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Implementation and effectiveness of teleneonatology for neonatal intensive care units: a protocol for a hybrid type III implementation pilot

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ABSTRACT

Background Telemedicine in neonatal care (TeleNeonatology) has the potential to improve neonatal outcomes, address capacity challenges and influence the emotional burden on parents. TeleNeonatology allows for real-time audiovisual communication between healthcare providers at different neonatal intensive care units (NICUs). Despite the high potential for multiple neonatal use-cases, TeleNeonatology is primarily being used for neonatal resuscitation and has yet to be widely implemented in Europe. Our study aims to evaluate both implementation strategies and effectiveness of TeleNeonatology in a pilot study in The Netherlands.

Methods A pre-post implementation study with hybrid type III design will be conducted from 1 January 2023 to 31 December 2024. The year 2023 will serve as a baseline period pre-implementation. From 1 January 2024, a TeleNeonatology device will be integrated within all communication between the NICU-level IV of the Erasmus MC hospital and the NICU-level II at Amphia Hospital. Outcomes of the implementation of the TeleNeo programme will be evaluated using a mixed-methods approach evaluating implementation outcomes, service outcomes and client outcomes. Feasibility, the primary implementation outcome, will be evaluated via a validated questionnaire for parents and personnel. Secondary implementation outcomes will be barriers and facilitators of implementation, based on semi-structured interviews and focus groups. A cost minimisation analysis, using decision trees, will be evaluated as service outcomes. Client outcomes will be assessed via parent-reported transfer experience questionnaires and interviews and the clinical outcomes NICU-level III transfer rate and length of stay.

Ethics and dissemination This study was reviewed by the Medical Ethical Committee of the Erasmus Medical Centre, who confirmed that the rules laid down in the Medical Research Involving Human Subjects Act do not apply (identification number: MEC-2023–0561). Results will be published in peer-reviewed journals in two separate scientific articles: the primary evaluation and the cost evaluation.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Telemedicine in neonatal care (TeleNeonatology) improves the quality of neonatal resuscitations and reduces neonatal transfers. Despite high potential for multiple use-cases, TeleNeonatology has not yet been widely implemented in Europe.

WHAT THIS STUDY HOPES TO ADD

⇒ This implementation pilot study, focusing on both implementation evaluation and clinical effectiveness, hopes to provide the information to enhance our TeleNeonatology programme and design a robust implementation strategy for the Southwest region of The Netherlands.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ By assessing feasibility, impact on clinical outcomes and costs, this study aims to facilitate the broader adoption of TeleNeonatology. This will ultimately enhance neonatal care delivery, improve the parental experience and contribute to a sustainable, value-based healthcare system.

INTRODUCTION

Telemedicine is the remote delivery of healthcare through electronic telecommunications.[1] Implementation of telemedicine in neonatal care (TeleNeonatology) facilitates real-time audiovisual communication to overcome distances between healthcare providers at different neonatal wards, for instance, between neonatologists at level III/IV neonatal intensive care units (NICUs) and paediatricians or healthcare providers and level I or II NICUs.[2 3] By providing a more comprehensive clinical picture of critically ill neonates, TeleNeonatology enhances the quality of care.[4] TeleNeonatology has been shown to improve neonatal outcomes, address capacity challenges in neonatal care and influence the emotional burden on

