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Failed implementation of a nursing intervention to support family caregivers: An evaluation study using Normalization Process Theory

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Abstract

Aim: To evaluate the failed implementation of the Carer Support Needs Assessment Tool Intervention for family caregivers in end-of-life care, within a trial context using Normalization Process Theory (NPT).

Design: An evaluation study was conducted to learn lessons from our trial, which was not successful due to the low number of participants. The evaluation study utilized various data sources, including published data from interviews and questionnaires, and unpublished data derived from emails and conversation notes.

Methods: Data were retrospectively collected. Thematic analysis was conducted guided by the NPT framework. This framework emphasizes that successful implementation of an intervention relies on its 'normalization', consisting of four constructs: coherence, cognitive participation, collective action and reflexive monitoring.

Results: Coherence (sense making): Nurses felt the intervention could contribute to their competence in assessing family caregivers' needs, but some were unsure how it differed from usual practice.

Cognitive participation (relational work): Nurse champions played a crucial role in building a community of practice. However, sustaining this community was challenging due to staff turnover and shortages.

Collective action (work done to enable the intervention): Nurses felt the Carer Support Needs Assessment Tool training enabled them to improve their support of family caregivers. However, contextual factors complicated implementation, such as being used to a patient rather than a family-focused approach and a high workload.

Reflexive monitoring (appraisal of the intervention): Positive experiences of the nurses with the intervention motivated them to implement it. However, the research context made nurses hesitant to recruit family caregivers because of the potential burden of participation.

Conclusion: Although the intervention demonstrated potential to assist nurses in providing tailored support to family caregivers, its integration into daily practice was

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not optimal. Contextual factors, such as a patient-focused approach to care and the research context, hampered normalization of the intervention.

Implications for the Profession and/or Patient Care: Assessing and considering contextual factors that may influence implementation of a complex care intervention is needed. The NPT provided a valuable framework for evaluating the implementation process in our study.

Impact: *What problem did the study address?* This evaluation study analysed the factors that promoted or hindered the implementation of a nursing intervention to support family caregivers in end-of-life care.

What were the main findings? Both the intervention and the intervention training have potential and value for nurses in providing tailored support to family caregivers. However, the implementation faced challenges due to organizational factors and the research context, including recruitment.

Where and on whom will the research have an impact? This insight is valuable for all stakeholders involved in implementing complex nursing interventions, including researchers, nurses and funders.

Reporting Method: This study has adhered to the relevant EQUATOR guidelines: Standards for Reporting Qualitative Research (SRQR).

Patient or Public Contribution: There was no patient or public involved.

Trial Registration: The trial was prospectively registered on the Dutch Trial Register (NL7702).

KEYWORDS

end of life, evaluation research, family care, nursing, nursing assessment, randomized controlled trials, research implementation, support

1 | INTRODUCTION

Most people approaching the end of life want to be cared for and die at home, in the presence of their closest relatives (Vidal et al., 2022). Family caregivers play a crucial role in end-of-life care at home. They not only spend time with their loved ones providing emotional support, personal care and medical treatments but also perform household tasks and coordination of care (Higginson et al., 2020; Rowland et al., 2017). These tasks and responsibilities affect work and leisure activities, social relationships, friendships, intimacy, freedom and emotional balance (Veloso and Tripodoro, 2016). The caring experience can create physical, psychological, social, spiritual and financial burdens and distress (Choi & Seo, 2019). Family caregivers commonly express needs concerning emotional support, disease-specific information, practical support, self-care and role responsibilities (Marco et al., 2022). However, their needs often remain unmet (Hashemi et al., 2018; Ullrich et al., 2021).

Effective nursing interventions to support family caregivers are needed (Murray et al., 2010). In recent years, there has been an increasing emphasis within the nursing profession on the evaluation of interventions in trials (Hudson & Payne, 2011) and the implementation of evidence-based interventions (Lambregts et al., 2016). A growing body of literature sheds light on a diversity of (nursing) interventions for family caregivers and their effects (Becqué et al., 2023). A review has shown that nursing interventions to support family

caregivers in end-of-life care can have a beneficial effect on the preparedness, competence, rewards and burden of family caregivers (Becqué et al., 2019).

However, intervention research in the healthcare field is complex. Interventions are situated within complicated care settings, where there are multiple interacting components, with involvement of different health professionals, vulnerable patients and their family caregivers (Greenhalgh & Papoutsis, 2018). In the context of end-of-life care, research complexity increases, due to seriously ill patients, family caregivers who are burdened, dropout due to death, gate-keeping and research ethics (Hui et al., 2013; Murray et al., 2010).

The Carer Support Needs Assessment Tool Intervention (CSNAT-I) is an evidence-based tool to identify the support needs of family caregivers in palliative home care. The tool consists of 15 questions identifying domains in which family caregivers may need more support, such as 'understanding patient's illness' and 'having time for yourself'. These domains fall into two distinct groupings: those that enable family caregivers to care (co-workers) and those that enable more direct support for themselves (co-client). (Ewing et al., 2013; Grande et al., 2017). The CSNAT-I has been widely used and investigated in different countries. Two trials investigated the impact of the CSNAT-I on family caregivers' well-being. A UK trial (Grande et al., 2017) found reduced early grief and improved psychological and physical health among family caregivers, while an Australian trial found reduced strain (Aoun et al., 2015). Given the

challenges that nurses face in systematically identifying the needs of family caregivers and establishing a dialogue (Becqué, Rietjens, et al., 2021), the CSNAT-I has the potential to positively impact the care of family caregivers in the Netherlands.

2 | BACKGROUND

To evaluate the effect of the CSNAT-I on family caregivers' outcomes, we conducted a trial (Becqué et al., 2020). The funding authority that encouraged the use of an experimental design granted a subsidy for our project for 3 years. The Medical Research Ethics Committee of Erasmus MC in Rotterdam reviewed our study protocol according to the rules laid down in the Medical Research Involving Human Subjects Act and approved the study [ref. NL68453.078.18].

The study involved seven homecare organizations, which were randomized by a computer into either the intervention group or the control group: the intervention group included four organizations, and the control group three. Within the organizations, some nurses were assigned to actively participate in the study. Participating nurses from both the intervention and control groups were asked to invite family caregivers of patients with a life expectancy of up to 6 months to participate in the study. The researcher informed the family caregivers about the procedures, asked them to sign informed consent to participate and distributed the questionnaires.

