Individualised follow-up for head and neck cancer—design of a prospective cohort study to assess its feasibility

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ABSTRACT
Introduction. It is a common practice for many cancer types to monitor patients after treatment to detect new disease manifestations early. For head and neck cancer (HNC), however, long-term routine follow-up is up for debate for several reasons. The benefits of prolonged routine follow-up on survival have not been proven. Also, cancer follow-up is putting increasing pressure on healthcare resources due to rising incidence and survival rates. Therefore, this study investigates a novel follow-up approach among HNC patients, giving them the opportunity to choose their own follow-up programme.

Methods and analysis. HNC patients are offered a decision-aided choice between standardised or individualised follow-up after 1.5 years of uncomplicated guideline-prescribed follow-up. Standardised follow-up entails continuing the 5-year guideline-prescribed schedule. Individualised follow-up means the patient only attends the outpatient clinic on their own initiative in case of physical symptoms or supportive care needs. Patients are educated on self-examination and when a control visit is necessary. The primary outcome measure is the feasibility of offering patients this choice. Secondary outcome measures are quality of life, costs, productivity loss and detection of new disease.

Ethics and dissemination. We believe that it is essential to let patients determine their follow-up programme based on their own values and preferences. If this choice is feasible, it can be implemented and investigated in other HNC care centres.

STRENGTHS AND LIMITATIONS OF THIS STUDY
⇒ This is the first prospective study to evaluate offering head and neck cancer patients a decision-aided choice about how to continue their follow-up 1.5 years after treatment.
⇒ This choice is assessed from many perspectives: patients’ and healthcare professionals’ views and also costs and the detection of new disease are considered.
⇒ Patients are invited to choose their own follow-up, because random allocation does not consider individual values and preferences.
⇒ Geographical, racial and ethnical diversity in our study population is probably compromised as this is a regional feasibility study.

INTRODUCTION
Worldwide, there were 19.3 million new cancer cases in 2020. The global cancer incidence is expected to increase by 47%, leading to an estimated 28.4 million new diagnoses in 2040. After treatment, it is a common practice to monitor cancer patients for a standard period of time in order to detect new disease manifestations and assess late and long-term treatment effects. Due to the rising incidence, both cancer treatment and follow-up care will put a pressure on healthcare systems, particularly in high-income countries where mortality rates are relatively low and cancer is increasingly being managed as a chronic disease. However, the effectiveness of standardised follow-up for detecting recurrences, increasing overall survival and meeting supportive care needs has been disputed for several cancer types.

Therefore, it is necessary to explore alternative follow-up approaches that meet patients’ needs without placing an undue burden on healthcare resources.

Head and neck cancer (HNC) is one of the cancer types for which the benefits of standardised follow-up after treatment are up for debate. HNC is a heterogeneous disease of the upper aerodigestive tract. The most common histology is squamous cell carcinoma, which predominantly manifests in the oral cavity, oropharynx, hypopharynx and larynx. Risk factors include tobacco and alcohol use and the oncogenic human papillomavirus (HPV). The latter is mainly associated with oropharyngeal cancer. HPV-positive oropharyngeal cancers have significantly better survival outcomes and the lowest risk of developing second primary malignancies compared with non-HPV associated HNCs. Despite these differences, medical guidelines around...
The world prescribe routine post-treatment follow-up for 3 years to lifelong.16–19

There are several aspects to consider as to why HNC patients could benefit more from individualised follow-up. First, the majority of HNC recurrences occur within 2 years after curative treatment, however, the incidence of second primary tumours remains stable until death.20–22 Second, most recurrences cause clinical symptoms and as a result a substantial number is discovered between routine follow-up visits.23–27 Third, it has not been proven that patients in whom recurrent disease is discovered in the asymptomatic phase have better treatment options and life expectancy than those with symptoms at the time of discovery.24 28 29 Therefore, the added value of 3 years to lifelong checkups for detecting cancer manifestations, which is routine practice in most countries, should be questioned.

