimes decreases and emergency visits and hospitalisation rates increase significantly, suggesting the value of efforts to promote continuity of both primary and specialty healthcare at this time.

Despite the rising number of publications about transition to adult healthcare, studies are typically small, single-centre studies using cross-sectional or retrospective methods. Most studies are of single disorders, most commonly type 1 diabetes. For example, in a recent systematic review of 37 systematic reviews, only 6 studies included patients from different diagnostic groups. The transition literature has mostly focused on patients’ and paediatric providers’ concerns prior to the transfer of care, with less data available about outcomes after the transfer of care. Indeed, the brief duration of follow-up within prospective studies commonly precludes assessment of meaningful change in health outcomes and anxiety is one of the most frequently identified barriers to successful transition, but its significance to transition outcomes remains unknown.

Cultural differences are also often overlooked in the literature. This has implications for the age at which transfer to adult services occurs, due to variation in the upper age limit of paediatric care between countries, and even greater differences in the age at which young people move away from their childhood home (which reduces opportunities for parent supervision). For example, in Finland, only 20% of young people aged 20–24 years still live with their parents, in comparison to 43% of their Australian peers. Countries also differ by the extent of social protections available to support health transitions including subsidised healthcare and health insurance, access to education and employment for people with chronic health conditions and disabilities, and access to supported accommodation.

Poor adherence with medication and medical appointments can result in increased use of emergency departments and more hospital admissions for preventable complications, with commensurately greater costs to the healthcare system than routine care. Poor health may also affect educational outcomes. Even in Finland, where both education and healthcare provision are publicly funded, adolescents with chronic health conditions are more likely to drop out of formal education than their peers. Beyond disease control, other life transitions around education and employment typically occur at a similar time as the health transition but with little understanding of how these different transitions relate to each other.

Pleasingly, there is international consensus about indicators and outcomes of a successful healthcare transition. These include health outcomes such as stable disease control, subjective outcomes such as quality of life and patient and family satisfaction with transfer of care and health service outcomes, such as the timing of the first consultation with the adult service being within 3–6 months after transfer and regular attendance at medical appointments.

Study aims and hypotheses
The three aims of this prospective study are to measure:
1. Changes in health outcomes including health-related quality of life (HRQoL),
2. Healthcare experiences and their association with adherence to care, and
3. Changes in anxiety related to transition among a cohort of Finnish and Australian young people with chronic health conditions and/or disabilities over the course of their transition from paediatric to adult services.

Our secondary aims are to assess how well the study centres adhere to international transition guidelines and their key elements, and to estimate the costs of transitional care. We also aim to assess adolescents’ participation in education and employment across these years.

Our primary hypothesis is that transition readiness and general self-efficacy will be stronger predictors of adherence to follow-up appointments, fewer emergency visits and continued education than chronological age. Our secondary hypothesis is that positive experiences of care will be associated with lower levels of anxiety across the healthcare transition and that positive care experiences and low anxiety will predict better health outcomes, better quality of life and lower costs of care.

METHODS AND ANALYSIS
Setting
Bridge is an international, prospective cohort study that will be conducted at two study centres: the New Children’s Hospital (NCH), Helsinki, Finland, and the Royal Children’s Hospital (RCH), Melbourne, Australia. In Finland, most participants will transfer to the Helsinki University
Hospital but some will also transfer to other hospitals and healthcare services in Finland. In Melbourne, most participants will transfer to hospitals in metropolitan Melbourne but some will transfer to health services in regional and rural Victoria.

The general study design is described in figure 1. Some similarities and differences between the two study centres relevant to young people with chronic conditions are summarised in table 1.

At both study centres, transition is viewed as a systematic process and all subspecialties have access to common resources, such as checklists to prepare patients for the transfer of care.

Eligibility criteria
At recruitment, inclusion criteria for adolescents were that they: were aged 15–24 years; had a chronic health condition and/or disability that was diagnosed at least 6 months earlier; require regular follow-up at adult health services; and are expected to transfer from paediatric to adult care facilities within 6–12 months after recruitment. They also needed to have the linguistic and cognitive capacities to independently communicate in one of the study languages (Finnish, Swedish or English).