After the family caregiver completed the initial questionnaire (Time 1), a nurse from the intervention group initiated the CSNAT-I. This intervention involved at least two home visits from nurses to family caregivers. The CSNAT-I is integrated into a person-centred process, led by the family caregiver and facilitated by the nurse. The CSNAT-I was introduced during the first visit, where the nurse provided the family caregiver with the tool, comprising 15 questions about support needs. The family caregiver then identified domains in which they need more support. The tool was either self-completed by the family caregiver or completed jointly with the

nurse. Subsequently, a conversation took place to determine the support needs, and the nurse discussed priorities with the family caregiver. This dialogue resulted in a shared action plan, encompassing agreed-upon actions or solutions, which may or may not be provided by the nurse. The participation of the nurses in the trial and CSNAT-I is shown in Table 1.

Therefore, nurses in the intervention group ($n=14$) were trained in the use of the CSNAT-I, including clinical reasoning on family caregivers' needs. The training programme consisted of an e-learning module, two plenary group sessions and two intervention sessions, totalling 23h. Recognizing the intervention could impact team members who were not trained as well, the remaining team members ($n=41$) also received the eLearning on the roles and needs of family caregivers (Pasma et al., 2020). This ensured they were also integrated into the new approach. Organizations in the control group also assigned nurses to actively contribute to the study. They received no additional training and provided 'care as usual', including the usual meeting with the family caregiver during the patient's home visit. In these meetings, the family caregiver's needs were discussed informally, and support was provided in the usual manner. More details about the study can be found in the study protocol (Becqué et al., 2020) and in Table 2.

Our aim was to include a total of 184 family caregivers. In June 2019, we recruited our first participant. After 7 months of numerous but ineffective efforts to improve recruitment, 17 family caregivers had been recruited, of whom only 12 family caregivers participated in the study out of the required 70. Five participants dropped out before completing the first questionnaire (T1) due to either the death of the patient or caregiver burden. Table 3 presents the measures implemented to enhance recruitment, including study site visits and reminders by mail. Additionally, Figure 1 illustrates the number of family caregivers included each month compared to the expected number of participants, along with the measures put in place over time.

Describing the participants ($n=12$), nine of the participating family caregivers were the spouses of the patients, mostly dealing with advanced cancer. The mean age of the family caregivers ($n=12$) was

TABLE 1 Nurses' participation in research and CSNAT intervention.

Participation in research (nurses from the intervention and the control group)	Participation in CSNAT intervention (nurses from the intervention group)
Assessing the family caregiver for inclusion criteria	First home visit: Introducing the CSNAT intervention to the family caregiver and providing instruction for completing the CSNAT tool
Providing a brief introduction about the research and asking if the family caregiver is interested in participating	Second home visit: Exploring the family caregiver's needs and discussing what the family caregiver found helpful in meeting those needs
Asking permission for the researcher to contact the family caregiver	Second home visit: Recording the family caregiver's needs and developing actions or solutions to meet those needs in a shared action plan
Leaving contact information for the researcher	Follow-up visits: Implementing the action plan, where the nurse can provide support, and following up on outcomes

Abbreviation: CSNAT, Carer Support Needs Assessment Tool.

TABLE 2 Summary of trial characteristics.

Title	The effectiveness of a nurse-led intervention to support family caregivers in end-of-life care: a cluster randomized controlled trial
Aim	To evaluate the effects of a structured nurse-led supportive intervention on family caregivers in end-of-life care at home and to evaluate the feasibility of this intervention
Design	Cluster randomized controlled trial
Setting	Seven home care services in the southwest region of the Netherlands were randomly assigned to the intervention group or the control group
Study population	Family caregivers of terminally ill patients (e.g. patients with advanced cancer or advanced organ failure) receiving home care Inclusion criteria: <ul style="list-style-type: none">• Caring for patients with a life expectancy of at least 2 weeks up to 6 months• 18 Years or older, able to provide written informed consent and able to complete a Dutch questionnaire
Intervention	<ul style="list-style-type: none">• Intervention group: Nurses systematically assess the supportive needs of family caregivers, using the CSNAT-I• Control group: Nurses provide care as usual
Outcomes	<ul style="list-style-type: none">• Primary outcome: Burden of family caregivers, measured using the Self-Rated Burden Scale (SRB)• Secondary outcomes: Caregiving reactions, measured using the Caregiver Reaction Assessment (CRA); Preparedness, measured using the Preparedness for Caregiving Scale (PCS); and Acute admissions, retrieved from patients' healthcare records
Recruitment	Nurses recruited family caregivers. The researcher informed the family caregivers about study purpose and intervention, asked for informed consent and sent the questionnaires
Data collection	Questionnaires (SRB, CRA and PCS) at four time points: <ul style="list-style-type: none">• Baseline (Time 1)• One month after baseline (Time 2)• One month after T1 (Time 3)• Four to six weeks following the patient's death (Time 4)
Statistical analyses	<ul style="list-style-type: none">• Descriptive statistics to describe the characteristics of family caregivers (e.g. age and relationship with the patient)• Multilevel/multivariate analyses to examine outcomes in the intervention and control group on Time 2• Repeated measures analysis of variance to assess the development of outcomes over time• Sample size calculation: total 184 family caregivers

Abbreviation: CSNAT, Carer Support Needs Assessment Tool.

73 years (range 63–84); with nine being female. At baseline, family caregivers reported spending an average of 68 h per week on caregiving and experiencing an average burden of 67 on the Self-Rated Burden Scale (ranging from 0 to 100) (van Exel et al., 2004). In the week before the death of the patient, this burden averaged 81 ($n = 6$).

The trial came to an early end at the beginning of the COVID-19 pandemic (1 April 2020). The included participants continued to receive care as initiated and to the extent possible given the COVID-19 circumstances.

We wanted to understand what happened during the implementation of the CSNAT-I during our trial and identify the lessons to be learned. Therefore, we conducted this evaluation study.

3 | STUDY

3.1 | Aim

The aim is to evaluate the implementation of CSNAT-I, a supportive intervention for family caregivers in end-of-life care, within a trial context using Normalization Process Theory (NPT).

4 | METHODS

4.1 | Design

A evaluation study was conducted using various data sources.