Another important issue is that many patients worry their cancer will progress or return after treatment, known as fear of cancer recurrence (FCR).30 31 FCR has a major impact on quality of life (QoL).32 33 It is not clear whether standardised visits exacerbate or relieve FCR. Previous research among patients with colorectal carcinoma suggests that a follow-up programme in which prescheduled visits are replaced by patient-education and access to care by self-referral does not influence FCR.34 In addition, long-term cancer survivors report being anxious before prescheduled visits.35 Patients with endometrial cancer reported that their anxiety, including fears of cancer recurrence, increased when hospital-based follow-up appointments were forthcoming. Patient-initiated follow-up was considered an appropriate alternative, provided participants were given information about the signs of relapse and to know who to contact if they had concerns.36 Finally, clinically significant levels of FCR in HNC patients seem to be related to decreased QoL.37 HNC patients also indicated that they desire more information about their treatment trajectory and involvement in the decision-making process.38

Overall, deintensifying standardised follow-up after HNC treatment seems to be sensible in the light of detecting cancer recurrences. Although patient-initiated follow-up does not seem to have a clinically poor impact on FCR, this relationship has been studied infrequently and remains a topic of debate.39 Also, reducing the frequency of standard control visits for all HNC patients may deny the different needs of individual patients.40 Therefore, we will implement and evaluate a decision-aided individualised follow-up programme that allows HNC patients to choose between: (1) continuing standardised follow-up with prescheduled follow-up visits and (2) individualised follow-up with symptom-based visits. Patients can decide on their follow-up strategy after completing 1.5 years of standardised follow-up.

Objectives and hypotheses

The INFLUENCE-study (Individualised Follow-Up for Head and Neck Cancer) is designed as a prospective cohort study to evaluate the feasibility of offering HNC patients the choice between standardised and individualised follow-up in a shared decision-making process with their physician, supported by a decision-aid. Secondary objectives are to study the effect of having this choice on FCR, QoL, medical costs, productivity losses and the timing and manner of detection of cancer recurrences and second primary tumours. We hypothesise that giving patients the choice between standardised and individualised follow-up is feasible and has a positive effect on FCR, while maintaining QoL and reducing medical costs. Because all patients are educated on corresponding symptoms and how to contact their physician in case they experience those symptoms, we expect to diagnose a similar rate of recurrences and second primary tumours in patients who opted for individualised follow-up.

METHODS AND ANALYSIS

Study setting

In the Netherlands, HNC was diagnosed in 3130 patients in 2019.41 HNC care is concentrated in eight head and neck oncology centres and six affiliated hospitals. The number of treated patients per centre varies from 70 to 600 patients annually. All centres are committed to using the protocols developed by the Dutch Head and Neck Society (Nederlandse Werkgroep Hoofd- en Hals Tumoren (NWHHT)), in which medical specialists from various fields collaborate, and the Allied Dutch Head and Neck Society (Paramedische Werkgroep Hoofd- en Hals Tumoren (PWHTT)), in which allied healthcare professionals collaborate. The Dutch guideline ‘Head and Neck Tumours’ prescribes 17 outpatient follow-up visits over 5 years with decreasing frequency after treatment.16 This study will take place in one of the largest Dutch head and neck oncology centres and its affiliated hospital.

Eligibility criteria

Adult patients treated with curative intent for a primary, pathologically proven carcinoma located in the nasal cavity/paranasal sinuses, nasopharynx, oral cavity, oropharynx, hypopharynx or larynx are eligible for inclusion after giving written informed consent. Patients must have completed 1.5 years of standardised follow-up care without major complications that need treatment or being diagnosed with recurrent or new cancers. Exclusion criteria are salivary gland cancers, neuroendocrine cancers, a language barrier or low literacy, which prevent the patient from using the Dutch decision-aid and other supportive materials, and (cognitive) limitations which prevent the patient from making an informed decision.

Follow-up care

Standardised follow-up

Standardised follow-up encompasses a predetermined schedule of post-treatment control visits by a medical specialist and an oncological nurse specialised in head and neck oncology (case manager) for 5 years—every 2 months in the first year, every 3 months in the second year, every 4 months in the third year and every 6 months in the fourth and fifth year.16
Individualised follow-up

Individualised follow-up entails that the patient only attends the outpatient clinic for a control visit on their own initiative in case of physical symptoms that may indicate cancer recurrence, supportive care needs or if they have other needs or questions related to their treated HNC.