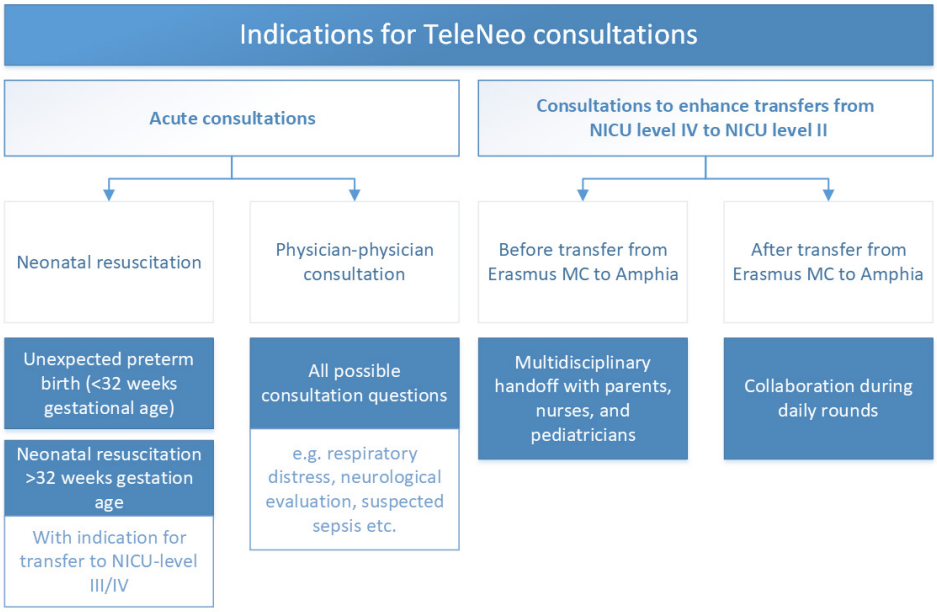

Figure 1 Indications for TeleNeonatology consultations.

parents during the hospital admissions and transfers.[3 5–15] TeleNeonatology use cases that have been evaluated to improve the neonatal hospital journey comprise neonatal resuscitation, specialist consultations and neurological evaluation before neonatal transportation and to provide expertise at lower-level NICUs.[5 6 9 12 15–19] Currently, the necessary TeleNeonatology technology has been developed, tested and evaluated in the USA. The technology is globally available, but not yet widely implemented in Europe or the Netherlands.

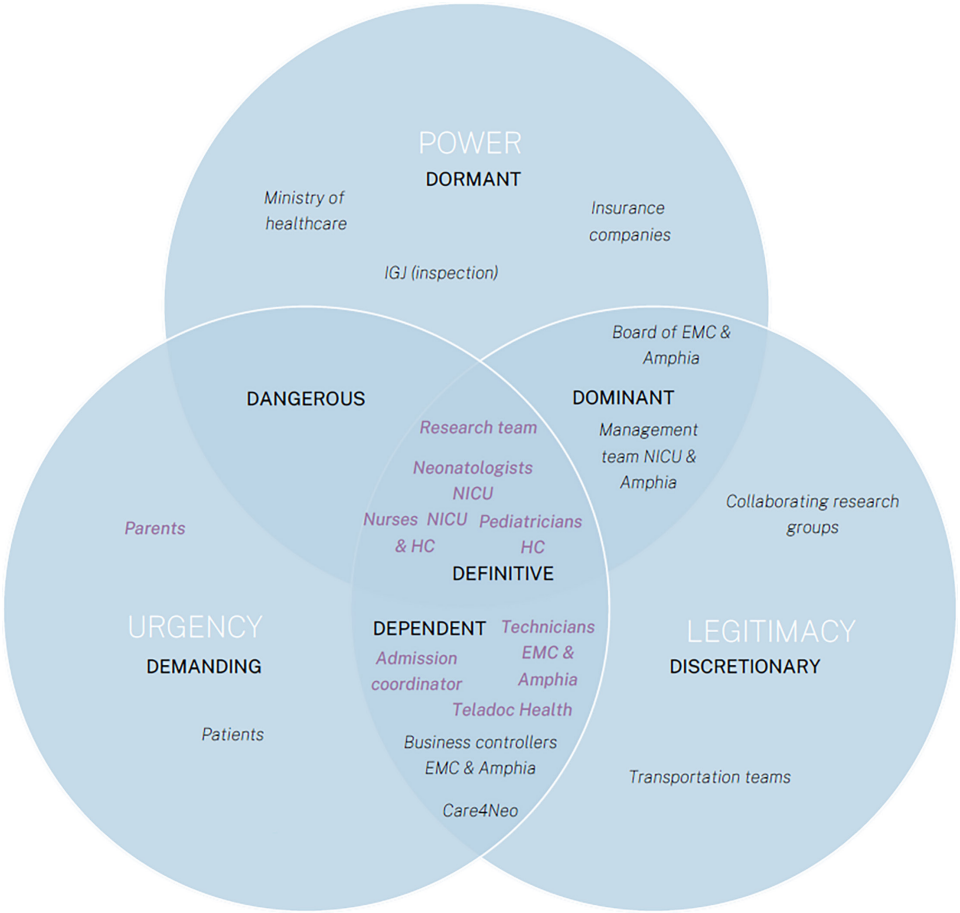

Figure 2 Stakeholder analysis according to the Salience Stakeholder Framework.