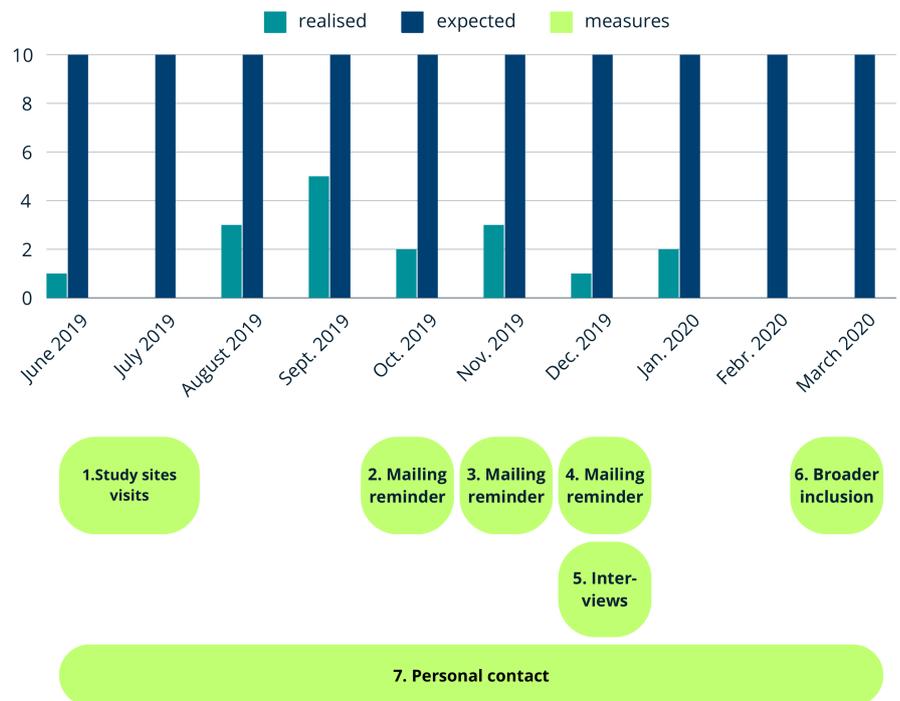
4.2 | Data collection

Originally, our data collection was not intended for this evaluation study, as our primary goal was to conduct a trial. We retrospectively selected data sources to evaluate the implementation process of the CSNAT-I during the trial study, spanning from preparation to implementation (October 2016 to March 2020). The data collection methods included the following: (i) published data, such as information from interviews and questionnaires; and (ii) unpublished data, such as data from interviews, emails, (conversation) notes and previous research. We developed a table to categorize all data used in our evaluation study, utilizing the four main constructs of the NPT (coherence, cognitive participation, collective action and reflexive monitoring) (Table 4).

TABLE 3 Measures to increase recruitment.

Measures prior to the start of the recruitment	
Visits to study sites	We provided information about the trial to managers and nurses and discussed potentially eligible study participants
Ensuring support from the site's management	We had a signed collaboration agreement with the management of the participating organizations
Training and intervision for the nurses	We provided training sessions for nurses focused on intervention skills and recruitment information
Measures during recruitment (June 2019 until April 2020)	
1. Visits to study sites (June–July 2019)	The researcher visited study sites to inform them about the inclusion and recruitment procedures using pocket flyers and flow charts
2. Mailing reminder (Oct. 2019)	We sent a reminder and asked nurses about factors affecting their inclusion and recruitment
3. Mailing reminder and information (Nov. 2019)	We sent a newsletter to celebrate 'the 10th enrolment' and provide tips and tricks to recruit study participants
4. Mailing reminder (Dec. 2019)	We sent a Christmas greeting with a reminder
5. In-depth interviews (Dec. 2019)	The researcher conducted two in-depth interviews on nurses' experiences with inclusion and recruitment
6. Broadening of inclusion criteria (March 2020)	We broadened the inclusion criteria to expand the study population to family caregivers of patients with dementia
7. Personal contact (June 2019 until April 2020)	The researcher was available 5 days a week via phone or email for nurses who had questions or needed support regarding the study

FIGURE 1 Numbers realized versus expected included family caregivers by month and measures to improve recruitment.



4.3 | Data analysis

4.3.1 | Theoretical framework

We conducted a qualitative, thematic analysis using a framework approach.

The NPT with its four constructs (May et al., 2015) provided the thematic framework for retrospectively evaluating the implementation

process of the CSNAT-I within the trial context. Normalization has been defined as the work people do when they engage in new or modified ways of thinking, acting and organizing work, which then becomes embedded in everyday practice and routines (May and Finch (2009)). To understand the process of normalization of a complex intervention, such as the CSNAT-I, there should be a focus on the dynamic processes of implementation. In this context, there are four mechanisms or constructs that can promote or inhibit normalization:

TABLE 4 Data sources.

NPT constructs →				
Information sources ↓	Coherence (sense-making work)	Cognitive participation (relational work)	Collective action (operational work)	Reflective monitoring (appraisal work)
Published data sources from our research project				
Study protocol (Becqué et al., 2020)	X	X	X	
Interview data about nursing support of family caregivers in current practice, <i>n</i> = 14 nurses (Becqué, Rietjens, et al., 2021)	X			
Data from nursing files about providing and reporting nursing support, <i>n</i> = 59 files (van Driel et al., 2021)	X		X	
Data from online questionnaire about evaluation CSNAT-I training with pre- and post-measurement. Pre-test <i>n</i> = 41 HCP, post-intervention, <i>n</i> = 25 HCP (Pasman et al., 2020)	X			X
Interview data about experiences of family caregivers with end-of-life care practices during COVID-19 pandemic, <i>n</i> = 25 family caregivers (Becqué, van der Geugten, et al., 2021)			X	
Unpublished data sources related to CSNAT-I				
Material CSNAT-I training for nurses, including CSNAT (tool)		X	X	
Interview data about nurses' experiences with the CSNAT-I, <i>n</i> = 2 nurses				X
Interview data about the usefulness of the CSNAT-I in practice, <i>n</i> = 4 family caregivers			X	X
Mail response and conversation notes with nurses and family caregivers about experiences with the CSNAT-I				X
Data from (telephone) interviews about experiences with the CSNAT-I, <i>n</i> = 3 nurses		X	X	X
Quantitative data on burden of family caregivers, obtained through the questionnaires, <i>n</i> = 14 family caregivers			X	X
Unpublished data sources related to research context				
Grant application for the intervention study	X	X		
List of nurses, from different home care organisations, who participated in the study (including dropouts)		X		
Instructional materials to support nurses in the inclusion process: pocketflyer, newsletter and flowchart			X	
Mailing conversation about inclusion process, <i>n</i> = 7 nurses		X	X	X

Abbreviations: CSNAT-I, Carer Support Needs Assessment Tool Intervention; HCP, healthcare professional; NPT, Normalization Process Theory.

