

BMJ Open Evaluating outpatient transition clinics: a mixed-methods study protocol

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ABSTRACT

Introduction: To support young people in their transition to adulthood and transfer to adult care, a number of interventions have been developed. One particularly important intervention is the transition clinic (TC), where paediatric and adult providers collaborate. TCs are often advocated as best practices in transition care for young people with chronic conditions, but little is known about TC models and effects. The proposed study aims to gain insight into the added value of a TC compared with usual care (without a TC).

Methods and analysis: We propose a mixed-methods study with a retrospective controlled design consisting of semistructured interviews among healthcare professionals, observations of consultations with young people, chart reviews of young people transferred 2–4 years prior to data collection and questionnaires among the young people included in the chart reviews. Qualitative data will be analysed through thematic analysis and results will provide insights into structures and daily routines of TCs, and experienced barriers and facilitators in transitional care. Quantitatively, within-group differences on clinical outcomes and healthcare use will be studied over the four measurement moments. Subsequently, comparisons will be made between intervention and control groups on all outcomes at all measurement moments. Primary outcomes are 'no-show after transfer' (process outcome) and 'experiences and satisfaction with the transfer' (patient-reported outcome). Secondary outcomes consider clinical outcomes, healthcare usage, self-management outcomes and perceived quality of care.

Ethics: The Medical Ethical Committee of the Erasmus Medical Centre approved the study protocol (MEC-2014-246).

Dissemination: Study results will be disseminated through peer-reviewed journals and conferences. The study started in September 2014 and will continue until December 2016. The same study design will be used in a national study in 20 diabetes settings (2016–2018).

BACKGROUND

Successful transfer from paediatric to adult healthcare services is a crucial aspect of high-quality care, but also forms a major

Strengths and limitations of this study

- The proposed study includes a controlled mixed-methods evaluation of process indicators, clinical and patient-reported outcomes. As such, it provides insights into the application and effects of a complex intervention.
- Based on the criteria of successful transition and an extensive literature research, we link possible outcomes to existing theory about the transition of young people with chronic conditions. This contributes to the development of a relevant evaluation framework for transitional care. In addition, we provide an approach that allows for comparisons between studies and even between disease groups.
- Some challenges associated with the design include the selection of control departments, response rates to the questionnaire and organisational issues around the chart reviews, particularly in case of transfer to other hospitals.

challenge for young people with chronic conditions.¹ The gap between paediatric and adult healthcare services appears to be large.² Studies showed that up to 25% of the young adults that have been transferred to adult healthcare services do not regularly attend follow-up visits in the hospital.^{3–4} Loss to follow-up may be a result of differences between paediatric and adult healthcare settings and a poor preparation for the transfer, but may also be affected by changes in social relationships and shifting roles.⁵ While adolescents become increasingly responsible for their own health, they generally show poor treatment adherence, which puts them at risk for poor health outcomes⁶ (eg, deterioration of lung function in cystic fibrosis (CF)). They value being seen as a competent partner in care, but too often feel that they are not included in important decisions about their own lives.^{2 5 7 8}

To support young people in their transition to adulthood and transfer to adult care, a number of interventions have been developed and implemented.^{9–11} One particularly

relevant intervention is the transition clinic (TC). TCs are often advocated as best practice in transition care for young people with chronic conditions.^{9 12–14} Although there is no common definition of a TC, the core principle is that professionals from paediatric and adult care are involved in the delivery of outpatient care in preparation for the upcoming transfer.^{9 15} While some TCs are focused on organising a smooth transfer to adult care and on good clinical outcomes,¹⁶ others have a broader focus including the transition to adulthood and associated psychosocial outcomes.¹⁷ Daily routines and used protocols differ considerably between TCs,¹⁸ and current literature lacks systematic descriptions of TCs' structures and working mechanisms.⁹ In addition, little is known about the effects of this intervention. A review in 2011 identified four evaluation studies of TCs, but these were all diabetes oriented.⁹ Although these studies found positive short-term health outcomes (better glycosylated haemoglobin (Hb1Ac) levels and less short-term complications) and follow-up rates, there is currently no evidence for (long-term) outcomes of TCs with regard to health outcomes, healthcare use, self-management and psychosocial functioning of young adults. Moreover, recent studies of TCs in other diagnostic groups did not include a controlled pre-post outcome evaluation,^{19–30} and as such could not provide sound evidence on outcomes of TCs.