The first 1.5 years after treatment

The first 1.5 years after HNC treatment consists of standardised follow-up for all patients. During the first routine control visit, 2 months after treatment, patients are educated about symptoms that could indicate a second or recurrent tumour in the head and neck region. This includes an explanation on how to examine their own neck for swellings and other abnormalities. Case managers are accessible for patients to assist them with non-oncological aspects of the treatment and aftercare, such as coping with the effects of the disease and treatment, and psychosocial issues. In addition, patients receive a link to a freely accessible web page where educational materials on self-examination of the head and neck area can be reviewed. They are also granted access to Oncokompas (www.oncokompas.nl in Dutch), a web-based eHealth application that supports cancer survivors in self-management by providing personal information based on health-related QoL and cancer-generic and tumourspecific symptoms. Finally, patients are preinformed about the choice of follow-up they will be offered after 1.5 years of standardised follow-up.

Intervention: choice of follow-up

Patients are invited to fill out a tailormade decision-aid at home before completing 1.5 years of uncomplicated standardised follow-up (www.nazorgkeuzehulp.nl in Dutch). This web-based tool clarifies the following: (1) the goals of cancer follow-up; (2) that most HNC recurrences occur in the first year after treatment and are usually accompanied by clinical symptoms; (3) that there are no proven survival differences between patients in whom HNC recurrence is detected in the asymptomatic or symptomatic phase. Furthermore, it explains the differences between the two follow-up strategies and their possible advantages and disadvantages. In the final step, patients answer questions about their personal preferences for follow-up care to increase their awareness of what aspects they consider important.

Patients are asked whether they want to continue standardised follow-up or switch to individualised follow-up during a decision-making consult 1.5 years after treatment. Both options are explained by their treating physician and case manager. The results of the decision-aid are discussed at the patient’s request. Patients are allowed to make a final decision during the decision-making consult. If the patient requires more time to think, a telephone consultation between the patient and the treating physician will be scheduled 2 weeks after the decision-making consult to make a final decision. All participating care providers are trained in shared-decision making prior to this study. During further follow-up, patients may at all times reconsider and change their decision and/or withdraw their consent for study participation.

Study recruitment

Healthcare providers will identify eligible participants and schedule a consult with an independent researcher directly after the decision-making consult. The researcher will explain the INFLUENCE-study and patients who are interested receive the study information letter. The researcher will contact interested patients 1 week after the consult to answer remaining questions about the study. Patients who are willing to participate will be asked by the researcher to complete the informed consent form. See figure 1 for a study flowchart. T1 is defined as the moment the patient has completed 1.5 years of standardised follow-up after treatment and is included in the study. T2 is defined as 1 year after inclusion. The study start date is September 2022. The enrolment period will extend over 12 months. Participants are followed for 1 year after inclusion. Afterwards, the collected data will be analysed and reported (see ‘Dissemination policy’). The expected study end date is September 2025.
Study outcomes
Primary study outcome—feasibility
The feasibility of offering HNC patients a choice between standardised and individualised follow-up is assessed using Bowen’s key areas of focus for feasibility studies as a framework.35 Primary outcome measures are demand and acceptability. Demand, the extent in which this new follow-up approach is likely to be used, is quantified by estimating the reach—the number of patients who received the decision-aid and the choice for follow-up in our clinical practice divided by the number of patients eligible to use the decision-aid and thus make a choice between the two follow-up programmes. The number of patients who opted for standardised or individualised follow-up is also registered. Acceptability, the extent to which the use of the decision-aid is suitable and attractive to patients, is primarily measured by a self-constructed questionnaire including questions from the System Usability Scale (SUS).44

Physicians and case managers receive an adjusted version of the Measurement Instrument for Determinants of Innovation (MIDI) to assess factors affecting the implementation of the decision-aid and individualised follow-up in daily clinical practice.45