1. 'Coherence': refers to the extent to which individuals or groups involved in the intervention can understand and make sense of it. This construct is related to the perceived meaningfulness, achievability and value of the intervention.
2. 'Cognitive participation': refers to the relational work undertaken by individuals who apply the new intervention to establish and maintain a community of practice around this intervention. This construct is related to the establishment of social relations, sharing knowledge and experience and creating a sense of ownership among the individuals applying the innovative intervention.
3. 'Collective action': refers to the operational work that individuals do to enact a set of practices as part of a new, complex intervention. This construct is related to the active engagement of individuals in implementing the intervention, including planning, executing and adapting the intervention to their specific context.
4. 'Reflexive monitoring': refers to the appraisal work that individuals do to assess and understand how a new set of practices affects them and others around them. This construct is related to the continuous reflection on and evaluation of the intervention's impact on individuals, groups and the broader system (May et al., 2015).

These four NPT constructs are not linear over time, but dynamically related to each other and the wider context, including the trial context, social norms and group processes (Murray et al., 2010).

4.3.2 | Thematic analysis

In conducting the thematic analysis, all data sources were carefully read to become familiar with the data. Subsequently, one researcher (YNB) coded the data deductively using the NPT constructs along with operationalization questions (Finch et al., 2015) (Table 5). The findings for each construct were ordered and mapped using Excel. Another researcher (EW) checked how the findings were interpreted and classified under the constructs and checked the completeness of the data extraction. Differences in interpretation were discussed to reach consensus. Then, the two researchers (YNB and EW) discussed patterns in the data to better understand the implementation process of the intervention. The patterns and final themes found (Table 5) were discussed with the whole research group.

4.4 | Ethical considerations

The trial that is the subject of this evaluation study was approved by the Medical Ethics Committee Erasmus MC of Rotterdam, The Netherlands (MEC-2018-1737), on 19 April 2019. The trial was also registered at the Dutch Trial Register (NL7702).

5 | FINDINGS

5.1 | Coherence

Coherence is the meaning and sense-making work that individuals do individually and collectively when they are faced with a new intervention (May et al., 2015).

In our study, the coherence or sense-making regarding CSNAT-I among nurses was insufficient.

5.1.1 | Distinction between usual and new practice

At the start of the study, CSNAT-I was a new intervention in the Netherlands (Becqué et al., 2020). In line with this, 68% of the nurses ($n=28$) indicated they did not know instruments or tools to assess the burden or support needs of family caregivers in end-of-life care (Pasma et al., 2020). On the other hand, when some nurses were introduced to the CSNAT-I, they indicated they already assessed family caregivers' needs and provided them with support. However, further discussion established that existing approaches were informal, mostly based on their experience and intuition (Becqué, Rietjens, et al., 2021).

5.1.2 | Nurses approach to family caregivers

The CSNAT approach, in which the family caregiver is seen both as co-worker and co-client, was not always consistent with nurses' existing

TABLE 5 Analytical framework and final themes.

Analytical framework: NPT constructs with operationalization questions	Final themes
Coherence <ul style="list-style-type: none"> - Is the intervention (CSNAT-I) easy to describe? - Is it clearly distinct from other interventions? How does the intervention differ from usual ways of working? - Does it have a clear purpose for all participants? - Do participants have a shared sense of the purpose of the intervention? - What is the potential value of the intervention for the work? 	<ul style="list-style-type: none"> - Distinction between usual and new practice - Nurses approach to family caregivers - Nursing competence
Cognitive participation <ul style="list-style-type: none"> - Are there key people who drive the intervention forward and get others involved? - Do they believe that participating in the intervention is a legitimate part of their nursing role? - Will they be prepared to invest time, energy and work in it? 	<ul style="list-style-type: none"> - Supporting family caregivers as nursing task - Difficult to build and sustain a community
Collective action <ul style="list-style-type: none"> - Does the intervention easily integrate into existing work? - How does the intervention affect the work of the user group/nurses? Does it promote or impede their work? - What effect does it have on working relationships, especially nurse-family caregiver? (Does it disrupt working relationships?) - Do nurses have confidence in other people's ability to use the intervention? - Do nurses require extensive training before they can use it? - Are there sufficient resources available to support the intervention? - Does it fit with the overall goals and activity of the organization? - Does management adequately support the intervention? 	<ul style="list-style-type: none"> - Extensive training - Organizational and social context
Reflexive monitoring <ul style="list-style-type: none"> - How do nurses perceive the intervention once it has been in use for a while? - Is it likely to be perceived as advantageous for nurses and family caregivers? - Can feedback on the intervention be used to improve the intervention in the future? 	<ul style="list-style-type: none"> - Success stories and positive experiences - Complex research context

Abbreviations: CSNAT-I, Carer Support Needs Assessment Tool Intervention; NPT, Normalization Process Theory.

approach to family caregivers. Nurses mentioned that the CSNAT is essentially a simple tool, but the CSNAT approach emphasizing the dual role of family caregivers was not obvious to nurses. Interviews showed that some nurses actually have a more 'instrumental' approach to family caregivers, in which they emphasize their co-worker role but not their co-client role (Becqué, Rietjens, et al., 2021).

The client is of course the most important person, everything revolves around the client's wish, but the family caregiver is continuously with the client. I give a lot of advice on how to deal with certain things they encounter, for example, pain relief.

(Interview nurse)

5.1.3 | Nursing competence

The CSNAT-I could contribute to nurses' ability to systematically assess family caregivers' needs and make a shared care plan to support them. The results of the pre-intervention questionnaire showed that nurses rated their support competencies as moderate. They felt moderately able to identify family caregivers' support needs (mean 6.4 on a 10-point scale) and to establish a support plan (mean 6.2 on a 10-point scale) (Table 6). Mostly novice nurses indicated a tool to assess the needs of family caregivers could be of added value.

What's important for those relatives to discuss? I think we're doing it intuitively, but maybe there are standard issues that are not mentioned or discussed.

(Interview nurse)

I think it would be nice to have tools provided that will make the burden of family caregivers even more transparent.

