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Detection of delirium by family members in the intensive care unit: Translation, Cross-Cultural adaptation and validation of the Family Confusion Assessment Method for the German-Speaking area

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Abstract

Aim: The aim of this study was the translation, cross-cultural adaptation and validation of the Family Confusion Assessment Method in critically ill patients.

Background: Delirium is a frequently unrecognized disorder in critically ill patients. Visiting family members might be the first to notice subtle changes in a patient's cognition and behaviour. The Family Confusion Assessment Method was developed to detect delirium by family members, but has not been available for the German-speaking area yet.

Design: A prospective validation study was conducted between January 2020 and October 2020.

Methods: The Family Confusion Assessment Method was translated into German according to the Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes. Subsequently, we compared the Family Confusion Assessment Method with the Confusion Assessment Method for the Intensive Care Unit in critically ill patients and their family members in a medical intensive care unit in Germany.

Results: We included 50 dyads of critically ill patients and their family members. The prevalence of delirium measured by Confusion Assessment Method for the Intensive Care Unit was 44%. Cohen's kappa coefficient was 0.84. The German Family Confusion Assessment Method had a high sensitivity of 95.5% and specificity of 89.3%. The positive predictive value and negative predictive value were 87.5% and 96.2% respectively.

Conclusions: These findings suggest that the German Family Confusion Assessment Method is an accurate assessment tool for delirium detection in the intensive care unit by family members. Furthermore, the results indicate that family members may identify delirium by the Family Confusion Assessment Method without prior training.

Impact: Collaborating medical staff with patients' family members to detect delirium in the intensive care unit may lead to early recognition of delirium.

KEYWORDS
delirium, Family Confusion Assessment Method, family members, intensive care unit, nurses, validation study

1 | BACKGROUND

Delirium is a complex neuropsychiatric syndrome characterized by acute disturbance of consciousness, attention and cognition (American Psychiatric Association, 2013). It is a common and severe manifestation of acute brain dysfunction in critically ill patients with incidence rates ranging from 30% to over 80% (Ely et al., 2001; Ouimet et al., 2007). Delirium is associated with a higher mortality rate (Ely et al., 2004; Salluh et al., 2015; van den Boogaard et al., 2010), longer duration of mechanical ventilation (Salluh et al., 2015), prolonged stay in the intensive care unit (Salluh et al., 2015) and cognitive impairment after discharge (Pandharipande et al., 2013; Salluh et al., 2015). Delirium is often not detected or misdiagnosed by ICU medical professionals (Han et al., 2009; Reznik et al., 2020; Van Eijk et al., 2009) or is considered an inevitable but harmless complication (Brummel et al., 2013). More than 60% of delirium cases remain unrecognized (Collins et al., 2010; Ritter et al., 2018; Spronk et al., 2009). The prevention and early recognition of delirium have high clinical relevance to minimize negative patient outcomes (Hshieh et al., 2015; Hsieh et al., 2013).

Family members could play a key role in the early recognition of delirium in the ICU (Fiest et al., 2020; Krewulak et al., 2019). They may notice subtle cognitive changes earlier than the medical staff (Fiest et al., 2020; Martins et al., 2014) and may prove to be an important resource for detecting delirium (Leigh et al., 2021; Mailhot et al., 2020).

Family-administered tools to measure delirium may consequently serve as valuable diagnostic adjuncts (Rosgen et al., 2018), but up until now they have hardly been explored in the ICU context. Three family-administered delirium detection tools, the Family Confusion Assessment Method (FAM-CAM), the Sour Seven Delirium Questionnaire (Sour Seven) and the Informant Assessment of Geriatric Delirium (I-AGeD) have been developed (Rosgen et al., 2018). In the original validation study of the FAM-CAM, Steis et al. (2012) validated the FAM-CAM on a sample of 52 dyads in the setting of community care. Mailhot et al. (2020) tested the psychometric criteria of the FAM-CAM on 108 patients in the emergency department.

So far, the FAM-CAM and the Sour Seven have been validated recently in critically ill patients in one ICU in Canada, however, the measurements were not done immediate consecutively, which is essential due to the fluctuating characteristic of delirium (Fiest et al., 2020; Krewulak et al., 2019). Furthermore, a German FAM-CAM can importantly contribute to further clinical use and research on the detection of delirium by family members for the ICU.

