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Considerations in preparing a multicenter study: Lessons learned from the Epilepsy Monitoring Unit Comfort Questionnaire (EMUCQ) validation feasibility study

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ABSTRACT

Purpose: It is recommended to perform a pilot testing before conducting a validation study of a novel questionnaire. Pilot studies may serve different purposes. The aim of this study was to assess the feasibility of a multicenter validation study, to recruit additional study centers, and to undertake orientating descriptive item analysis of the 44-item Epilepsy Monitoring Unit (EMU) Comfort Questionnaire (EMUCQ).
Methods: During a six-month sampling period, the EMUCQ was administered to eligible EMU patients. The patients filled out the questionnaire at two time points. Additional centers were recruited in Germany and Austria, and ethics votes obtained. In descriptive item analysis central tendency, variability, item distribution and item difficulty were calculated.
Results: A total of 44 EMU patients participated in the study. Eight additional EMUs agreed to join the planned validation study. Recruitment of the centers took four months. Another six months passed to obtain all the ethics votes. Floor and ceiling effects could be detected in 32 items. One item with the lowest median showed the low item difficulty. Another five items showed medians with the height of 6. In four items, high difficulty indices could be observed.
Conclusion: A good network has turned out to be very helpful while planning a multicenter study. Enough time must be scheduled, because obtaining an ethics vote may take quite a long time. No conclusive statements regarding item properties could be made as this was a feasibility study.

1. Introduction

When persons suffer from refractory epilepsy or seizures of any unknown origin, hospitalization in an epilepsy monitoring unit (EMU) is recommended. Usually, EMU patients are hospitalized for five days, whereas under certain circumstances, the stay might last longer (e.g., when patients undergo invasive epilepsy surgery examination) or even shorter (e.g., when diagnosis can be made earlier). To establish a clear diagnosis and an appropriate therapy, it is necessary that the patients should have seizures while hospitalized in the EMU, to be thoroughly analyzed by epileptologists [1–3]. So, these patients are observed by a specially trained staff as they take electroencephalogram, video, and audio records day and night. While the patients appreciate this high-quality diagnostic method and the support given by nurses and doctors, they also perceive some kind of discomfort [4–8]. Owing to a seizure-related risk of injury [1], safety arrangements are made in EMUs. These may include restricted ambulation, guard rails, and being accompanied by a nurse when going to the toilet [2,3,9–11]. Some patients, therefore, decide to remove themselves from the EMU [4] thus not allowing physicians to accurately diagnose the epilepsy syndrome or localize the seizure onset zone. The patients are more likely to overcome stressful situations if they experience high levels of comfort. Comfort comes along with a feeling of being understood, strengthened, and at ease [12]. It is a nursing goal to enhance a patient's comfort by conducting comfort-enhancing measures. The impact of these interventions should be measured by comparing patient comfort before and after the action is undertaken. To assess comfort levels, Kolcaba [13] has developed the General Comfort Questionnaire (GCQ). The 48-item GCQ was tested with 256 adult patients. Items reflected a three-factor structure indicating the three types of comfort: relief, ease, and transcendence [13]. With Kolcaba's permission, in a rigorous procedure, the GCQ was translated from American English into German and

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adapted for use in an EMU for adult patients [14]. The next step in the process will be a validation study to assess the psychometric properties of the Epilepsy Monitoring Unit Comfort Questionnaire (EMUCQ).

The quality of a clinical trial depends on the quality of the instrument being used to measure changes in the observed outcome. To gain high-quality results researchers need instruments of high validity, reliability, and responsiveness as defined by the COnsenus-based Standards for the selection of health Measurement INstruments (COSMIN) group [15]. Measures are assessed in terms of these properties by the instrument developer in a full study. Therefore, the study is not an appendix to a greater project, but it is a separate study that should be designed and conducted carefully. Otherwise, no useful evidence would be gained [16]. In light of this, a foregoing pilot or feasibility study is preferable. To conduct psychometric testing, an adequate sample size is required following the classical test theory. Various recommendations have been made as to what is meant by *adequate*, but there is no consensus on this matter. For testing newly developed instruments, sample sizes differ between two and 50 respondents per item, with the most common being ten per item, to conduct an exploratory factor analysis (EFA) [16,17]. If the factor structure of the instrument is already known, such as in this study, where the instrument is based on an already existing one and theory-driven changes were made, a confirmatory factor analysis (CFA) will be suitable [16]. With this method, a hypothesized factor structure, as part of testing the construct validity, namely structural validity, is evaluated. If the results of the CFA are unsatisfactory, an EFA should follow [18]. Regarding the CFA sample size, Polit and Yang [16] recommend samples with about 200 respondents and larger ones when the normality assumption would be highly violated. Bühner [19] states that a sample size of 200, ideally of 250, would be considered sufficient for conducting a CFA. This was supported by Marsh, Hau, Balla, and Grayson [20] in a Monte-Carlo study with the additional hint that more would be better depending on the number of indicators per factor. According to Comrey and Lee [21] and Gorsuch [22], acceptable results could be gained in case of EFA with 300 participants. Therefore, it was intended to collect at least 300 questionnaires in the planned validation study. However, if unforeseen difficulties in data collection arise, 250 questionnaires were considered as a minimum. To develop a valid instrument that could be used in EMUs throughout the country, it was decided to include four additional centers in Austria. Since nurses and medical staff in hospitals have low time resources, one intention of cognitive interviewing, which was included in the EMUCQ development procedure, was the testing of the comprehensibility of the instructions section [23]. In this way, EMU personnel do not have to explain how to fill out the questionnaire to the patients.