(Interview nurse)

5.2 | Cognitive participation

Cognitive participation is the relational work that individuals do to build and sustain a community of practice around a new technology

TABLE 6 The extent to which nurses (N=41) see family caregiver support as their task and the estimation of their own capacities with regard to supporting family caregivers.

Scores between 1 and 10 (with higher scores being better)	N = 41	
	Mean	Range
How well do you think you are able to identify what kind of support needs family caregivers have?	6.4	2-9
How well do you think you are able to draw up a plan together with the family caregiver for their support needs?	6.2	2-8
To what extent do you believe it is your task to support family caregivers in the care of their loved ones?	8.5	3-10
To what extent do you believe it is your task to support family caregivers in their own support needs (such as respite care)?	8.1	3-10

Source: Pasman et al. (2020).

or complex intervention (May et al., 2015). We found that there was a widespread recognition of the importance of supporting family caregivers, which fostered engagement. However, the process of building and sustaining a community of practice faced difficulties due to organizational challenges.

5.2.1 | Supporting family caregivers as nursing task

From different perspectives (management/staff, nurses and education), supporting family caregivers was recognized as important and seen as a nursing task.

Several home care organizations indicated their willingness to participate in our study and signed a collaboration agreement. Nursing staff broadly agreed that supporting family caregivers was in line with their care policy, representing a positive shift in care for family caregivers.

We have discussed the project with the home care nurses, and it seems like a valuable and instructive project to participate in.

(Email home care manager)

The CSNAT-I fits well with the nursing work domain. In the pre-intervention questionnaire, home care nurses (n=41) indicated that they believe that it is their task to support family caregivers in the care they provide to their loved one (mean 8.5 on a 10-point scale) and in their own needs, such as through organizing respite care (mean 8.1 on a 10-point scale) (Pasman et al., 2020) (Table 6).

5.2.2 | Difficult to build and sustain a community

Having a champion was an important factor in implementing and driving the intervention forward. We attempted to find individuals within the participating organizations and teams, such as managers and specialized palliative care nurses, who could facilitate the implementation and drive the intervention forward. Some organizations formally appointed a champion, to promote and encourage the team members to use CSNAT-I and to liaise with the researcher. In other organizations, it was not clear who the champion was, with the

palliative nurse in the team not taking up the champion role on their own initiative, as expected.

The researcher experienced short lines of communication with champions and also noticed a feeling of responsibility among the champions to drive the intervention forward. If there was no formal champion in a nursing team, communication was less direct and the researcher had less insight into how implementation was progressing.

Our data sources provide little insight into the extent to which the intervention is adopted among team members who were not fully trained but are still involved. A nurse said that she felt reluctant to introduce the CSNAT-I to her team members:

Do I have to read that [CSNAT-I information] too? You already feel burdened to come up with something new.

(Interview nurse)

In addition, managers and nurses mentioned it was difficult for all teams to maintain continuity in their team due to rapid staff turnover and staff shortages due to staff leaving the job or illness. As a result, the implementation of the intervention was temporarily halted, failed or new nurses had to be introduced to how to work with the intervention. For example, a home care manager sent the following email:

I hate to report but we are currently unable to start [implementing the intervention] for the following reasons: We are in the middle of a reorganisation within the home care organisation, with really all the consequences this has; Shortage in the labour market; Too high sick leave. Sorry but I can't control this.

(Email home care manager)

5.3 | Collective action

Collective action represents the operational work that individuals do to enact a set of practices, whether these represent a new, complex healthcare intervention (May et al., 2015). The organizational and social context at the time of the study included several challenges.

5.3.1 | Extensive training

Nurses were trained to use the CSNAT-I through a training programme consisting of an e-learning, two plenary group sessions and two intervision sessions (Becqué et al., 2020). Most nurses (11/13, 85%) felt the training enabled them to provide more 'tailored' support to family caregivers of patients in the last phase of life. The training also provided the majority of nurses with new knowledge or insights in the following areas: conversation skills with a family caregiver (10/13=77%), identifying needs of family caregivers

(9/13=69%) and providing support to family caregivers during the last phase of life in general (8/13=62%) (Pasman et al., 2020).

Especially about informal care support options, this training really provides eye openers!

(Questionnaire evaluation training, nurse)

The intervention was embedded in a research trial. Nurses were also instructed on how to invite family caregivers to participate in the study and what criteria they had to meet. This aspect was not covered during training but addressed during a separate instructional moment, often during a team meeting, at the beginning of the recruitment period. The researcher had created a pocket flyer, containing the criteria and a literal text that could help nurses to recruit family caregivers (Becqué et al., 2020).

5.3.2 | Organizational and social context

We found that several factors in the organizational and social context influenced nurses' ability to meet the needs of family caregivers and support them, as shown in Table 7.

Firstly, the tasks and roles of nurses in the participating teams differed, making it a non-homogeneous group. This raises the question of whether the intervention was appropriate to all nurses' roles and tasks, and if the right nurses were trained. Secondly, nurses stated the healthcare system is mainly patient centred, and registration systems do not include a separate assessment or care plan for family caregivers (Becqué, Rietjens, et al., 2021).

I think there's still benefit to be achieved in mentioning the family caregivers separately in the care plan. To consciously take the time for them.

(Interview nurse)

Our file study supported this finding, showing that needs and support interventions for family caregivers were barely reported in the nursing files (van Driel et al., 2021).

Thirdly, some nurses experienced workload pressures and time constraints, making them feel they had insufficient time to support family caregivers (Becqué, Rietjens, et al., 2021). However, nurses received support from the management to participate in the research and use the CSNAT-I.

TABLE 7 Organizational and social factors influencing nursing support.

Organizational factors	Societal factors
<ul style="list-style-type: none"> • Organization of care • Late referrals • Registration systems 	<ul style="list-style-type: none"> • Societal and policy developments • Late referrals • Pandemic

Note: Modified table: Becqué, Rietjens, et al. (2021).

Another barrier to supporting family caregivers is a 'self-care approach' to care. During the interviews, nurses indicated some nurses and family caregivers advocate a 'self-care' approach, in which family caregivers participate in the patient's self-care for as long as possible before seeking professional care (Becqué, Rietjens, et al., 2021).

Family caregivers first want to do it [caring for the patient] all themselves and only at the end can they hand over the care.

(Questionnaire evaluation training, nurse)

This approach can lead to late referrals for nursing support for patients and family caregivers. Nurses explained when faced with late referrals, their primary focus is on managing the 'crisis' situation, leaving little room for providing adequate support to family caregivers (Becqué, Rietjens, et al., 2021).