Since an assessment tool for delirium detection by family members is currently not available for the German-speaking area. This study aimed to (1) provide a German translation and cultural adaption of the FAM-CAM, (2) validate the German FAM-CAM version's diagnostic accuracy, and (3) further detect delirium against the reference standard Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) expert assessment in critically ill patients.

2 | THE STUDY

There are a few studies worldwide, which have validated the FAM-CAM in different settings. This study is one of the first studies worldwide to evaluate the detection of delirium by family members in critically ill patients, and the first study in this field for the German-speaking area.

2.1 | Aim

The aims of this study were the translation, cross-cultural adaptation and validation of the Family Confusion Assessment Method in critically ill patients.

2.2 | Design

We conducted a prospective monocentric diagnostic study to validate the FAM-CAM (Bossuyt et al., 2015). The study was carried out in a 14-bed medical ICU of a university hospital in Germany. This study is reported according to the Standards for the Reporting of Diagnostic Accuracy Studies (STARD) (Cohen et al., 2016) and registered in the German Clinical Trials Register (DRKS00016930). This study was conducted in line with the ethical principles of the Declaration of Helsinki (General Assembly of the World Medical Association, 2014; World Medical Association, 2001). Approval was granted by the Ethics Committee of the University Regensburg, Germany (13.03.2019/19-1350-101).

2.3 | Participants

Inclusion criteria for critically ill patients were: (1) 18 years and older; (2) intensive care stay ≥48 h; (3) RASS-score of −3 or higher; (4)

ability to communicate in German (at least C1 level of the Common European Framework of Reference for Languages) and (5) signed informed consent form. Moribund cases and patients with acute intoxication were excluded.

Family members were defined as persons who either lived together with the critically ill patient or had direct contact with the critically ill patient at least once a month with additional regular contact by phone or comparable means of communication. The degree of biological relationship played no role in the design of this study. Further inclusion criteria for family members were (1) 18 years and older; (2) at least one previous visit to the ICU; (3) ability to communicate in German (at least C1 level of the common European framework of reference for languages) and (4) signed informed consent form

2.4 | Delirium assessment tool

We selected the CAM-ICU assessed by an intensivist trained in delirium detection as the reference standard in our study because it is the most widely used assessment tool for delirium detection in the ICU (Cardoso et al., 2012; Chen et al., 2021; Gusmao-Flores et al., 2012).

2.5 | Validity and reliability/rigour

The FAM-CAM was developed based on the Confusion Assessment Method (Inouye et al., 1990) and is an 11-item assessment tool for detecting delirium by interviewing family members (Inouye et al., 2011). The assessment evaluates four distinct features of delirium: acute onset and fluctuation course, inattention, disorganized thinking and altered consciousness (Inouye et al., 2011; Steis, Evans, et al., 2012). In the original validation study, the FAM-CAM demonstrated a sensitivity of 88% (95% CI = 47–99), specificity of 98% (95% CI = 86–100) and reliability (kappa) of 0.85 (95% CI = 0.65–1.0) in 52 community-dwelling elderly patients and their caregivers. No specific training is necessary for the use of the FAM-CAM (Inouye et al., 2011; Steis, Evans, et al., 2012).

2.6 | Translation process

The FAM-CAM was translated according to the Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes of the International Society for Pharmacoeconomics and Outcome Research (ISPOR) (Wild et al., 2005).

The permission to translate and use the instrument was obtained from the original author and from the American Geriatrics Society. Subsequently, three physicians with very high expertise and clinical knowledge in ICU delirium did three forward translations of the FAM-CAM into German independently. Each of them represented a German-speaking country, that is, Germany, Austria or Switzerland, and they were all native speakers of the target language and fluent in English. Following this process, the research team evaluated the three forward translations and, by consensus, drafted a preliminary final version.

A cognitive debriefing was followed using the specifications of the ISPOR guideline (Wild et al., 2005). Cognitive debriefing interviews for the FAM-CAM's cultural adaption were conducted with medical staff (physicians, nurse scientists, clinical nurse specialists, registered nurses) and lay people in Austria, Switzerland and Germany. The participants from the target population evaluated the 11 items of the preliminary German FAM-CAM about their comprehensibility of language and content. In short, the comprehensibility of language and content of each item were queried using a questionnaire. Furthermore, the participants evaluated the layout of the preliminary German FAM-CAM. In addition, the participants could make optional comments to each item. The evaluation used a scale from 1 to 6 (1 = very good, 2 = good, 3 = satisfactory, 4 = sufficient, 5 = poor, 6 = deficient). The research team evaluated the results of the cognitive debriefing. In case of additional comments, a revision of the test item was checked.