In general, there is inconclusive evidence considering the effectiveness of transitional care. Also, although a large part of transition is generic and not disease specific, comparisons between disease groups and more general evaluations of interventions are rarely conducted. As paediatric or young adult diagnostic groups are often small, including more groups could be beneficial for effectiveness research. Moreover, a non-categorical approach would allow professionals of different disciplines to learn from each other.¹¹ The recently formulated consensus indicators for successful transition³¹ could be helpful for such comparisons and more generic evaluations. Furthermore, little information is provided about important elements of interventions used in transitional care,^{10 32} and there is still little research into young people's and healthcare professionals' experiences with such interventions.^{4 33 34}

METHODS AND ANALYSIS

Study aim

The proposed study evaluates the experiences with and outcomes of TCs. It aims to gain insight into the added value of a TC compared with usual care (without a TC) along the following research questions:

1. How do structures and daily routines differ between TCs and usual care?
2. What are healthcare professionals' experienced barriers and facilitators for the organisation of a TC?
3. What are the differences in clinical outcomes and healthcare use of young people who were seen at a TC and those that received usual care?

4. What are the differences in self-management outcomes, experiences and satisfaction with the transfer to adult care and perceived quality of care of young people who were seen at a TC and those that received usual care?
5. What are the differences between TCs and usual care with respect to the criteria for successful transition?³¹

Study design

A TC is a complex intervention that cannot easily be evaluated through a randomised controlled trial. It is important to explore how complex interventions form a part of and work within their contexts, so that possible working mechanisms could be revealed and the eventual outcomes could be attributed to the intervention.³⁵ Therefore, the use of a mixed-methods design is advocated in the evaluation of complex interventions.^{36 37} To answer the research questions, a mixed-methods study with a retrospective controlled design will be used. The TC will be compared with usual care, that is, transfer to adult care without the use of a TC. Elements studied considering the formats of transitional care will be as follows: TC setting, availability of a written transfer, involved professionals, age group seen at TC, number of TC visits young people have before transfer, presence of dedicated professionals in adult care, structure and content of the TC consultations (including subjects discussed), and use of other interventions to support transition such as individual transition plans.

The qualitative part of this study will be conducted first and is expected to provide insight into the development, underlying thoughts, organisation, structure, team, facilitators and barriers of transitional care, both in the form of a TC and as standard care (without TC). Two data collection methods will be employed: *observations* during consultations with young people and *semi-structured interviews* with healthcare professionals. The quantitative part explores young people's experiences with transitional care and clinical, healthcare and self-management outcomes among those who received care at a TC and those who did not. Data collection methods will include *retrospective chart review* and *survey* among young adults transferred to adult care. An overview of the data collection methods per research question is presented in [table 1](#).

Study setting

Purposive sampling will be used to select TCs in the Erasmus University Medical Center—Sophia Children's Hospital in Rotterdam. Previous research provided an overview of departments that have a TC in Erasmus University Medical Center.³⁸ TCs operating for 4 years or longer will be selected and invited to participate, because these are expected to have more or less embedded and standardised TC structures and routines. Also, selecting longer existing TCs would allow for larger study samples, because a larger number of young people would be treated at the TCs over time. For each

Table 1 Data collection methods per research question

Research questions	Data collection method	
	Quantitative	Qualitative
1. How do structures and daily routines differ between TCs and usual care?	Not applicable	Observations of healthcare practice and semistructured interviews with healthcare professionals
2. What are healthcare professionals' experienced barriers and facilitators for the organisation of a TC?	Not applicable	Observations of healthcare practice and semistructured interviews with healthcare professionals
3. What are the differences in clinical outcomes and healthcare use of young people who were seen at a TC and those that received usual care?	Retrospective chart reviews of young people's medical records	Not applicable
4. What are the differences in self-management outcomes, experiences and satisfaction with the transfer to adult care, and perceived quality of care of young people who were seen at a TC and those that received usual care?	Survey among young people	Not applicable
5. What are the differences between TCs and regular transition care on the criteria for successful transition?	Retrospective chart review of young people's medical records and survey among young people	Not applicable

TC, transition clinic.

participating TC, a control setting that provides usual care to the same diagnostic groups in one of the other University Medical Centres in the Netherlands will be selected. All departments will be contacted by email to inform them about the study and to ask for their cooperation, followed by a phone call (in case of no reply). After consent, two researchers will visit the centres to explain the study in more detail. The teams will then be asked for suggestions for control settings that can be contacted to ask for participation.