1.1. Aim of the study

It is recommended to perform pilot testing before conducting a validation study. The pilot studies may serve different purposes [24–26]. The purpose of this study was to assess the feasibility of a multicenter study. Therefore, all procedures were conducted as planned for the following study. It was the aim (a) to determine how long it would take to collect the required number of questionnaires, (b) to recruit additional centers, and (c) to undertake an initial descriptive item analysis to detect trends regarding the missing values and item properties. It was not the aim to undertake changes in the EMUCQ.

2. Methods

The EMUCQ development and validation study follows an exploratory–sequential mixed-method design. In this design a qualitative strand (development stage of a questionnaire) is followed by a quantitative strand (validation stage of a questionnaire) [27]. In this article, the pilot study for the quantitative strand has been described. It is a quantitative descriptive study and part of the first author's PhD thesis.

2.1. Ethical considerations

The study was submitted to the local ethics commission (reference number 415-EP/73/700-2016) and has been conducted in accordance with the guidelines in the Declaration of Helsinki. All the patients received both written and verbal information by the first author. To enable the researcher to match the questionnaires from the baseline to follow-up, and to protect the confidentiality of the patients, they were asked to create a code by themselves.

2.2. Setting and participants

The study was carried out in the four-bed EMU of the Department of Neurology, Paracelsus Medical University, Salzburg, Austria. A consecutive sampling strategy was used to recruit patients who were at least 18 years of age, able to read and understand German language, not mentally disabled, able to sign the informed consent form, and currently hospitalized at the EMU with a planned length of stay for at least five days. It was the aim to include 30–50 participants [16,25] during a period of six months.

2.3. Data collection

During the data collection period, which lasted from January to June 2018, the first author distributed the EMUCQ to the patients. They were asked to complete the EMUCQ twice: on the second day of their stay and once more the day before discharge from the EMU (usually the fourth day). In the first round, the patients were asked to give additional information regarding demographic data and fill out four visual analog scales (VASs). In the absence of a gold standard for assessing comfort levels, the VASs will serve as instruments to test the convergent validity in the planned field study [16,28]. Additionally, in the field study the results of the second round will be used to assess changes in comfort levels over time. In this feasibility study, the second round was necessary to calculate the dropout rate. On the cover page of the questionnaire, the patients could find brief information about the construct *comfort*, how to use the Likert-type scale, and how to generate the code. The EMUCQ itself is a 44-item paper–pencil instrument that consists of 22 positively and 22 negatively worded items. The Likert-type scale ranges from 1 (strongly disagree) to 6 (strongly agree), resulting in a final score of at least 44 points and a maximum of 264 points. A higher score indicates higher comfort levels [14]. The VASs are horizontally located lines of 100 mm in length each and are placed on one page. As defined by Kolcaba and Steiner [28], they measure the three types of comfort (relief, ease, transcendence) and the total comfort level.

2.4. Data analysis

The SPSS 23 (IBM SPSS Statistics for Windows, Version 23.0, IBM Corporation, Armonk, NY) was used for data analysis. Descriptive statistics were computed to describe the sample characteristics and item properties. The item analysis included examinations regarding missing values, central tendency (median, mean), variability (quartile, range, standard deviation [SD]), item distribution (skewness), and item difficulty. Additionally, a visual assessment of bar graphs and boxplots was undertaken. The missing values over 5% were considered relevant [16]. The mean scores should be close to 3.5, which marked the scale midpoint [16] and not range in the end of the scale (1–1.99; 5.01–6). The items should be normally distributed, which was assumed if the value of skewness divided by the value of the standard error of skewness was lower than 1.96 [29]. A floor or ceiling effect was assumed if an item was extremely skewed (absolute value >2) [16,30] or at least 20% of the respondents chose the highest or the lowest answer option [31]. The item difficulty was computed by dividing the item score of all the participants ($\sum_{v=1}^{n} x_{vi}$) by the highest possible score