Afterwards, a bilingual native English speaker and physician who is also fluent in German performed the back translation from the target language into English. The cross-cultural researcher had no knowledge of the original version of the FAM-CAM.

Next, the back-translated version was compared with the original FAM-CAM. The back translation was sent to the original author and to the American Geriatrics Society. Finally, the FAM-CAM's original author and the American Geriatrics Society approved the English back translation of the German forward translation.

The German translation of the FAM-CAM is covered by the copyright of the original. It can be obtained from the website of the American Geriatrics Society (AGS) CoCare®: HELP (https://help.agscocare.org/).

2.7 | Outcome measures

The primary outcome measure was Cohen's kappa coefficient comparing the German FAM-CAM and the reference standard CAM-ICU assessed by an expert. Secondary measures were the sensitivity, specificity and the negative and positive predictive value of the German FAM-CAM for detecting delirium in critically ill patients.

2.8 | Data collection

A total of 50 dyads of ICU patients and their corresponding family members were recruited from January 23, 2020 to August 31, 2020. A member of the study team recruited eligible ICU patients with at least one family member present. Eligible study participants were directly approached in the ICU. Once written informed consent was given, they were included in the study.

We documented the sociodemographic data of family members directly. The patient characteristics were collected from the

electronic health records in the ICU. The FAM-CAM and CAM-ICU were collected independently in the ICU. First, the FAM-CAM was performed by the family members. The eleven questions of the FAM-CAM were read to the family members respecting their privacy, and their responses were registered independently and blinded for the second assessor. Only one family member was included per critically ill patient. Afterwards, the family members were asked to leave the patient's room.

Then, one of the four especially trained ICU physicians independently and blinded to the results of the FAM-CAM assessment performed the CAM-ICU to determine the presence of delirium. The critically ill patients were unaware of the results of the FAM-CAM and CAM-ICU.

2.9 | Ethical considerations

This study was performed in line with the principles of the Declaration of Helsinki and approved by the Ethics Committee of the University Hospital Regensburg of the University of Regensburg (13.03.2019/No.19-1350-101). Written informed consent for publication of their details was obtained from all study participants.

2.10 | Data analysis

Descriptive statistics were used to describe characteristics of all study variables. For the analysis of the two groups (patients with and without delirium), t-test, Mann–Whitney U test and chi-square test were used appropriately defining a significant difference at a p-value <.05. The Cohen's kappa coefficient was performed using the inter-rater reliability between the two raters (McHugh, 2012). Sensitivity, specificity and positive and negative predictive values for the German FAM-CAM were calculated using crosstabs.

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) 27 software and the MedCalc Statistical Software Version 19.6.4.

3 | RESULTS

3.1 | Cognitive debriefing

Cognitive debriefing was conducted on a total of 28 participants. The median age of the participants was 39 [IQR 28–50] years. Eleven participants were female, and 17 were male. In total, 21 participants had a medical background, and 7 participants had no medical background. The participants with medical backgrounds were divided into the following categories: (1) physicians, (2) nurse scientists, (3) clinical nurse specialists and (4) registered nurses.

The participants had a high level of clinical experience, that is, the median experience was 14 [5–25] years. Participants with medical backgrounds worked in the following fields: (1) intensive care unit, (2) surgery, (3) internal medicine and (4) research (details are presented in appendix Table S1).

The analysis of the cognitive debriefing interviews showed that except for one each questionnaire item of the German FAM-CAM was evaluated as very comprehensible in the domains language and content (see appendix Table S2). Consequently, the translation of the one item evaluated differently was modified.

3.2 | Validation process

We recruited a total of 50 dyads of critically ill patients and their corresponding family members. 52 dyads who met the inclusion criteria were invited to participate in the study (Figure 1). In total, two family members refused to participate in the study. In each case, the reasons for refusal were disinterest and family reasons.