Sample size and power calculations
To ensure sufficient sample size for all outcome measures, we conducted two power calculations. First, we wished to detect a difference in clinic attendance from 80% to 90% between groups of low and high transition readiness. With a power of 90% and \( \alpha = 0.05 \) (two-sided), 85 patients will be needed in each group. Assuming a dropout rate of 20%, 213 patients will be required. Second, we wished to detect at least a 5% change in HRQoL over time (from 0.85 to 0.90 or vice versa as measured by the 16D score). With a power of 90% and \( \alpha = 0.05 \) (two-sided), we will need 190 patients in each group, which totals to 475 once the same dropout rate of 20% is factored in. We also set a minimum target of 250 patients at each study site. We conducted one more confirmatory power analysis using the General Linear Mixed Model Power and Sample Size tool. This analysis confirmed that 480 patients would be sufficient to detect changes in repeated measures of HRQoL also using the Paediatric Quality of Life Inventory (PedsQL).

Patient recruitment
At NCH, healthcare professionals in different subspecialty clinics identified adolescents who were expected to transfer to adult services within the next 6 months. Between September 2017 and August 2019, a research nurse uninvolved in patient care met 306 consecutive, eligible adolescents and their 281 parents/guardians face-to-face when they attended a routine outpatient appointment. The nurse provided patients with both verbal and written information about the Bridge study. A parent/guardian of those younger than 18 years was also invited to participate. Altogether 279 adolescents and 214 parents/guardians (91% and 76%, respectively) provided written informed consent. After a maximum of...
two reminders, 253 adolescents and 189 parents/guardians (83% and 67% of those approached, respectively) completed the baseline survey either via Webropol, a secure online data capture system, or by pen-and-paper. Patients received a movie ticket (value $10) for each survey; parents received no reimbursement.

At the RCH, between October 2018 and August 2020 staff from the Transition Support Service invited eligible adolescents to participate in the study when they attended routine transition appointments within 12 months prior to their expected transfer of care. The study coordinator also identified and invited eligible adolescents who did not have an upcoming transition appointment to participate in the study by phone or email. A total of 367 adolescents and 380 parents/guardians were invited, of whom 259 adolescents and 261 parents/guardians provided written informed consent (71% and 69%, respectively). Participants completed the baseline survey either by pen-and-paper or via REDCap, a secure online data capture system. A parallel approach to recruitment occurred with a parent of eligible participants. Patients received a gift voucher (value $10) for each survey; parents received no reimbursement.

### Baseline measures, exposures and confounders

#### Transition readiness and self-efficacy

The Am I ON TRAC for Adult Care (ON TRAC) questionnaire has a knowledge scale of 14 items and a behaviour index of 9 items. The knowledge scale scores range from 14 to 56 (and 11 to 44, if adolescents indicate they are not taking any medications). The behaviour index scores range from 9 to 45 (8 to 40, if adolescents are not using medications). High transition readiness is defined as adolescents responding ‘agree or strongly agree’ to at least 8 of the 9 items (7/8, if patient is not using medications) of the behaviour index. Nine additional items were chosen from other generic transition readiness questionnaires (eg, the Transition Readiness Assessment Questionnaire) to provide more detail on adolescent patients’ self-efficacy, such as being able to book their own clinic appointments, and managing daily activities such as preparing meals.

#### Health status

Adolescents report how much their condition has impacted them during the past week using the Visual Analogue Scale (VAS) (where 1 indicates ‘very much’ and 7 indicates ‘very little’). Clinical condition-specific markers and treatment details will be obtained from individual patient records for the last year prior to the transfer of care. Participants will be grouped into one of three categories, in the context of the specific disorder: (1) good disease control and/or adherence, (2) some evidence of concern and (3) poor disease control and/or adherence or more severe disease/condition, as described in Table 2.

### HRQoL

Adolescents will complete two measures of HRQoL at each time point. The 16D is a validated, generic scale.