Based on the selection criteria and the previous overview of TCs in the Erasmus MC,³⁸ two pulmonology departments treating CF, two gastroenterology departments treating inflammatory bowel disease (IBD) (Crohn's disease and ulcerative colitis) and two endocrinology departments treating Turner syndrome (TS), congenital adrenal hyperplasia (CAH) and hypopituitarism will be invited to participate in the study.

Study procedures

Observations

Participant observations will be conducted at the TCs and at the outpatient control clinics. The aim is to observe about 8 hours in total at each setting. Young people and their parents will receive information about this study from their healthcare professional and all parties involved will be asked to provide written consent to the presence of the observer during their consultations. At the TCs, the consultations between young people, their parents and healthcare professionals will be observed, as well as the preparation of the professionals. In the control settings, regular consultations with young people and their parents will be observed. Attention will be paid to

different themes including coordination of the transition process, structure, content of consultations and use of interventions. The researchers will take field notes and write down their findings in narratives.

Semistructured interviews

Healthcare professionals from paediatric and adult care, working at all participating departments will be invited for semistructured interviews by obtaining their email addresses through the departments' heads, who are asked to inform their teams about the study on beforehand. Non-responders will be reminded by email or a telephone call. Professionals from all relevant disciplines that participate in transitional care (eg, doctors, nurses, psychologists, dieticians, social workers, physiotherapists, etc) will be included.

Themes that will be addressed during the interviews are based on the literature, such as the validated 'You're welcome' quality criteria that determine whether a clinic can be typified young people-friendly,^{39 40} the 'Mind the Gap' tool that is used to assess transfer readiness,⁴¹ and experiences of young adults, parents and professionals.^{2 5 7 8 42 43} Examples of topics are as follows: reasons for (not) setting up a TC, usefulness of the TC, barriers and facilitators, coordination of the TC, structure and content of transitional care and changes over time, involved healthcare professionals, use of interventions and added value of the TC for young people, their parents and healthcare professionals. Interviews will last for ~1 hour.

Retrospective chart review and survey

Of each outpatient department, all patients who have transferred to adult care 2–4 years prior to data



collection will be selected for retrospective chart review and the survey. In case a patient has been transferred to adult care in another hospital, the clinician of the children's hospital will obtain contact details. Patients with severe intellectual disabilities or known psychiatric problems will be excluded. Information about such problems will be derived from the patient charts. An information letter accompanied by an invitation for participation in the survey and a consent form will be sent to all selected patients. A reminder letter will be sent to non-responders after 2 weeks, followed by a telephone call after 4 weeks. The survey will be sent to all patients that provided consent after chart review. For the chart review, both data from paediatric and adult care will be collected at four measurement moments: T-2, the second year before transfer; T-1, the year before transfer; T1, the year after transfer; and T2, the second year after transfer.

Process and outcome measures for chart review and survey

Although there are no agreed outcome measures for 'successful transition', several studies and study protocols for the evaluation of transitional care provide insights in important areas of outcome and process measures.^{34 44–46} These include clinical outcomes, healthcare-related measures (medical follow-up) and psychosocial outcomes. Also, a recent international Delphi study provided insight into key indicators for successful transition,³¹ while another one recently identified key transition outcomes.⁴⁷ We differentiate between process and (patient-reported) outcome measures.

Since 'no-show after transfer' is seen as an important process measure for transitional care,^{7 31 45} it is selected as a primary process outcome in this study. Information about no-show will be derived from the patient charts. In the chart review, the following secondary measures will be assessed: clinical outcomes, number of consultations and hospital admissions, therapeutic regimen, and if available quality of life. Specific measures are based on previous research (see references in the tables) and were discussed with professionals working in the specific fields of endocrinology, CF and IBD.

With respect to the outcome measures retrieved through the survey, young people's 'experiences and satisfaction with transfer' will be considered a primary patient-reported outcome in this study. In the survey, the following secondary outcomes will be assessed: healthcare-related and self-management outcomes, experiences with current care and quality of life. These outcome measures are based on literature around transfer of young people, both disease-specific and more generic (see references in the tables).