Lastly, the COVID-19 pandemic in 2020 made it impossible to continue the study because the focus of home care at that time was on controlling the virus and less on supporting family caregivers (Becqué, van der Geugten, et al., 2021).

5.4 | Reflexive monitoring

Reflexive monitoring refers to the appraisal work that individuals do to assess and understand the ways that a new set of practices affects them and others around them (May et al., 2015). Nurses in our study recognized the value of the CSNAT-I through their own positive experiences, which led to an increased awareness of the family caregivers' position and improved communication. However, the research context posed challenges for nurses.

5.4.1 | Success stories and positive experiences

After the training, nurses could practise the intervention under supervision, and then the CSNAT-I was used for 9 months during the study. Positive experiences with the CSNAT-I motivated the nurses to implement it.

Participants noted afterwards they did not realize beforehand they were lacking knowledge and skills (Pasman et al., 2020). Some nurses reported the value of the CSNAT-I afterwards when they had applied it in practice and had a success story or positive experience. One nurse shared about his positive experience:

I did not expect this positive experience with the CSNAT either because I think of myself as a competent nurse, knowing, able and doing it all, but of course, that is not true at all. You also need your tools. Surely the CSNAT brought something extra. I found that remarkable. I have used tools before, like a screening for frail elderly or something, a huge questionnaire, and

what comes out is relatively not as much as with this simple tool as I have experienced so far.

(Interview nurse)

Nurses recognized the value of using the CSNAT-I for both their own care and for the family caregiver. Some nurses indicated they were more aware of and acknowledged the family caregiver's dual position. A nurse reported:

Seeing family caregivers as clients, as part of the client system and naming them explicitly in care plan and assessment.

(Questionnaire evaluation training, nurse)

In addition, the CSNAT-I helped nurses to have more open conversations with the family caregiver. Nurses reported conversations often took place only with the family caregiver, apart from the patient. The CSNAT-I supported them in asking more in-depth questions about the needs of the family caregiver. Ultimately, using the CSNAT-I provided a broader picture of the patient-family caregiver situation, and family caregivers were more fully seen.

Once your eyes are opened by the CSNAT, it goes on effortlessly. It is not that you did not see the family caregiver, but when you have such a list [CSNAT tool] in your mind, you really see a family caregiver, you become more aware of it. It is not just "how are you?" but specifically filling in the questions of what do you need.

(interview home care nurse)

You ask deeper questions, which means you also come across other things than the usual ones.

(Interview nurse)

Nurses were also clear on the benefits for family caregivers. According to the nurses, the family caregivers felt more 'heard and seen', and the CSNAT-I helped them express their tasks and needs.

Nurses indicated that the CSNAT-I worked positively; there were no indications that the intervention did not work.

5.4.2 | Complex research context

The use of the CSNAT-I was embedded in a research context in which nurses had to recruit family caregivers. This was found to be a limiting factor for nurses to use the intervention.

Some nurses found it difficult to recruit family caregivers for the trial because they were worried about overburdening the family caregivers with additional research tasks. Additionally, nurses mentioned struggling to initiate conversations with family caregivers about the study, including using words like 'palliative phase' and 'death', because some family caregivers were not ready to talk about this topic, according to the nurses.

Some people you do not approach [for the study] because they are still so focused on life.

(Interview nurse)

Often we can see it is not going well [with the patient] but the family does not want to see it yet and then it is difficult to start a conversation about this study.

(Email nurse)

The nurses explained they made their own judgements on whether or not to enrol a family caregiver in the study. This judgement was based on, for example, whether a family caregiver was already overburdened, whether a family caregiver was receptive to talking about the situation or on nurses' intuition.

Actually you know the people, that may sound conceited, you just know 'this person I should not ask' [for participating in the study]. You just feel it very quickly. That might not be a good thing either.

(Interview nurse)

I do not want to burden them [family caregivers].

(Interview nurse)

Conversely, nurses reported that all approached family caregivers agreed to participate in the trial; none declined, according to their accounts. Some participants reported positively about being involved in the study, with one family caregiver stating during a phone conversation with the researcher:

I appreciate the attention given to informal caregivers, so I am happy to participate in the research.

(Family caregiver)

One inclusion criterion was that patients of family caregivers had a life expectancy of less than 6 months. This criterion was evaluated using the surprise question: 'Would I be surprised if this person would die within 6 months?'. The nurses were not used to the surprise question. They faced challenges in assessing life expectancy due to the unpredictable nature of the illness process or the reluctance of general practitioners to provide explicit estimates of life expectancy.

It is quite difficult that a life expectancy of six months maximum is requested. For some clients it is difficult to assess, and then suddenly they are terminal and again you are too late.

(Email nurse)

Furthermore, prior to the study, all home care teams had estimated the number of patients with a short life expectancy they typically cared for. However, the actual number of eligible family caregivers turned out to be significantly lower than expected

(Figure 1). Nurses frequently reported that they had few patients in the terminal stage of illness in their care or even experiencing patient stops. They also indicated late referrals of family caregivers played a role.

We often get late patients and their family caregivers in care. By late I mean 1–2 weeks before death. In such a situation, you try to get the situation on track. This is not a good time to start talking about the study.

(Note telephone conversation nurse)

Lastly, the family caregivers and their loved ones were found to be very vulnerable. A significant number of family caregivers ($n=5$) had already dropped out before the baseline measurement due to death of the patient. One family caregiver expressed that she experienced too much care burden and that she had no time to fill in the questionnaire (Figure 2).

6 | DISCUSSION

Our evaluation of the implementation of the CSNAT-I using the NPT shows that the intervention could not be optimally normalized in nurses' routine practice. Despite the CSNAT-I being promising, mainly contextual factors, such as a patient-focused approach to care and the organization of work structures, and the research context in which nurses had to recruit family caregivers for the study, posed a challenge to normalizing the intervention.

6.1 | What happened

Various factors positively supported the implementation and normalization of the CSNAT-I. All nurses and staff supported the idea that family caregiver support is an essential element within the nursing profession. This aligns with the Dutch nursing professional profile which states: 'Being ill is increasingly about being able to function rather than having disorders: individual adaptability is proving to be a crucial factor in 'healthy' functioning. The importance of self-care and informal care is therefore given greater emphasis' (Lambregts et al., 2016).