#### Table 2: Guidelines for grouping patients into three categories according to disease control and/or adherence

<table>
<thead>
<tr>
<th>Diagnosis group</th>
<th>Good control and/or adherence</th>
<th>Some evidence of concern</th>
<th>Poor control and/or adherence or more severe condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>Mean of HbA1c values ≤53 mmol/mol</td>
<td>Mean of HbA1c values 54–69 mmol/mol</td>
<td>Mean of HbA1c values ≥70 mmol/mol</td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>VAS 1–2; at least 80% of faecal calprotectin results &lt;100 µg/g and always &lt;300 µg/g; medication unchanged or reduced; no inpatient care</td>
<td>VAS 3–5; &lt;80% of faecal calprotectin results within target range or exceeds 300 µg/g even once; no significant medication changes; no inpatient care</td>
<td>Any one of the following: VAS 6–7; changes in medication, need for oral corticosteroids and/ or commencement of biological medication; episode of inpatient care</td>
</tr>
<tr>
<td>Rheumatology, arthritides</td>
<td>Oligoarthritis: JADAS10 or cJADAS10 ≤0.5; polyarthritis: JADAS10 or cJADAS10 ≤0.7</td>
<td>Oligoarthritis: JADAS10 or cJADAS10 0.6–2.8; polyarthritis: JADAS10 or cJADAS10 0.8–4</td>
<td>Oligoarthritis: JADAS10 or cJADAS10 &gt;2.8; polyarthritis: JADAS10 or cJADAS10 &gt;4</td>
</tr>
<tr>
<td>Neurology, epilepsy</td>
<td>No seizures in the past year; no adverse effects of medications; no inpatient care</td>
<td>No seizures in 6 months; adverse effects of medication possible; no inpatient care</td>
<td>Seizures despite medication</td>
</tr>
<tr>
<td>Neurology, disabilities</td>
<td>No need for RAH or actualised as planned; no need for aids or use actualised as planned; no need for ORT or actualised as planned</td>
<td>RAH or aids use not actualised as planned; no need for ORT or actualised as planned</td>
<td>Needs RAH, aids and/or ORT but none actualised as planned</td>
</tr>
</tbody>
</table>

Patients with rare conditions (eg, congenital heart defects, solid organ transplants or connective tissue diseases) will be categorised according to symptoms, clinical and laboratory findings and changes in medication.

cJADAS, clinical Juvenile Arthritis Disease Activity Score; HbA1c, glycated haemoglobin; JADAS10, 10–joint Juvenile Arthritis Disease Activity Score; ORT, outpatient rehabilitation therapy (may include occupational, physical and/or speech therapy); RAH, rehabilitation at home; VAS, Visual Analogue Scale.

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that measures HRQoL in 16 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, discomfort and symptoms, depression, distress, mental function, vitality, appearance, school and hobbies and friends. Each dimension has five response options. The 16D yields a single index (range 0–1) that can be used to assess quality adjusted life years and cost-effectiveness. A higher index implies better HRQoL.

The PedsQL is a validated, generic measure. It consists of 23 items within four domains: physical, emotional, social and school. Items are scored on a 5-point Likert scale (total range 0–100). Inclusion of this second measure is primarily to facilitate international comparisons due to its frequent use.

Anxiety
The Spielberger State-Trait Anxiety Inventory (STAI) is a self-report instrument of 40 items, scored on a 4-point Likert scale. Adolescents will complete the six-item short form at each time point. The introductory statement was modified to indicate how adolescents and parents/guardians feel about managing the health conditions and the transfer of care to adult services. In Australia, non-specific psychosocial distress is also measured using the six-item Kessler 6 (K6) scale. The K6 yields scores between 6–30, with lower scores indicating higher psychosocial distress.

Experiences of care
Participants will evaluate their experiences of care before and after transfer using the Adolescent Friendly Hospital Survey which was developed and validated at the RCH. This survey has 13 indicators, 8 of which are not included within the ON TRAC questionnaire.

Risk-taking behaviour
Adolescents will complete a validated 10-item questionnaire that explores use of tobacco and other nicotine products, alcohol and drug use and any risky situations that they have encountered while using substances.