Secondary study outcomes—feasibility
Another aspect of feasibility is the effect of the innovation, which are the decision-aid and the choice between different follow-up strategies, on those involved. The shared decision-making process is evaluated by Dutch translated versions of the Shared Decision-Making Questionnaires for patients and physicians (SDM-Q-9; SDM-Q-doc).46 Decisional conflict and regret are measured by validated Dutch translated versions of the Decisional Conflict Scale (DCS) and the Decisional Regret Scale (DRS), respectively.47 48

To get insight into the effectiveness of the choice for follow-up, we will evaluate the following: FCR assessed by the Cancer Worry Scale (CWS) and QoL assessed by the EORTC Quality of Life Questionnaire Core 30 (QLQ-C30), EORTC Quality of Life Questionnaire Head & Neck (QLQ-H&N35) and EuroQol 5-Dimension (EQ-5D-5L) questionnaires.49–52

The INFLUENCE-study also focuses on practicality in terms of medical costs and productivity loss. The number of outpatient visits and diagnostic tests during the follow-up year after the choice for follow-up will be determined and compared for standardised and individualised follow-up. Patients also receive the Erasmus University Institute for Medical Technology Assessment’s Medical Cost Questionnaire (iMCQ) and Productivity Cost Questionnaire (iPCQ).53 54

Other outcomes
Date and manner of detection (routine visit or patient-initiated visit; asymptomatic or symptomatic), localisation, stage and treatment will be registered for all cancer recurrences and second primary tumours occurring during this study. See table 1 for a detailed description of all outcome measures.

Input variables
Patient characteristics (age, sex, educational level, daily activities, tumour and treatment characteristics) for all participants will be registered.

Expected sample size
Annually, around 500 patients who meet our inclusion criteria are treated in our university medical centre and our affiliated hospital. Considering a 2-year survival rate of 80% and an estimated study eligibility rate of 75% lead to 300 patients who can participate in this study. A participation rate of 70% is anticipated, resulting in 210 potential candidates. A waiting-room survey among HNC patients indicated that approximately 25% would opt for individualised follow-up after the decision-making process, without having received detailed information or the educational materials and decision-aid. Thus, we expect to end up with a group of 55–85 patients who choose individualised follow-up and 125–155 patients who choose standardised follow-up. Including our affiliated partner hospital will make it more likely that this number of participants will be met. Sample-size calculations were not performed as this is a feasibility study.

Data collection and management
Patient, tumour and treatment characteristics will be collected from participants’ electronic patient records and stored in Castor Electronic Data Capture (CastorEDC).55 Data collection forms are available on reasonable request. All questionnaires will be sent through CastorEDC. The decision-aid, information on (self-)examination of the head and neck area and questionnaires will be provided on paper in case the patient does not have access to or use electronic devices. Data will be stored in the Digital Research Environment (DRE), a web-based platform to handle data in a secure environment.

Participants will be given a unique identification code on entering the study. The identification code will be recorded on a code list and kept in a secure digital environment. Data that will be collected as part of this study will be linked to the identification code. Original study forms will be kept on file at the participating site. Modifications to the data stored in the original database will be documented.