Table 1 Barriers for the implementation of TeleNeonatology

NASSS domains[32]	Barriers[12 33 34]
Condition	-
Technology	Perception of the technology being too complex Too much time for set-up Poor connectivity or audio-video quality No connection with electronic patient records in other hospitals
Value proposition	Failure to see the need or added value Unclear goals/aims of the TeleNeonatology service Generalisability of international effectiveness of TeleNeonatology is unclear
Adopters	Fear of excessive increase in workload Fear of being replaced Fear of paternalistic/judgemental tone of remote colleagues. Perceived friction among providers at different hospitals Changes to the patient/family–clinician relationship Resistance to change routine care
Organisation	Capacity changes for both NICUs Insufficient time and staff Cost barriers: billing, reimbursement, uncertainties on return on investment Liability risk Difficult stakeholder management, mainly indirectly involved parties
Wider system	Licensed tertiary care and (too) strict guidelines on the provided care per level of NICU to reach full potential Reimbursement of telemedicine consultations and increased care expertise
Adaptation over time	The intensity of care at NICU-level IV is likely to increase over time with nationwide discussions on extending NICU care to preterm born before 24 weeks of gestational age Technology is likely to improve/evolve in the coming years

NASSS, Non adoption, Abandonment, Scale-up, Spread and Sustainability; NICU, neonatal intensive care unit.

In The Netherlands, neonatal care is provided across NICUs, neonatal high care wards and medium care wards,[20] respectively corresponding to NICUs level III/IV, level II and level I as defined by the American Academy of Paediatrics.[21] Even though high quality of neonatal care is provided in the Netherlands, opportunities to improve quality of care are present. First, capacity strain in neonatal care is an urgent problem in The Netherlands, frequently resulting in transfers of pregnant women or their vulnerable neonates.[22] Second, parents from critically ill neonates experience stress, especially when their neonates are exposed to NICU admissions and transfers.[23] Third, despite high ambitions and efforts in The Netherlands, neonatal outcomes can be improved compared with other high-income countries.[24] These capacity issues and avoidable transfers, combined with the drive to improve patient and parental outcomes, underscore the need to review neonatal care and allocation guidelines. TeleNeonatology, with its potential to improve clinical outcomes and reduce transfer rates to higher-level NICUs, emerges as a promising solution to enhance neonatal care in the Netherlands.

An implementation pilot is the first step towards effectively implementing a TeleNeonatology programme.[25] Therefore, this hybrid implementation-effectiveness study has two aims:

1. To evaluate the implementation strategies used for our TeleNeonatology programme.
2. To evaluate the effectiveness of TeleNeonatology in our region in The Netherlands.

METHODS

Study design and participants

In order to facilitate a robust implementation and adoption of TeleNeonatology in the 11 hospitals in the Southwest region of The Netherlands, we will perform an extensive evaluation of this pilot implementation in two hospitals: the NICU level IV of the Erasmus MC hospital and the NICU level II at Amphia Hospital. Following the advice from implementation science[26] and design practices,[27] this study will evaluate the desirability, usability and viability of our TeleNeonatology programme by assessing implementation outcomes, service outcomes and client outcomes. Outcomes will be evaluated for the different participants: healthcare providers in both hospitals, parents and patients.

Since the evaluation of the implementation will be the primary outcome, our study follows the hybrid type III structure.[26] The implementation pilot will be conducted from 1 January 2023 to 31 December 2024. The year 2023 will serve as a baseline period for the pre-post implementation comparison. From 1 January 2024 to 31 December 2024, a movable TeleNeonatology device from Teladoc Health (Teladoc Lite with Boom Arm) will be implemented in the level II NICU at the Amphia. The TeleNeonatology will function as an obligatory add-on service to the communication between healthcare providers in the level II and level IV NICU. We have defined the following indications for use of *TeleNeo consultations*: neonatal resuscitation, physician–physician consultation, prior to and during handoff and collaboration during daily rounds