Worries and unmet needs
Adolescents’ worries are assessed in a framework based on the HEADSS assessment. Participants are asked whether they have any worries regarding: home or family life, education or employment, healthy lifestyle (diet, exercise and sleep), friends and activities, emotional well-being or mental health, accidents and injuries, substance use (smoking, alcohol, cannabis and other drugs), sexual health and contraception, fertility or abuse. They are also asked about any concerns around confidentiality of healthcare and self-management. For any topic that adolescents are worried about, a further question inquires whether this topic has been discussed at the NCH or RCH, respectively.

Outcome measures
Changes in self-efficacy, health status and HRQoL
These will be measured in the 1-year and 2-year follow-up questionnaires using the same tools as at baseline.

Adherence to care
Adherence to medications and follow-up appointments will be measured 1 and 2 years after the transfer of care by self-report. We will also enquire about common reasons for missing medications and appointments. In Finland, data linkage will be used to acquire data on missed follow-up appointments and emergency admissions due to avoidable causes from hospital administrative data.

Costs of care
We will use hospital administrative data to estimate the cost of care for each patient during the transition process (1 year before the transfer of care to 2 years after the transfer of care). We will consider costs of actualised care as well as potential costs of more frequent follow-up visits and potential savings of avoidable hospital admissions.

Educational and employment outcomes
At each time point, we ask adolescents about their educational and employment status and their level of satisfaction about this. Reasons for dissatisfaction will also be sought.

Parent/guardian data
Transition readiness
Parents/guardians will evaluate their child’s transition readiness and self-efficacy using ON TRAC, which provides an opportunity for comparison with adolescents’ responses.

Health status
Parents/guardians report how much their child’s condition has impacted their child during the past week using theVAS (where 1 indicates ‘very much’ and 7 indicates ‘very little’), similar to adolescents.

Anxiety
Parents/guardians rate their own level of anxiety in relation to the transfer of their child’s healthcare using the STAI six-item short form, similar to adolescents. In Australia, non-specific psychosocial distress among parents/guardians will also be measured using the K6.

Experiences of care
Parents/guardians will evaluate the experiences of care from their own perspective using the Adolescent Friendly Hospital Survey.

Worries and unmet needs
Parents’/guardians’ worries concerning their child are assessed in a framework based on the HEADSS assessment, similar to adolescents. For any topic that parents/guardians are worried about, a further question inquires whether this topic has been discussed at the NCH or RCH.

Analysis plan
We will adhere to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines in reporting quantitative findings. We will report demographic and descriptive data as numbers and percentages.
for categorical variables and mean values with SD (or in case of skewed distribution, medians with IQRs) for continuous variables.

Since disease activity, HRQoL, experiences of care, transition readiness and anxiety may influence each other, we will conduct cross-sectional analyses to evaluate these interactions. Age, sex and education status will be accounted for as possible confounders, and data will be clustered according to the country of residence, when appropriate.

ORs will be calculated to estimate the predictive value of key transition elements (eg, ON TRAC scores) on clinic attendance, emergency visits and avoidable hospitalisations. Multivariable regression analyses will be conducted to account for confounders in cases of continuous measures (eg, HRQoL). For longitudinal data analyses, generalised estimation equations, linear mixed effects modelling or cross-lagged panel models will be used. If needed, multiple imputation methods will be used to replace missing values.

Our study will also generate qualitative data as some questions require a descriptive response from participants. The analysis and reporting of these findings will follow the Consolidated criteria for Reporting Qualitative Research.51

Patient and public involvement
In Finland, 15 young patients who participated in a transition camp prior to their transfer of care gave feedback on the first draft of the questionnaire. They were satisfied with the content of the questionnaire and especially highlighted the importance of including questions regarding their feelings, support needs and social and educational transitions in addition to the medical outcomes. Summaries of study results will be disseminated to study participants via email/mail.

DISCUSSION
The Bridge study is an international, prospective observational study that plans to follow adolescents across the critical years when their specialist medical care is transferred from child-oriented to adult-oriented health services. Patient follow-up is expected to be completed in 2022. By using a predetermined data collection and analysis plan, this study will fill several of the evidence gaps regarding transition of care.