Statistical methods
Input variables
Sociodemographic and clinical characteristics will be analysed using χ²-test, Fishers’ exact test or t-test to evaluate the comparability of the participants who chose to continue standardised follow-up and participants who opted for individualised follow-up at T1. Further analyses will be adjusted for significant differences in sociodemographic and clinical characteristics between both groups.
<table>
<thead>
<tr>
<th>Area of focus — feasibility</th>
<th>Assessment</th>
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<tr>
<td><strong>Primary outcome — feasibility</strong></td>
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<tr>
<td>Demand</td>
<td>Electronic patient records</td>
<td>Reach: absolute number of participants divided by the estimated number of eligible participants; number of patients who chose standardised or individualised follow-up</td>
<td>Patients</td>
<td>T2</td>
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<tr>
<td>Acceptability</td>
<td>Self-constructed questionnaire on use and added value of the decision aid; SUS</td>
<td>10 questions about the presentation, actual use and perceived added value of the decision-aid; 10 items providing an assessment of the usability of the decision-aid on a 5-point scale from strongly disagree to strongly agree</td>
<td>Patients</td>
<td>T1</td>
</tr>
<tr>
<td>Demand, acceptability, implementation</td>
<td>Adjusted MIDI-questionnaire</td>
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<td>Physicians</td>
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<tr>
<td><strong>Secondary outcomes — feasibility</strong></td>
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<tr>
<td>Acceptability</td>
<td>SDM-Q-9</td>
<td>9 items rated on a 6-point scale from completely disagree (0) to completely agree (6) from a patient perspective</td>
<td>Patients</td>
<td>T1</td>
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<tr>
<td></td>
<td>SDM-Q-doc</td>
<td>9 items rated on a 6-point scale from completely disagree (0) to completely agree (6) from a physician perspective</td>
<td>Physicians</td>
<td>T1</td>
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<td></td>
<td>DCS</td>
<td>16 items considering decisional conflict rated on a 5-point scale from strongly agree (0) to strongly disagree (4)</td>
<td>Patients</td>
<td>T1</td>
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<td></td>
<td>DRS</td>
<td>5 items considering decisional regret rated on a 5-point scale from strongly agree (0) to strongly disagree (4)</td>
<td>Patients</td>
<td>T2</td>
</tr>
<tr>
<td>Insight into effectiveness</td>
<td>CWS</td>
<td>6 items on worries after cancer treatment rated on a 4-point scale from almost never/not at all to almost always/very much</td>
<td>Patients</td>
<td>T1; T2</td>
</tr>
<tr>
<td></td>
<td>EORTC QLQ-C30</td>
<td>30 items organised in 5 functional scales (physical, role, emotional, cognitive and social), 3 symptom scales (pain, fatigue and emesis) and a global health and QoL scale rated on a scale from 0 to 100 (100 meaning perfect QoL for functional scales or heavy burden for symptom scales)</td>
<td>Patients</td>
<td>T1; T2</td>
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<tr>
<td></td>
<td>EORTC QLQ-H&amp;N35</td>
<td>7 multi-item scales (pain, swallowing, senses, speech, social eating, social contact and sexuality) and 11 single items (teeth, mouth opening, dry mouth, sticky saliva, coughing, feeling ill, use of pain killers, nutritional supplements, feeding tube, weight loss and weight gain) rated on a scale from 0 to 100</td>
<td>Patients</td>
<td>T1; T2</td>
</tr>
<tr>
<td></td>
<td>EQ-5D-5L</td>
<td>Descriptive health status: 5 dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) rated from 1 (no problems) to 5 (extreme problems). Visual health status: visual analogue scale from ‘worst health you can imagine’—‘best health you can imagine’</td>
<td>Patients</td>
<td>T1; T2</td>
</tr>
<tr>
<td>Practicality</td>
<td>Electronic patient records</td>
<td>Number of outpatient visits and diagnostic tests during the follow-up year after the choice for standardised or individualised follow-up</td>
<td>Patients</td>
<td>T2</td>
</tr>
<tr>
<td>Practicality</td>
<td>IMCQ</td>
<td>31 items to assess patient reported general medical consumption (primary and secondary care, including medicine use)</td>
<td>Patients</td>
<td>T1; T2</td>
</tr>
<tr>
<td>Practicality</td>
<td>IPCQ</td>
<td>18 items to assess patient reported productivity losses in hours (considering absenteeism, presenteeism and unpaid work)</td>
<td>Patients</td>
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</tr>
<tr>
<td>Other outcomes</td>
<td>Electronic patient records</td>
<td>In case of recurrent/second primary tumour(s): date of diagnosis, clinical and pathological characteristics, date and type of treatment</td>
<td>Patients</td>
<td>T2</td>
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<tr>
<td>Input variables</td>
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Continued
Descriptive analyses and χ² primary tumours will be compared for both groups using t-tests, date and type of treatment of all recurrent and second patients visits and diagnostic tests and their tariffs as stated by the Dutch Healthcare Authority.