After applying the CSNAT-I in practice, many nurses recognized the potential value of the CSNAT-I for their own practice, as well as for the family caregivers. This is not obvious in an era where patient-centred care is the norm (Austin et al., 2017; Diffin et al., 2018). A review of implementation studies showed that appraisal of the value of the intervention is an important facilitator in implementation (Cummings et al., 2017). Nurses in our study also valued the training. Cummings et al. (2017) identified training and education as key factors for successful implementation, as they promote understanding of tasks and responsibilities and facilitate a shared understanding of purpose.

Some of our participating teams successfully assigned champions, who demonstrated responsibility for the implementation of

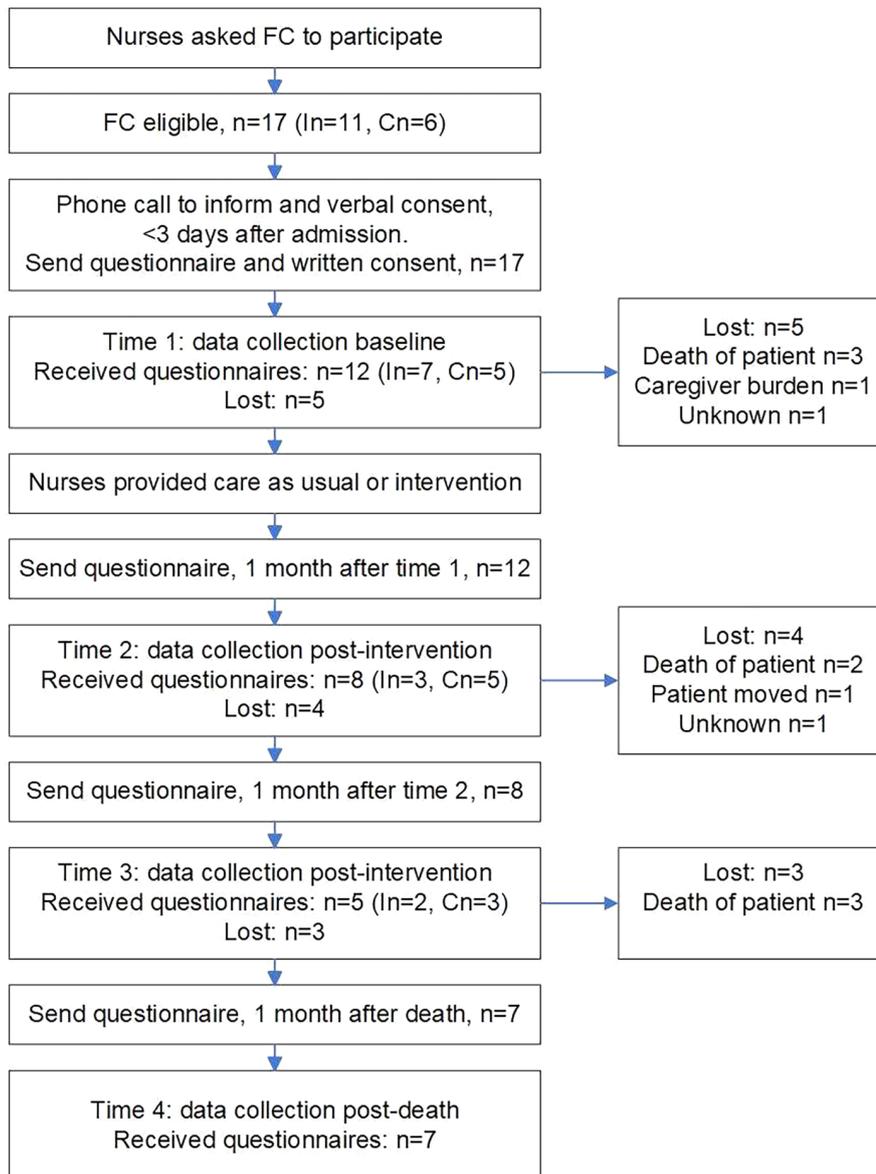


FIGURE 2 Flowchart of the inclusion of family caregivers. Cn, number of participants in control group; FC, family caregiver; In, number of participants in intervention group.

the CSNAT-I. Several studies highlight the importance of assigning a champion to facilitate acceptance of the new intervention (Cummings et al., 2017; Diffin et al., 2018; Horseman et al., 2019). Diffin et al. (2018) found that an internal facilitator, who is empowered with sufficient authority to change practice, being part of a supportive team of facilitators and having a strong position within the service, can contribute to successful implementation of the CSNAT-I.

Despite the positive factors, the recruitment of participants was difficult, and the implementation of the CSNAT-I proved to be challenging. The NPT analysis reveals several factors contributing to this situation. Some nurses expressed they already assess the needs of family caregivers. A lack of differentiation between existing and new practices may be problematic. Individuals may resist interventions that merely replicate existing practices when they do not recognize the benefits of the new intervention (Cummings et al. (2017)).

Organizational factors, such as time pressure, staff turnover, organization of care and late referrals, were cited by the nurses as barriers to implementing the intervention in practice. This is in line with other studies (Nilsen & Bernhardsson, 2019). Implementation of interventions is complex due to the interrelated and interacting factors of the 'open system' involved (Greenhalgh & Papoutsis, 2018).

Another influencing factor was the COVID-19 pandemic, which had an impact on conducting our trial study. During the first wave of the pandemic, nurses' focus was on stopping the spread of the virus and caring for ill patients, rather than supporting family caregivers and participating in a trial study (Zee et al., 2023). Meanwhile, preventive measures, such as a visitor ban and isolation measures, kept family caregivers at a distance, restricting the quality of emotional support for them (Yildiz et al., 2022). Our trial study on supporting family caregivers in end-of-life care had to be stopped just when family members needed it the most.

Nurses also indicated the research context was a significant barrier to implementing the intervention. One major factor was the reluctance of nurses to include family caregivers in our study, as well as the challenge of identifying patients with a short life expectancy, which led to hesitations in inviting eligible family caregivers to participate in our trial. This phenomenon, where healthcare providers prevent access to eligible patients and family caregivers for research recruitment, is referred to as 'gatekeeping'. Our findings align with a review conducted by Kars et al. (2016), which identified nurses' concerns about burdening family caregivers and about disclosing patients' poor prognosis or discussing end-of-life issues as reasons for gatekeeping. However, research by Aoun et al. (2017) showed that, in contrast to health professionals' concerns, family caregivers appreciate the opportunity to participate in research. They find benefits in their involvement, such as gaining insight into their support needs and contributing to improved support for future family caregivers. In addition to gatekeeping, other factors that influenced recruitment were premature death and late referrals of potential study participants. Hui et al. (2013) found that high attrition rates are common in supportive and palliative care trials.