An observational cohort design was chosen as the predictive value of long-standing transition recommendations remains understudied. The international study setting increases the generalisability and validity of the results. The study sites are in countries that have publicly funded healthcare systems to minimise the effect of private insurance and other financial barriers on adolescents’ access to healthcare. To reduce selection bias, participants were consecutively recruited until the required number was reached. To reduce response bias, in Finland, research nurses/assistants outside of the usual care team contacted patients. The prospective design will help to reduce recall bias as most questions inquire about recent experiences or emotions. Observation bias is unlikely due to the planned length of follow-up (2 years).

Limitations
Differences between the two study sites pose a number of limitations. These relate to systemic differences between the healthcare systems, the health services available and the legal frameworks allowing access to patient data in Finland and Australia. Other differences relate to the individual administrative and data access mechanisms present across the two sites, the variability in patient cohorts (inclusion of those with intellectual disabilities, autism spectrum disorder and behavioural difficulties in Australia) and parental data availability after transfer (parent/guardian questionnaire data is only available from the Australian cohort and patients under 18 years in Finland). Attempts to accommodate these differences to allow comparison of the cohorts will be maximised.

Despite efforts to reduce bias, some patients may be lost to follow-up, a feature of other transition studies, which may skew the study results. This is likely to be a greater limitation for the Australian cohort as patients are transferred to multiple adult hospitals, each with differing administrative and medical record systems, in comparison to Finland where the majority are expected to transfer to a single adult service. In case of attrition >20%, we will conduct careful analyses between the baseline characteristics of retained and lost participants.52 Some selection bias may have occurred as Australian patients who were invited to participate by their transition care team may have been more likely to participate if they were receiving support from the transition support service. The impact on the outcomes are unclear, as while some patients will be referred to the transition team due to greater needs, they may also be expected to receive greater transition support.

The study population is patients who can independently respond to study questionnaires, due to the well-known discrepancies between patient and proxy responses.53 54 Patients whose education and employment are most severely affected by their chronic illness or disability, such as young people with intellectual disability or communication challenges, are therefore not included, which will reduce the representativeness of the study.

The COVID-19 pandemic will create unanticipated limitations. Infection control measures have led to major disruptions and sudden changes in the care of many groups of patients with chronic health conditions across both paediatric and adult systems. At both sites, this includes a rapid shift to telehealth instead of face-to-face consultations, and potential delays in the timing of transfer and first visit to adult services. Furthermore, the effect of COVID-19 may affect other aspects, such as emotional health and well-being, and wider impacts on engagement in education and employment.55 For this
reason, we have decided to add questions regarding the effects of COVID-19 to the follow-up questionnaires.

CONCLUSION
Successful transition is often judged using data from specific disease measures such as laboratory values and medication adherence. Other measures of transition, including the psychosocial impacts of the process, are understudied and may benefit from greater attention. The Bridge study is designed to assess both of these aspects in an approach that aims to address holistic healthcare needs for adolescents transitioning to adult healthcare, and their families.

Ethics and dissemination
The Bridge study conforms to the Declaration of Helsinki. The Ethics Committee for Women’s and Children’s Health and Psychiatry at the Helsinki University Hospital (HUS/1547/2017) and the RCH Human Research Ethics Committee (38035) have approved the Bridge study protocol. Adolescents and their participating parents/guardians have received both verbal and written information explaining the purpose of the study and they have provided informed consent. Adolescents receive a minor compensation for filling the research questionnaires which take 30–45 min to complete. In Finland, patients aged 15 or older may provide consent to participate without approval from their parents.

Results will be presented at scientific meetings and published in international peer-reviewed journals. Summaries will be provided to the funders of the study as well as patients and their parents/guardians.

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Contributors The study concept and design was conceived by SK, EC and SS. HL, PJM, K-LK, TR, MT and KA assisted in refining the study questionnaires and study design. SK, EC, HL, AT and MK are responsible for data collection. Analyses will be conducted by SK, HL, AT and MK with the help of statisticians. SK prepared the first draft of the manuscript. All authors critically revised the manuscript and approved the submitted version.

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