Secondary study outcomes
The validated SDM-Q-9, SDM-Q-doc, DCS, DRS, CWS, QLQ-C30, QLQ-H&N35, EQ-5D-5L, iMCQ and iPCQ will be analysed and compared according to their manual. The QLQ-C30, QLQ-H&N35 and EQ-5D-5L of our entire group of participants will also be compared with a historic cohort of HNC patients, as these data are collected as part of the Dutch Head and Neck Audit (DHNA) to monitor the quality of HNC care. Cost analyses will include a difference in total costs for standardised and individualised follow-up based on the absolute number of outpatient visits and diagnostic tests and their tariffs as stated by the Dutch Healthcare Authority.

Other outcomes
Date of diagnosis, clinical and pathological characteristics, date and type of treatment of all recurrent and second primary tumours will be compared for both groups using descriptive analyses and χ²-test, Fishers’ exact-test or t-test.

Research ethics approval
The Radboud University Medical Ethics Review Committee has reviewed the study protocol (dossier 2021-13108), site-specific informed consent forms, participant education and recruitment materials and other requested documents. The committee ruled that this study does not fall under the Medical Research Involving Human Subjects Act (WMO) and approved of the study.

Protocol amendments
Important protocol amendments will be communicated to all involved medical specialists and allied health professionals through the NWHTT and their in Nijmegen-Arnhem subdivision. The amendments will be communicated to the Radboud University Medical Ethics Review Committee.

Patient and public involvement statement
In the Netherlands, HNC patients are united in the HNC patient organisation (PVHH). This study protocol was developed in collaboration with the PVHH and based on individual interviews with different HNC patients. The PVHH supports this research project and agreed to disseminate the results to their members through social media and the PVHH newsletter.

The SPIRIT 2013 statement and checklist (Standard Protocol Items: Recommendations for Interventional Trials) were followed to outline this study protocol (online supplemental appendix A).

ETHICS AND DISSEMINATION
The INFLUENCE-study is the first prospective study to evaluate the feasibility of offering HNC patients a choice about how to continue their follow-up beyond 1.5 years after treatment. This choice is assessed from patients’ and healthcare professionals’ perspective. Costs and practicability are also considered. We expect that making this choice is feasible, has a positive effect on FCR, maintains QoL, reduces medical costs and has no negative impact on the detection of cancer recurrences. In addition, we would like to present an example for optimising follow-up care in other cancer types.

The INFLUENCE-study has some limitations. It could be argued that a randomised controlled trial is the preferred method to determine the best follow-up approach. However, in view of personalised medicine and the varying needs of cancer patients, we believe that it is essential to let patients determine their follow-up programme based on their own values and preferences. In addition, well-designed preference trials are capable of providing valid results.

Finally, patients who would not choose individualised follow-up would probably not voluntarily participate in a randomised trial at the risk of being assigned to it, creating bias in the results.

Another limitation of the INFLUENCE-study is that patients are recruited from a specific region in the Netherlands, compromising geographical and probably racial and ethnic diversity within our study population. If this study is conducted on a national scale in the future,
the study population will better reflect the Dutch HNC patient population. This will make future results more generalisable.

If the choice between standardised and individualised follow-up is feasible, the next step will be to implement and investigate this choice in other head and neck oncology centres in the Netherlands. This could improve QoL, reduce medical costs and lower the burden of unnecessary routine follow-up visits on healthcare resources in the Netherlands and other countries with similar clinical practices.

Dissemination policy
Knowledge that results from the INFLUENCE-study will be shared with the PVHH, NWHHT and PWHT. Results will be presented at national and international meetings in the fields of head and neck oncology and shared decision-making, reported in peer-reviewed international journals and a PhD-thesis, and on the NWHHT website.

Contributors RPT and HAMM conceived of the study. RPT, JHAMK, RPMHG, JvGT-G and GvDB are grant holders. RPT, JHAMK, RPMHG, JvGT-G, GvDB and CvdW initiated the study design and implementation. CvdW was responsible for the original draft of this manuscript. All authors contributed to refinement of the study protocol and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. See the Methods section for further details.

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