The demographic and clinical characteristics of the 50 critically ill patients and family members are presented in Tables 1 and 2 respectively. Six family members were unwilling to provide information about their age, and one family member was unwilling to give information about his marital status. The missing demographic data were indicated as missing.

Most of the critically ill patients included were male (n = 31, 62%), with a median age of 60.5 [51–71] years. The most common diagnoses at ICU admission were liver disease (n = 10, 20%), gastrointestinal disease (n = 8, 16%), postoperative care (n = 6, 12%), respiratory insufficiency (n = 5, 10%) and metabolic disease (n = 5, 10%). The median length of stay in the ICU was 4 [2–14] days. The median SAPS II score was 24 [15–32]. The median days of mechanical ventilation were significantly longer in ICU patients with delirium compared with patients without (8 [3–16] vs. 7 [3–15], p < .001 respectively). According to the reference standard, the CAM-ICU, a total of 22 ICU patients (44%) had delirium.

Among the family members, the majority were female (n = 34, 68%) with a median age of 50 [36–61] years. Most family members were married (n = 33, 66%) and were spouses (n = 19, 38%), children (n = 16, 32%) or life partners (n = 6, 12%). Most family members (n = 28, 56%) lived together with the critically ill patient.

The FAM-CAM and the CAM-ICU could be collected completely from all 50 dyads. Cohen's kappa coefficient between the CAM-ICU and the FAM-CAM ratings was 0.84 (95% CI 0.69–0.99, p < .001). The sensitivity of the German FAM-CAM was 95.5% (95% CI 77.2–99.9) and the specificity was 89.3% (95% CI 71.8–97.7). The positive predictive value and negative predictive value were 87.5% (95% CI 70.5–95.3) and 96.2% (95% CI 78.6–99.4) respectively (Figures 2 and 3).

4 | DISCUSSION

In this prospective validation study, we translated the FAM-CAM into German according to the ISPOR-Guideline (Wild et al., 2005) and validated the score against a CAM-ICU expert assessment. The