We categorised the variables into background, process and outcome variables. [Table 2](#) presents an overview of relevant background variables to be collected; [table 3](#) explains the operationalisation of included process measures; and [table 4](#) elaborates on the operationalisation of the outcome measures.

Table 2 Relevant background variables

Variables	Operationalisation	Data collection method
Date of birth	dd/mm/yyyy	Chart review
Date of diagnosis	dd/mm/yyyy	Chart review
Gender	Male/female	Chart review
Comorbidity	Yes/No	Chart review
Educational level	High/medium/low*	Survey
Type of education	Special education or not	Survey
Disability benefits	Yes/No	Survey

*Low: junior vocational or secondary general low; medium: secondary general high or senior vocational; high: higher educational institutions or university.

Data analyses

Qualitative analyses

Interviews are audio taped, transcribed verbatim and imported into Atlas.ti 7.0. Interview transcripts and observation narratives will be coded thematically by two researchers independently. Themes will be derived from the topic lists used during the interviews, and if applicable, subthemes will be derived from the data.⁸⁶ Details will be collected on the contents of the intervention, structure and working ways, and possible changes over time. Furthermore, healthcare professionals' experiences with transitional care, as well as experienced facilitators and barriers will be explored. As such, these analyses will provide answers on the first two research questions.

Quantitative analyses

First within-group differences on clinical outcomes and healthcare use will be studied over the four measurement moments with analysis of variance (ANOVA) tests (chart review data). Subsequently, comparisons will be made between intervention and control groups on clinical outcomes, healthcare use, self-management outcomes, experiences and satisfaction with the transfer to adult care and the perceived quality of current care. Independent samples t-tests and χ^2 tests will be used to do so. These analyses will provide answers on the third and fourth research questions. The fifth research question is based on criteria for successful transition. To establish these, we used the recently established indicators of successful transition.³¹ The indicators or criteria that reached international consensus on being essential or very important for a successful transition and our operationalisation and data collection method per criteria are presented in [table 5](#). Again, comparisons will be made between intervention and control groups with χ^2 tests. Data per diagnostic group will be analysed. For the overall analysis of the generic outcomes (all but the clinical outcomes), all data will be compiled. Quantitative analyses will be performed with IBM SPSS 21.0.

Table 3 Operationalisation of process measures

Area*	Variable	Operationalisation	Measurement moment†	Data collection method
Transfer	Date of transfer	dd/mm/yyyy	T0	Chart review
	Availability written transfer	Yes/No	T0	Chart review
	Written transfer recipient	Description	T0	Chart review
	Current healthcare provider	Centre	T0	Chart review
Medical follow-up ^{3 7 31 45 48–61}	No-show at first appointment in adult care‡	Yes/No	T1	Chart review
	First appointment in adult care cancelled	Yes/No	T1	Chart review
	Scheduled consultations	Number per year	T-2, T-1, T1, T2	Chart review
	Missed consultations	Number per year	T-2, T-1, T1, T2	Chart review
	Time between last appointment in paediatric care and first appointment in adult care	Months	T-1, T1	Chart review
	Hospitalisations related to chronic condition	Number per year	T-2, T-1, T1, T2	Chart review
	Length of hospitalisations	Days	T-2, T-1, T1, T2	Chart review
	Emergency department visits	Number per year	T-2, T-1, T1, T2	Chart review
Healthcare	Topics discussed during consultations	The need for more attention for discussion of non-medical issues, and the frequency of communication about these topics during consultations	Not applicable	Survey

*References include general and disease-specific studies that included and/or recommended similar outcome measures to study transition.

†T-2: the second year before transfer; T-1: 1 year before transfer; T0: transfer; T1: the year after transfer; and T2: the second year after transfer.

‡Primary measure.

Sample size: In an IBD sample of young people, it was found that 78% of the young people who were directly transferred versus 29% of those transferred through a TC had at least one recorded non-attendance at clinic after transfer.¹⁹ Since attending scheduled visits in adult care is an indicator for a successful transition,³¹ and no other studies provided relevant information on any of the indicators, we performed a sample size calculation based on this indicator and the results found by Cole and colleagues. Based on their numbers, an α of 0.05 and a power of 0.95, we calculated that in the intervention and control group, the sample size should be 72 or more. Sample size calculation was performed with G*Power 3.2.1.