Table 2 Implementation strategies

Determinant	Objective	Method[35]	Practical Strategy	Timeline
Training of the TeleNeo team				
Skills and knowledge	Create experts in the use of the Teladoc (local champions/TeleNeo experts)	e-learning	e-learning from Teladoc	2 months prior to implementation
		Discussion	Meetings on study design, how to use TeleNeo and define use cases	6 and 3 months prior to implementation
		Imagery	Demo try-out sessions with manikins and patients	1 month prior to implementation
Knowledge	Train admission coordinators to have a coordinating role	Discussion	Meetings on study design, how to use TeleNeo and use cases	2 months prior to and during implementation
Education Amphia physician and nurses				
Knowledge	Inform physicians and nurses on the why and how of TeleNeo	Advance organisers	Standard operating procedures, summary documents	1 month prior to implementation
			Summary posters and pocket cards	
Attitude and knowledge	Increase awareness of the relevance and purpose of TeleNeo	Implementation intentions	Group presentation with TeleNeo motivation and aims, followed by interactive discussion	4 months prior to implementation
		Advance organisers elaboration, imagery	Kick off presentation with a reflection on prior input and a demo of the Teladoc	2 weeks prior to implementation
Skills	Increase self-efficacy to use the Teladoc	Imagery	Instruction video*	2 months prior to implementation
		Guided practice	Walk-in hours to try out the Teladoc	2 weeks prior to implementation
Education physicians and nurses EMC				
Knowledge	Inform physicians and nurses on the why and how of the TeleNeo study	Advanced organisers	Standard operating procedures	1 month prior to implementation
			Summary posters and documents	
Attitude and knowledge	Increase awareness of the relevance and purpose of TeleNeo	Implementation intentions, imagery	Group presentation with TeleNeo motivation and aims, followed by interactive discussion and demo of Teladoc	2 months prior to implementation
Skills	How to use Teladoc	Imagery	Instruction video*	2 months prior to implementation
Maintenance during the pilot				
Attitude and top-of-mind	Remind the target group of the TeleNeo study during the pilot and provide feedback	Reminders	Updates in newsletters of Amphia and EMC	3 months and 1 month prior to and during implementation
			Pocket cards and summary posters	1 month prior to implementation
		Feedback	2-monthly update email	During implementation

*the instruction video is available via: https://youtu.be/rJY8AbfZG-s

(figure 1). These use cases are based on expert consensus from both hospitals and literature.[2 3 11 28–30]

Context description, barriers and facilitators

Inventarisation of the stakeholders and barriers for implementation was performed by the research team. Stakeholders were assessed using the salience stakeholder model to evaluate their power and legitimacy (figure 2).[31] Directly involved stakeholders are patients and their parents, neonatologists and nurses at the level IV NICU, paediatricians and nurses at the level II NICU, the daily coordinator, the research team and the technical project manager. Barriers and facilitators were categorised using the Non-adoption, Abandonment, Scale-up, Spread and Sustainability (NASSS) framework.[32] Barriers found in literature[12 33 34] were grouped by the NASSS domains and supplemented by the research team using the NASSS-based questionnaire (table 1).[32]

Implementation strategies

The implementation strategies, their design based on the observed barriers in table 1 using an intervention

Table 3 Outcome measures, categorisation based on Proctor, et al.[38]