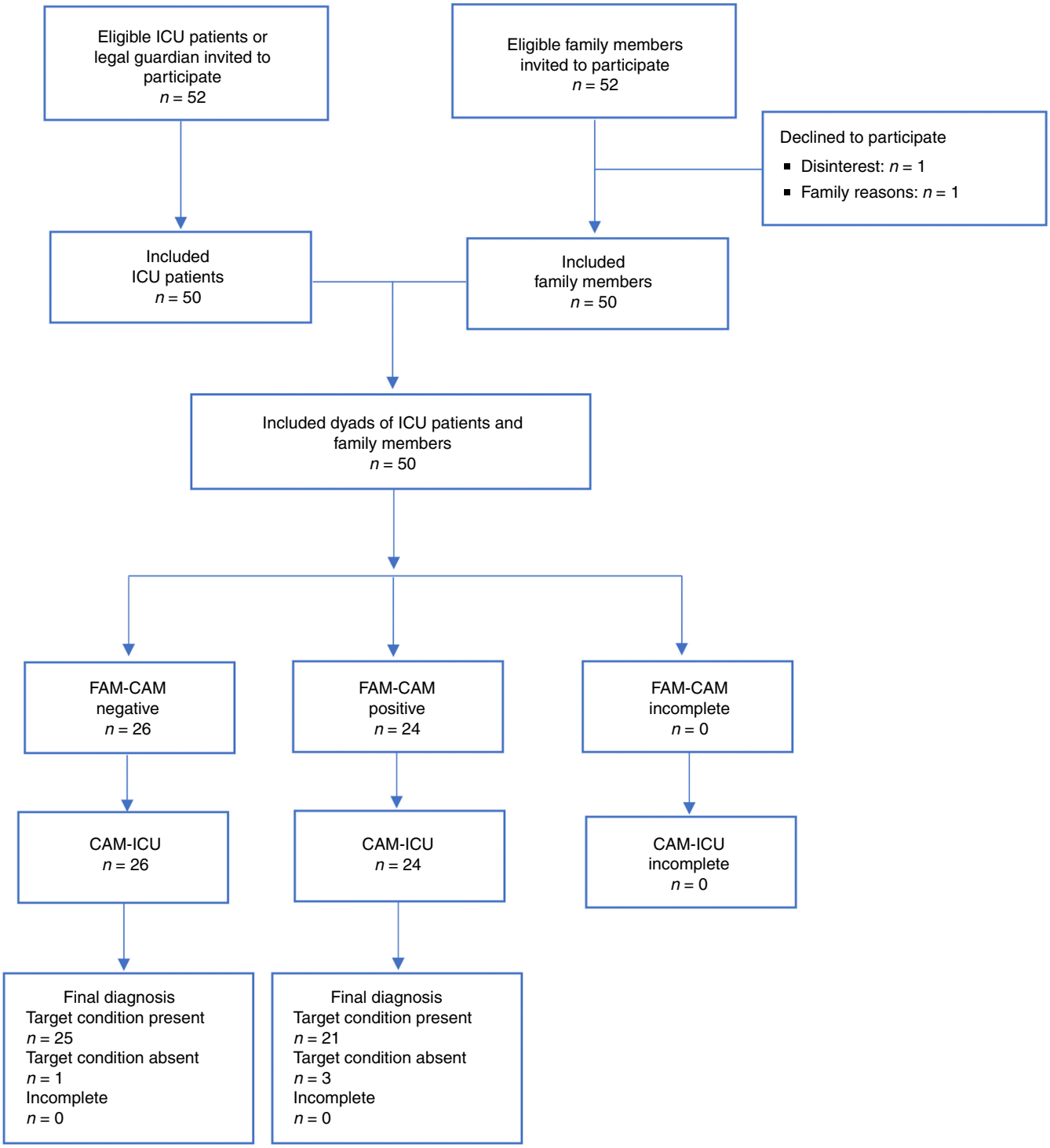

FIGURE 1 Flow diagram of participants

German FAM-CAM showed very good psychometric properties and an excellent diagnostic validity and reliability with a high sensitivity and specificity.

The inter-rater reliability of 0.6 (95% CI 0.3–0.9) and 0.7 (95% CI 0.4–1.0) in comparison with the DSM-IV criteria and CAM, respectively, was lower than in our study compared with the CAM-ICU. The sensitivity was slightly lower (75% (95% CI 35–95) for DSM-IV and 86% (95% CI 42–99 for CAM)) while the specificity was similar (91% [95% CI 74–97]) (Martins et al., 2014). A higher prevalence of delirium of 48% was present in the paired cohort in Fiest et al., investigating the FAM-CAM in the ICU setting as well. Interestingly, the sensitivity (54.1% [95% CI 45.3–62.7]) was much lower as well as was the specificity (76.8% [95% CI 70.9–82.1]) using the DSM-V criteria instead of the CAM-ICU. In addition, no additional benefit of the FAM-CAM in combination with the ICDSC or CAM-ICU could be found. Importantly, there is no information provided about the time

TABLE 1 Baseline characteristics of ICU patients

Characteristics	ICU patients with delirium (*n* = 22) 44%	ICU patients without delirium (*n* = 28) 56%	Total (*n* = 50) 100%	*p* value
Gender (female), *n* (%)	11 (22)	8 (16)	19 (38)	.121[a]
Age, yr., median [IQR]	63 [56–68]	59 [45–73]	60.5 [51–71]	.625[b]
Cultural background, *n* (%)				.551[c]
Germany	19 (38)	26 (52)	45 (90)	-
Southeast Europa	1 (2)	-	1 (2)	-
Central Europa	2 (4)	1 (2)	3 (6)	-
Russia	-	1(2)	1 (2)	-
Admission diagnosis, *n* (%)				
Respiratory insufficiency	1 (2)	4 (8)	5 (10)	-
Hepatic/Liver disease	4 (8)	6 (12)	10 (20)	-
Gastrointestinal disease	2 (4)	6 (12)	8 (16)	-
Sepsis/Septic shock	2 (4)	2 (4)	4 (8)	-
Haemorrhagic shock	2 (4)	-	2 (4)	-
Postoperative care	3 (6)	3 (6)	6 (12)	-
Postresuscitation care	3 (6)	-	3 (6)	-
Metabolic disease	2 (4)	3 (6)	5 (10)	-
Neoplasms	2 (4)	1 (2)	3 (6)	-
Other disease	1 (2)	3 (6)	4 (8)	-
Clinical parameters, median [IQR]				
ICU length of stay (days)	8 [4–16]	3 [2–6]	4 [2–14]	**.002**[b]
SAPS II Score	28 [18–33]	21 [13–32]	24 [15–32]	.148[b]
Sofa Score	7 [5–9]	5 [3–7]	5 [3–8]	**.013**[b]
TISS-28	10 [10–15]	7 [5–13]	10 [5–15]	**.010**[b]
Mechanical ventilation (days)	8 [3–16]	7 [3–15]	8 [3–16]	**.001**[b]
Medications, *n* (%)				
Analgesic	11 (22)	2 (4)	13 (26)	**.001**[a]
Sedative	12 (24)	4 (8)	16 (32)	**.002**[a]
Antipsychotic	10 (20)	8 (16)	18 (36)	.217[a]
Delirium, *n* (%)				
Hyperactive	4 (18)	-	4 (18)	-
Hypoactive	18 (82)	-	18 (82)	-