ETHICS AND DISSEMINATION

To ensure data confidentiality, the following procedures will be followed. Patients' personal identification information will only be available to the healthcare team and two researchers who are not part of the healthcare team. These researchers will sign a non-disclosure agreement (NDA). Other researchers will receive anonymised data. Patient numbers will be secured with passwords known by the researchers that signed the NDA and one

member of the healthcare team. Young people and their parents (in case of minors who can be included in the observation part of the study) will receive an information letter from the doctor who is in charge of the treatment. They will be asked to provide written informed consent per study part. They are also asked to provide consent for matching the data from the surveys and chart reviews. Data will be processed anonymously and respondent numbers will be used to link data from the chart review to data from the survey. If applicable, pseudonyms will be used in the interview transcripts and observation narratives. The Medical Ethical Committee of the Erasmus Medical Centre approved the study protocol (MEC-2014-246). Study results will be published in international peer-reviewed journals, and will be presented at national and international conferences. The study started in September 2014 and is anticipated to continue until December 2016. The same study design will be used in a national study in 20 diabetes settings, starting in April 2016 until 2018.

DISCUSSION

Structuring the transition process by means of a TC is advocated to organise collaboration between paediatric

Table 4 Operationalisation of outcome measures

Area*	Variable	Operationalisation	Measurement moment† (for chart review data) or measurement scale and psychometrics (for survey data)	Data collection method
Clinical outcomes in cystic fibrosis ^{58–60 62–65}	Pulmonary functioning	FEV1 value	T-2, T-1, T1, T2	Chart review
	Acute pulmonary exacerbations	Use of antibiotics: yes/no, and frequency	T-2, T-1, T1, T2	Chart review
	Pseudomonas infection	Yes/No	T-2, T-1, T1, T2	Chart review
	Body mass index	Value	T-2, T-1, T1, T2	Chart review
Clinical outcomes in IBD ^{51 56 66}	Surgical treatments	Number per year	T-2, T-1, T1, T2	Chart review
	Medications	Use and type	T-2, T-1, T1, T2	Chart review
	Endoscopies	Number per year	T-2, T-1, T1, T2	Chart review
Clinical outcomes in endocrinology ^{57 67}	Body mass index	Value	T-2, T-1, T1, T2	Chart review
	Blood pressure	Systolic and diastolic	T-2, T-1, T1, T2	Chart review
	For those with TS: thyroid function	TSH/FT4 value	T-2, T-1, T1, T2	Chart review
	For those with CAH: androgens	17-OHP/androstenedione value	T-2, T-1, T1, T2	Chart review
	For those with hypopituitarism: testosterone level	Value	T-2, T-1, T1, T2	Chart review
	For those with hypopituitarism: insulin-like growth factor	IGF-1 level	T-2, T-1, T1, T2	Chart review
	For those with hypopituitarism: FT4 level	Value	T-2, T-1, T1, T2	Chart review
	Medications	Use and type	T-2, T-1, T1, T2	Chart review
Healthcare-related outcomes	Experiences and satisfaction with transition to adult care‡ ^{7 32 44 52 53 55 60 66 68–72}	Experiences on two domains: (1) organisation of healthcare related to transition and (2) satisfaction with preparation for transfer	On Your Own Feet Transition Experience Scale (OYOF-TES) ⁴ (validated 18-item scale with 5-point Likert scales, $\alpha=0.92$) + self-reported satisfaction on a 1–10 scale	Survey
	Perceived quality of care ^{7 32 44 52 53 55 60 66 68–72}	Patient centeredness on five domains: (1) empowerment, (2) design of practice, (3) goal-setting/alignment, (4) problem-solving and (5) coordination/follow-up	Patient Assessment of Chronic Illness Care (PACIC) (validated 20-item scale with 5-point Likert scales) ^{73 74}	Survey
Self-management-related outcomes	Self-management ¹¹	Chronic condition self-management	Partners in Health Scale (PIH) (validated 12-item scale with 9-point Likert scales) ^{75 76}	Survey
	Independence during consultations ⁷⁷	Self-reported independent behaviours during consultations with healthcare providers	Independent Behaviours During Consultations (IBDC) (validated 7-item scale with 5-point Likert scales, $\alpha=0.79$) ⁷⁷ + self-reported independence on a 1–10 scale	Survey
	Self-efficacy ^{7 46 51 53 61 66 70 71 78 79}	Disease-related self-efficacy on four domains: (1) knowledge about the condition, (2) coping, (3) competencies	On Your Own Feet Self-efficacy Scale (OYOF-SES) (validated 16-item scale with 4-point Likert scales) ⁸⁰	Survey