Outcome category		Outcome measure	Data collection/source
Implementation outcomes	Feasibility	Adjusted Telehealth Usability Questionnaire (online supplemental file 1)[36] **Primary outcome**	Questionnaire for parents: <5 days after TeleNeo consultations
			Questionnaire for healthcare providers: midway and at the end of the pilot
	Adoption	% consultations as part of eligible moments	Admission coordinators and the local research team keep track
	Appropriateness/acceptability	Healthcare providers perceived impact on patient management	TeleNeo survey after each consultation (online supplemental file 1)
		Healthcare providers perceived use cases and usefulness	Semi-structured interviews with healthcare providers (10 to 12), two focus groups with healthcare providers Amphia (one with nurses, one with paediatricians)
		Parental perceived use cases and usefulness	Semi-structured interviews with parents and Care4Neo, one focus group
Service outcomes	Timeliness	Demand patterns	Teladoc call logs
			TeleNeo survey after each consultation (online supplemental file 1)
		Integration in daily work	Monthly evaluation sessions with the research team
	Safety	Technical failures	TeleNeo survey after each consultation (online supplemental file 1)
			Teladoc call logs
		Secondary transfers (transfer >2 hours after the TeleNeo consultation decided a transfer was not needed)	Electronic Health Records/transportation administration
	Costs	Cost minimisation analysis using a decision tree model (figure 3)	Electronic Health Records, Teladoc call logs, TeleNeo survey after each consultation
Client outcomes	Clinical outcomes	Transfer ratio to level IV NICU, compared with literature and retrospective cohort	Electronic Health Records
		Length of stay at level II and IV NICU, compared with retrospective cohort	Electronic Health Records
		Illness severity on arrival of the transportation team (TRIPS-II Score) compared with retrospective cohort	Electronic Health Records/transportation administration
	Patient-Reported Outcome Measures	Parental transfer experience survey based on Ballantyne *et al*[23] and the NICU/HC Transfer Quality Scale [39], (online supplemental file 1)	Questionnaire for parents: <7 days after transfer
		Parental reported quality of care	Semi-structured interviews (4 to 6)

mapping approach,[35] will focus on the local healthcare providers' attitude towards the value of TeleNeonatology, their skills and self-efficacy regarding the technology (table 2). An instruction video will be one of these strategies. Furthermore, we will train 'TeleNeo experts' to extend the reach of the research team. During the pilot, pocket cards, summary posters and 2-monthly updates will be used as strategies to enhance the maintenance.

Outcome measures

We will use a mixed-methods approach for the implementation, service and client outcomes (table 3). The primary outcome will be the feasibility, an implementation evaluation measure, of the TeleNeonatology programme and technology.

The feasibility is influenced by acceptability and appropriateness and will be the main quantitative outcome evaluated with the adjusted Telehealth Usability Questionnaire (aTUQ, online supplemental file 1).[36] The aTUQ is a validated questionnaire with 21 questions on the usefulness, ease of use, technical aspects, reliability and satisfaction of TeleNeonatology evaluated on a five-point Likert scale.

As secondary outcomes, we will expand the list of barriers and facilitators with views from stakeholders. Furthermore, we will evaluate the service outcome measures timeliness, safety and costs, since these are relevant outcomes to determine in the scale-up and maintenance strategy. Lastly, the effectiveness of the

TeleNeonatology programme will be evaluated for client outcomes, NICU transfer rate and length of stay and parental-reported experience. These client outcomes will be compared with the retrospective cohort.

Data collection

Implementation outcomes

The previously mentioned validated quantitative questionnaire (aTUQ, online supplemental tables 3 and 4) will be collected to evaluate feasibility and filled in by parents within 7 days of a TeleNeo consultation and by healthcare providers at two time points: midway and at the end of the pilot. Moreover, semi-structured interviews with 10–20 stakeholders, one focus group with nurses and one focus group with paediatricians will be conducted guided by the NASSS domains with the purpose of evaluating appropriateness and acceptability of the implementation. Furthermore, during the pilot, monthly meetings with the research team will be used to evaluate the adoption and the implementation process using a Plan-Do-Check-Act format. Lastly, design thinking methods, including a co-creation session, will be applied to the implementation evaluations to improve feasibility and acceptability.

Service outcomes

To evaluate timeliness, call logs from Teladoc and TeleNeo consultations surveys (online supplemental tables 1 and 2) after each consultation will be used to analyse demand patterns. Also, monthly meetings with the research team will be used to analyse and improve the integration of TeleNeonatology into workflows. Safety outcomes will be evaluated in the TeleNeo consultation surveys and using data collected for healthcare purposes from the Electronic Healthcare Records. A decision tree model will be used to evaluate the costs of the TeleNeonatology programme (figure 3).

Client outcomes

Client outcomes will be collected using the Electronic Health Records from included patients and compared with a historical cohort. This historical cohort consists of all patients transferred or consulted between the Erasmus MC NICU level IV and the Amphia NICU level II between 1 January 2023 and 31 December 2023. A parental transportation experience questionnaire, developed in collaboration with the Dutch patient and parent association Care4Neo (online supplemental table 5) and semi-structured interviews, will be used to evaluate parental experience with provided care and their well-being.

Patient, parent and healthcare provider data collection will be anonymised and managed using the CASTOR EDC data collection tool.