Abbreviations: ARDS, Acute Respiratory Distress Syndrome; ICU, Intensive Care Unit; IQR, interquartile range; SAPS, Simplified Acute Physiology Score; SOFA, Sepsis-related organ failure assessment; TISS-28, Therapeutic Intervention Scoring System.

[a]Chi-square test.

[b]Mann–Whitney *U* test.

[c]Fisher's exact test.

Bold indicates significant difference in the groups ($p < .05$).

differences between the different assessments, which might impact the results substantially due to the fluctuating nature of delirium.

In addition, it was highlighted by the authors that the family members in their study might have had a different understanding of delirium than medical professionals (Fiest et al., 2020).

Furthermore, in our study the CAM-ICU assessor was blinded to the FAM-CAM (assessment) which was not the case in the original study by Steis, Evans, et al. (2012). In the eCare for Eldercare study, which is part of the original study, some of the trained interviewers were not blinded to the results when assessing participants with the CAM (Steis, Prabhu, et al., 2012). Only Mailhot et al also used the double-blinding approach in their study investigating. In this study, in the emergency department setting, the authors tested the ability of the FAM-CAM to detect delirium in patients with or without dementia compared with the reference standard, the CAM. In addition, the authors had the objective to examine whether the FAM-CAM can perform similarly in patients with or without dementia (Mailhot et al., 2020).

In our study, we used only one administration method, that is interview, for the FAM-CAM assessment. In the original validation study outside the ICU, different administration methods, that is, paper and pencil, personal computer and smartphone, were used for the FAM-CAM, which may have an effect on the results (Steis, Evans, et al., 2012).

Finally, in our study, the time interval between the performance of the FAM-CAM and the CAM-ICU was only a few minutes apart, which is particularly important due to the fluctuating behaviour of the delirium. In most other studies, the time intervals are not provided, or the standard assessment method was performed independently the same day (Fiest et al., 2020; Martins et al., 2014; Steis, Evans, et al., 2012). Only Mailhot et al., performed the FAM-CAM and the reference standard, directly one after the other (Mailhot et al., 2020).

TABLE 2 Demographic characteristics of family members

Characteristics	Family members ($n = 50$)
Gender (female), *n* (%)	34 (68)
Age, yr.	
Age, median [IQR]	50 [36–61]
Missing	6 (12)
Marital status, *n* (%)	
Single	10 (20)
Married	33 (66)
Widowed	-
Divorced	2 (4)
Life partnership	4 (8)
Missing	1 (2)
Relationship to ICU patient, *n* (%)	
Spouse (Wife/Husband)	14/5 (28/10)
Life partner	6 (12)
Mother	3 (6)
Daughter	13 (26)
Son	3 (6)
Sibling (Sister/Brother)	3/0 (6/0)
Other relative	3 (6)
Frequency of contact with ICU patient, *n* (%)	
Living together	28 (56)
Direct contact at least once a month (with regular phone contact in between)	22 (44)

Abbreviations: ICU, intensive care unit; IQR, interquartile range.

4.1 | Limitations

There are several limitations to our study. The FAM-CAM was only tested on a sample of one medical ICU. This may limit the generalizability of the study. No sample size calculation was performed but the number was chosen similar to the other published validation studies (Martins et al., 2014; Steis, Evans, et al., 2012). We also did not use the standard psychiatric criteria as a reference standard but the expert CAM-ICU, most used in the ICU setting.