Continued

Table 4 Continued

Area*	Variable	Operationalisation	Measurement moment† (for chart review data) or measurement scale and psychometrics (for survey data)	Data collection method
	Adherence ^{7 51–54 56 58 62 81 82}	during consultations and (4) medication Self-reported adherence to medical treatment	Medication Adherence Rating Scale (MARS-5) (validated 5-item scale with 5-point Likert scales) (R Horne, M Hankins. The Medication Adherence Report Scale (MARS): a new measurement tool for eliciting patients' reports of non-adherence. Unpublished Working paper 2007) ⁸³ + self-reported adherence on a 1–10 scale	Survey
Quality of life	Quality of life ^{44–46 51–53 58 62 63 67 68 71 81 84}	Health-related quality of life on four domains: (1) physical, (2) emotional, (3) social and (4) school/work	Paediatric Quality of Life Inventory Young Adult (PedsQL_YA) (validated 23-item scale with 5-point Likert scales) ⁸⁵	Survey

*References include general and disease-specific studies that included and/or recommended similar outcome measures to study transition.

†T-2: the second year before transfer; T-1: the year before transfer; T0: transfer; T1: the year after transfer; and T2: the second year after transfer.

‡Primary outcome.

17-OHP, 17-hydroxyprogesterone; CAH, congenital adrenal hyperplasia; FEV1, forced expiratory volume in 1 s; FT4, free thyroxine; IBD, inflammatory bowel disease; IGF-1, insulin-like growth factor-1; TS, Turner syndrome; TSH, thyroid-stimulating hormone.

**Table 5** Operationalisation of the criteria for successful transition³¹

Original criteria	Operationalisation: successful transfer if...	Data collection method
1 Patient not lost to follow-up	Young adult attended first planned consultation in adult care: <i>yes/no</i>	Chart review
2 Attending scheduled visits in adult care	Young adult has no missed consultations in the 2 years after transfer: <i>yes/no</i>	Chart review
3 Patient building a trusting relationship with adult provider	Young people trust their current healthcare provider: <i>a score higher than 6 points on a 10-point scale</i>	Survey among young adults
4 Continuing attention for self-management	There is sufficient attention for self-management (including non-medical) topics: <i>average score of 3 or higher on 5-point scale</i>	Survey among young adults
5 Patient's first visit in adult care no later than 3–6 months after transfer	The first consultation in adult care takes place within 6 months after transfer: <i>yes/no</i>	Chart review
6 Number of emergency room visits for regular care in the past year	There were no emergency room visits due to acute disruption of the disease in the 2 years after transfer: <i>yes/no</i>	Chart review
7 Patient and family satisfaction with transfer of care	Young people are satisfied with the transfer process: <i>a score higher than 6 points on a 10-point scale</i>	Survey among young people
8 Maintain/improvement of standard for disease control	The standard for disease control evaluation is met in the year after transfer: <i>yes/no</i>	Chart review

and adult care and for better preparation of all parties involved.^{9 12–14} Apparently, this recommendation has been taken up by the field. While Crowley and colleagues found only four evaluation studies of TCs in 2011,⁹ there has been a marked increase in the publication of evaluation studies of TCs since 2015. We found new studies in the fields of epilepsy, urology, diabetes, CF, IBD, kidney disease, HIV and rheumatology.^{19–30 87 88} Still, the proposed study is unique in its design. First, because only two published studies included a historical control group in the study design.^{19 24} Our approach goes even further by including similar controls in the same time frame, adding the patient questionnaire and employing a pre-post design.

Second, our proposed design includes a significant qualitative study part that is expected to provide important insights into the daily routines, structures and working elements of TCs. Only one existing study employs qualitative data collection methods. Still, this study included a prospective evaluation among young adults²⁹ and therefore provides no insights into the TC model. Therefore, it is still unclear what TC models are implemented and what the best model might be.^{15 89} Our study could provide some answers to this question since we study components and outcomes of different TC models employing a standardised evaluation framework and the same data collection methods, which enables comparisons.