Data analysis

Quantitative data will be analysed descriptively and for client outcomes (table 3) compared with our control group using the X^2 test for proportions and categorical variables, the independent t-test for continuous data and the Mann–Whitney U test for skewed data. For the primary outcome feasibility, a minimum score of four

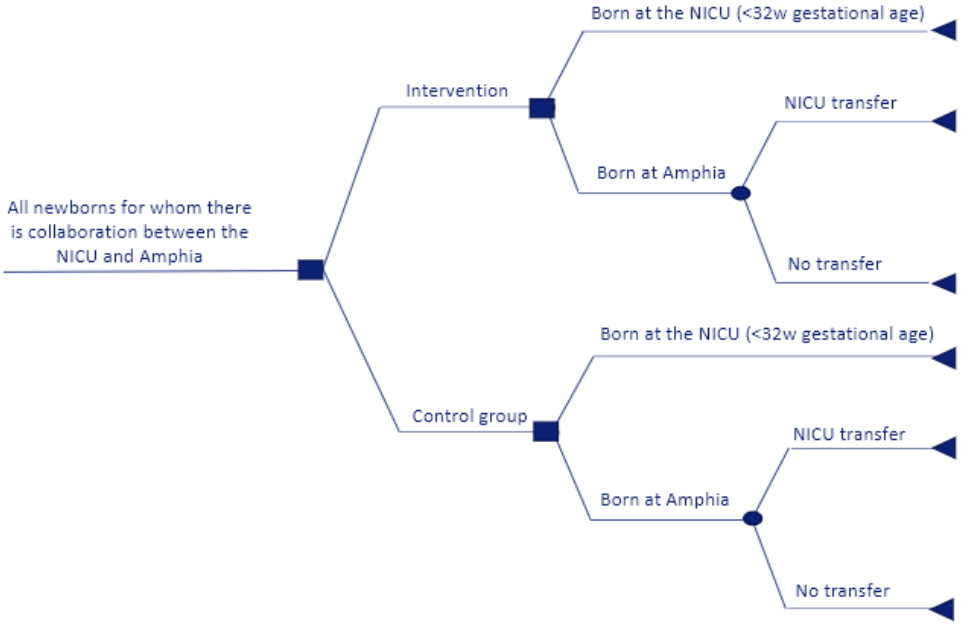

Figure 3 Decision tree for cost minimisation analysis.

out of five on the Likert-scale question '*In summary, I am satisfied with TeleNeonatology*' will be deemed sufficient. An inductive thematic analysis will be used to identify determinant themes for implementation out of the interviews.[37]

Patient and public involvement

Patient and parent advocacy association Care4Neo was involved in the design of the trial. They will also be involved in the conduct of the trial and the reporting and dissemination of the results.

ETHICS AND DISSEMINATION

This study was reviewed by the Medical Ethical Committee of the Erasmus MC with identification number: MEC-2023–0561. Informed consent will be asked for completing the questionnaires. Exception consent was applicable for safety outcomes and demand patterns. The committee confirmed that the rules laid down in the Medical Research Involving Human Subjects Act (also known as the Dutch abbreviation WMO) do not apply.

We plan to submit separate articles for open access publication to relevant journals. The primary and most of the secondary outcomes will be combined in an article on the evaluation of the implementation pilot. The cost analysis will be discussed in a separate article.

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Contributors JW, HT, RB, MK and IR were involved in the conceptualisation of the study design. JW will be the research coordinator, responsible for data curation and drafted the protocol manuscript. HP, AJ, RB, HT and IM will be 'TeleNeo experts' on both study sites. JB interviewed the research team and designed visualisations for this manuscript. SH provided advice on the methodology and feedback on the manuscript draft. MK provided advice on methodology, with a mean focus on the design projects. NL provided advice on the cost analysis. MS was responsible for technical resources and the workflow. All authors reviewed the manuscript. HT is the guarantor.

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Competing interests No, there are no competing interests.

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

Patient consent for publication Not applicable.

Ethics approval This study involves human participants, but Erasmus Medical Center Ethical Committee (reference number: MEC-2023-0561) exempted this study. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Not applicable for this protocol. Data obtained in the TeleNeo pilot are available upon reasonable request.

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