6.2 | Lessons learned

Several lessons can be learned from implementing the CSNAT-I, a supportive intervention, in the context of palliative home care and within a research context.

6.2.1 | Implementation of the CSNAT-I

First, we found that a clear distinction between existing and new practices is important for successful implementation. When the difference between the two is not clear, nurses may resist the change, believing they are already applying its principles. The CSNAT-I was originally developed as an assessment tool (Ewing et al., 2013). Over time, the emphasis shifted from the tool to the CSNAT-intervention, underscoring that it is not merely a tool but also a comprehensive intervention (<https://csnat.org/>). This shift in perspective can make the distinction between existing practice and the new intervention clearer and more significant for nurses.

Second, our study highlights the need to assess and take into account contextual factors that may influence implementation. NPT provided a useful framework to identify these factors and to understand how they (may) affect the implementation and normalization process. We recommend process evaluations, structured by NPT, to identify influencing factors early and develop appropriate implementation strategies.

Third, our study shows that the CSNAT-I and the training have potential and may be valuable for both family caregivers and nurses in practice. The CSNAT-I can help family caregivers consider and express their support needs, while it also can help nurses systematically

identify the needs of family caregivers and establish an open dialogue with them (Ewing et al., 2013).

6.2.2 | Implementation in a research context

Fourth, recruitment challenges significantly impacted our trial despite our efforts to improve participation through site visits, information dissemination and reminders. Despite these measures, recruitment fell short of our expectations. Recruitment for palliative care trials is complex and research indicates a significant knowledge gap regarding effective recruitment strategies (Preston et al., 2016; Treweek et al., 2018). A review conducted by Preston et al. (2016) revealed a lack of strong evidence supporting any single strategy to assist healthcare professionals in recruiting participants for research studies. The most promising strategy identified involved assigning a specific staff member to the team responsible for recruiting participants to studies; however, underlying studies were found to be subject to a high risk of bias. Another review by Houghton et al. (2020) found that effective communication is a crucial factor, with face-to-face invitations being preferred by study participants. Clear information on potential harms and benefits of participation is not only essential to address the concerns and uncertainties of eligible individuals but is also beneficial for recruiters. A review by Kars et al. (2016) aligns with this idea, stating that understanding participants' experiences and views regarding research participation can help gatekeepers complement their perspectives and alleviate their concerns. Benefits such as the opportunity to help others in the future can motivate both potential participants and recruiters. Utilizing quotes from previous participants can further clarify participants' considerations (Treweek et al., 2018).

Although the primary focus of our training was to train nurses in using the intervention, rather than supporting them in recruiting participants, incorporating recruitment issues into the training could have enhanced our recruitment outcomes. Appointing a team member responsible for recruitment could have been helpful too.

Furthermore, we have learned that conducting an randomized controlled trial (RCT) in dynamic and complex nursing practice is challenging. Although RCTs are often considered the gold standard for informing evidence-based care practices, they definitely have their limitations. RCTs can hardly take into account the diversity of nursing practices. Their strict rules of objectivity and stringent control of contextual variables make them unsuitable for the nursing practice, which is inherently complex and contextual. Furthermore, RCTs provide limited information about the effectiveness of interventions—whether an intervention achieves its intended outcome (Baldi et al., 2014). Interventions always interact with their context. The effects of a complex intervention often depend on its context, implying that an intervention may be effective in one setting but ineffective in another. Therefore, solely focusing on the effectiveness of interventions is insufficient. Instead, we should consider

the intervention's workings—when, why and how it works—to inform its implementation in various settings (Skivington et al., 2021). Alternative research designs, such as mixed methods studies or action research, which go beyond intervention effectiveness, are needed (Farquhar et al., 2011). These approaches offer a more comprehensive perspective on 'the real world', enabling a more in-depth examination of the effect of the intervention and its applicability in nursing practice.

In light of the above points, it becomes especially crucial to recognize that poor recruitment and subsequent failure of trials contribute to research waste. Every year, substantial amounts of money and energy are wasted on seriously flawed research (Gillies et al., 2019). Whereas the funder required us to complete the study within 3 years and because the intervention we studied was previously tested and validated, we did not consider it feasible or necessary to conduct a time-consuming feasibility study. In hindsight, a feasibility study prior to starting the full trial would have been useful. As outlined in the framework for developing and evaluating complex interventions (Skivington et al., 2021), it is essential to verify whether specific progression criteria, related to the study design (such as recruitment) or the intervention itself, are met before proceeding further. Feasibility studies can help optimize the study design and implementation, increase the value of the study, avoid methodological vulnerabilities and prevent research waste.

6.2.3 | Limitations

Our evaluation study has several limitations. Firstly, the data collection was retrospective and not specifically focused on this evaluation study; instead, it was primarily intended to assess outcomes of the intervention in a trial. In hindsight, we could have conducted additional interviews with nurses and family caregivers, for example, to gather more targeted data. Another limitation is that the NPT primarily examines the professional perspective and not the family caregiver perspective. Assessing their perspective could have provided a fuller understanding of why the trial failed. Additionally, the role of the researcher was not considered in this evaluation study. For instance, the researcher was not affiliated with the nursing teams and had an independent role. Collaboration with the nurses mostly occurred at a distance, which presented challenges. However, the researcher tried to enhance nursing participation in the trial, for example, by offering regular contact moments.

7 | CONCLUSION

While the Carer Support Needs Assessment Tool Intervention showed promise in helping nurses provide tailored support to family caregivers, it appears that its integration into daily practice was not optimal. Several contextual elements, such as organization structures and a patient rather than a family-oriented approach, hindered the normalization of the intervention. Additionally, the research

context in which nurses had to recruit family caregivers proved to be challenging.

AUTHOR CONTRIBUTIONS

YNB, JACR, AVDH and EW: Made substantial contributions to conception and design, acquisition of data or analysis and interpretation of data; involved in drafting the manuscript or revising it critically for important intellectual content; given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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CONFLICT OF INTEREST STATEMENT

No conflict of interest has been declared by the authors.

PEER REVIEW

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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