Finally, the evaluation studies we found vary in the outcome measures they use to evaluate the TC. While almost all evaluate whether or not young people attend adult care after transfer, some are interested in young people's satisfaction with the care delivered and programme components,^{26 28 88} and others look at disease-specific outcomes or adherence.^{19 22 24 29 87} Still, none of the studies clarify why certain outcome measures were

chosen. We selected our outcome measures after extensive literature research, linking possible outcomes to current ideas about the transition of young people with chronic conditions. By doing so, we provide a relevant approach allowing for comparisons of transitional care between disease groups (eg, based on the criteria for successful transition³¹).

There are some challenges associated with our study design that need to be addressed. First, the current lack of insight into different TC models complicates the selection of outcome measures for the quantitative evaluation. We are not able to select these based on the content of the interventions. However, we view transition in the light of the definition proposed by Blum and colleagues in 1993 as 'a multifaceted, active process that attends to the medical, psychosocial, and educational/vocational needs of adolescents as they move from the child-focused to the adult-focused health-care system', and as such transition 'implies an increase in independent behaviour and personal autonomy'.⁹⁰ They further stated that 'the optimal goal of transition is to provide health care that is uninterrupted, coordinated, developmentally appropriate, psychosocially sound, and comprehensive'.⁹⁰ Starting from this point of view, we conducted an extensive literature study and selected outcome measures that reflect these goals. Although not all TC models may include elements aimed at improving the whole transition process, we believe the selection of a wide variety of outcome measures may enable the comparisons of different TC models.

The second challenge, in connection with the lack of insight in TC models, considers the selection of control departments. The core principle of TCs is that health-care professionals from paediatric and adult care are involved in the delivery of outpatient care in preparation for the upcoming transfer. However, the focus of this

care (eg, medical and/or psychosocial needs) differs between TCs. This means that when defining usual care, that is, selecting control departments, we can only select on whether or not professionals from paediatric and adult care actively collaborate in the delivery of transitional care. It might be that even in the control setting some sort of collaboration is established, diluting the differences between usual care and care at a TC. To cope with this issue, we will also conduct qualitative research at these control sites. As such, we can specifically define what usual care in the control departments entails and how this differs from care in the intervention departments.

Furthermore, the retrospective character of the quantitative data might be a limitation. As participants will be asked to think about their transfer experiences from 2–4 years ago, this might lead to recall bias. Finally, the chart review and survey carry operational challenges with them. Most hospitals use different electronic patient record systems, and charts from 4 years ago may not even be digitalised yet. Also, there are usually very general formats within record systems, making it unclear whether or where information is available. To overcome these challenges, there will be close collaboration with at least one healthcare professional from each participating department. This professional will help us to draft a grid for chart review, and will explain their patient record system to us and show us where to find the required information. Since chart reviews include a very precise task, these will be conducted in teams of two researchers (who both will be instructed by the healthcare professional). Another challenge is the fact that it is not uncommon for young people to transfer to other hospitals, including some that may not be included in the study. This complicates the retrieval of post-transfer data for that group. Still, in the Netherlands, information from patient charts may be requested from the information department in the hospitals after written consent from the patient. Consent from young people who transferred to other hospitals will be sought. As for the survey, the response rate of young adults may be a problem. It is well known that response rates to questionnaires in adolescents and young adults are usually low.^{91 92} To anticipate this issue, all young people who fill out the questionnaire will be presented with a gift voucher of €10. Furthermore, parents are an important actor when it comes to transitional care, and it would be good to include them in the survey part. However, we anticipate difficulties in locating the parents of the young people, since we study a group of young adults transferred 2–4 years ago. Therefore, we chose to focus on the young people alone.

Finally, the observations are current, while the quantitative evaluation is retrospective. This may complicate the use of the qualitative data from the observations to understand the outcomes of the evaluation. Still, we conduct qualitative interviews with professionals to gain insight into any changes that occurred in the working

ways of the TC in the past 5 years. This will support the interpretation of the observational and quantitative data.

Contributors JNTS and AvS conceived of the study. All authors participated in its design. JNTS carried out the literature study and drafted the manuscript, while the others contributed to refinement. All authors have read and approved the final version.

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Data sharing statement Our manuscript describes a study protocol. As such, we cannot elaborate on additional unpublished data (yet).

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