A strength of this study is that the cognitive debriefing was conducted in Austria, Switzerland and Germany. The comprehensibility of the 11 items in terms of language and content was tested for the entire German-speaking area. Thus, a linguistically and contextually focused adaptation of the 11 items of the German FAM-CAM could be ensured.

Another strength of this study is the high response rate from family members. Only two family members refused to participate in the study. One of the findings from the pilot study by Krewulak et al. was that family members often refused to participate in the detection of delirium in the ICU. Reasons for refusal included family members being overwhelmed by the involvement in delirium detection in the ICU (Krewulak et al., 2019). In the present study, the family members were open to participate in the detection of delirium in the ICU and it was shown that family members can play an active role in the detection of delirium which is in line with results from previous studies (Fiest et al., 2020; Mailhot et al., 2020).

Another strength of our validation study is that we showed that family members could recognize delirium without prior training in the ICU. Family members understood the 11 questions/items of the FAM-CAM very well.

		Confusion Assessment Method for Intensive Care Unit (Reference Standard)		
		Delirium $n = 22$ (44%)	No Delirium $n = 28$ (56%)	Total $n = 50$ (100%)
Family Confusion Assessment Method (Index Test)	FAM-CAM positive	21 95.5% (77.2% - 99.9%)	3 87.5% (70.5% - 95.3%)	24
	FAM-CAM negative	1 96.2% (78.6% - 99.4%)	25 89.3% (71.8% - 97.7%)	26
	Total	22	28	50

FIGURE 2 Diagnostic accuracy of the German FAM-CAM

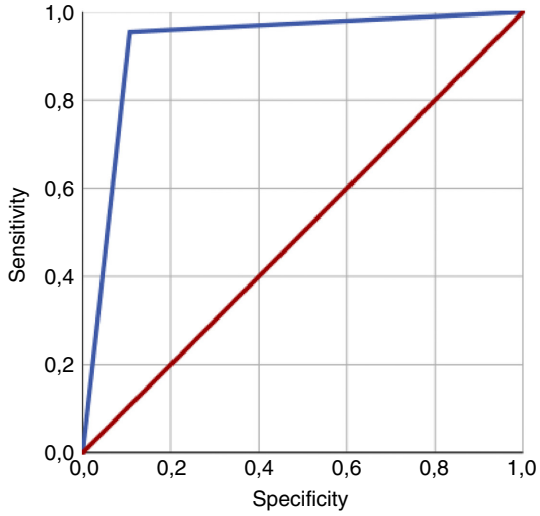

FIGURE 3 Receiver operation characteristic curves for German FAM-CAM compared to the CAM-ICU

Area Under the Curve

			Asymptotic 95% Confidence Interval	
Area	Std. Error	Asymptotic Sig.	Lower Bound	Upper Bound
,924	,043	,000	,839	1,000

5 | CONCLUSION

In conclusion, our findings suggest that the German FAM-CAM is an accurate, valid and reliable assessment tool for the detection of delirium in critically ill patients by family members in the intensive care unit. Family members at the bedside are willing to participate in the detection of delirium in the ICU. They may provide accurate information to identify whether delirium is present in critically ill patients. The results of this study may have a positive impact on nursing practice. Delirium patients are often very time-consuming for the nursing professionals. The early detection of delirium by the FAM-CAM could, therefore, have a positive impact for the nursing staff. Furthermore, the FAM-CAM is a tool, which can strengthen the family-centred care in the intensive care unit.

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CONFLICT OF INTEREST

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All other authors declare no conflicts of interest in this study.

CLINICAL TRIAL REGISTRATION NUMBER AND NAME OF TRIAL REGISTER

German Clinical Trials Register, no. DRKS00016930.

AUTHORS' CONTRIBUTIONS

Greindl, Mayer, Lingg and Schaller conceived the study and participated in the study design. Greindl recruited the patients and collected the data. Greindl and Schaller analysed the data. All authors were responsible for the interpretation of the results. Greindl drafted the manuscript, and all authors reviewed and revised the manuscript for intellectual content. All authors have seen and approved the final version of the document.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/jan.15227.

DATA AVAILABILITY STATEMENT

All data generated or analysed during this study are included in this published article [and its supplementary information files].

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