$(n \cdot \max(x_i))$ multiplied by 100. As the response options started with 1 and not 0 the formula had to be corrected by subtracting the lowest possible score $(\min(x_i))$ of the given answer. In summary, it means $P_i = \frac{\sum_{v=1}^{n}[x_{vi} - \min(x_i)]}{n[\max(x_i) - \min(x_i)]} \cdot 100$ [32]. There are no right or wrong answers in the EMUCQ, which is why the item difficulty pertains to *symptomatic* (easy) and *not symptomatic* (hard) answers [32]. Fisseni [33] describes the values between $P = 0.2$ and $P = 0.8$ as suitable indicators of middle item difficulty. P must be multiplied by 100 to correspond to the convention of Kelava and Mossbrugger [32]. In this study, the data from the first time of collection were used to calculate the descriptive item statistics. Negatively worded items were reverse-coded before conducting computations. As the EMUCQ-items are ordinal variables, medians instead of means should be computed. The medians of the rating scales often do not differ broadly, and therefore, reporting the means would be preferable [19]. Furthermore, if there are more than five numbers of values, the ordinal variables may be treated as being continuous [34]. As the EMUCQ includes a 6-point Likert scale, this approach was followed. To get comprehensive information, both means and medians were reported.

3. Results

3.1. Sample characteristics

In the projected time span of six months, 105 patients (47 eligible) were admitted at the EMU.

All eligible patients were asked to participate in the study and 44 agreed. The reasons for refusal were extraordinary tiredness or possible release from the EMU the next day. One patient did not reveal the reason. All the participants filled out the questionnaire in the first round, which took them between seven and 12 min. In total, 40 of them participated also in the second round. Most of the participants were female (n = 24), had completed vocational training (n = 19) and were full-time employees (n = 11). For more details please see Table 1.

Table 1
Characteristics of participants (N = 44).

		N	%
Gender	Female	24	54.5%
	Male	20	45.5%
Age (mean: 35.21 years)	≤20 years	8	18.2%
	21–40 years	22	50.0%
	41–60 years	8	18.2%
	≥61 years	6	13.6%
Marital status	Single	22	50.0%
	Married/Unmarried Couple	14	31.8%
	Divorced	4	9.1%
	Widowed	2	4.5%
	Missing	2	4.5%
Education	Compulsory School	9	20.5%
	High School (Diploma)	7 (4)	15.9%
	Vocational Training (Additional High School diploma/Master Tradesman Certificate)	19 (2/5)	43.2%
	University Graduate	8	18.2%
	Missing	1	2.3%
Employment status	Student	4	9.1%
	Apprentice	3	6.8%
	Self-employee	5	11.4%
	Full-time Employee	11	25.0%
	Part-time Employee	4	9.1%
	Housewife/Househusband	2	4.5%
	Unemployed/Sick Leave	7	15.9%
	Retired	8	18.2%

3.2. Descriptive item analysis

Relevant missing values could be detected in two of the 44 items. While the means of 15 items were near the scale midpoint, 25 means were rated higher and four means lower. A similar picture was given by the medians. The full range of response options was covered in 39 items. However, not all options were ticked in four of these items. A total of 22 items were considered to be normally distributed. Even so, a ceiling or floor effect could be observed in ten of these items. All the 20 left-skewed items showed a ceiling effect, and one of them was extremely skewed. Both right-skewed items displayed a floor effect. The difficulty of 39 items ranged between the recommended indices of 20 and 80. One item ranged slightly lower and four items higher. For more details, please refer to Table 2.

3.3. Dropout rate and time span

In total, 40 complete questionnaire sets could be collected. Four patients did not participate in the second round of questioning, which corresponds to a dropout rate of 9.1%. Therefore, to collect at least 300 questionnaire sets a sample size of 330 would be needed. This meant that each of the Austrian centers should collect 66 data sets—this would take more than nine months. The data collection period of the field study was projected with a maximum of six months (starting with October 2018) in the study plan. Enhancing recruiting period was no option because this would have meant an obvious violation of the very strict study plan and time line. Therefore, it was decided to include additional centers in German-speaking countries.

3.4. Recruiting additional centers

When validating a questionnaire, it is important to mind the linguistic area in which it should be used [35]. The southern German linguistic area comprises Baden-Wuerttemberg (Germany), Bavaria (Germany), the German-speaking Switzerland, the Principality of Liechtenstein, South Tyrol (Italy), and Alsace (France) apart from Austria [36]. To keep the study as simple as possible, it was decided to only include Austrian and German centers. In April 2018, the chairpersons of four Austrian and eight German EMUs were asked to participate in the study via e-mail. Among them, two Austrian and three German EMUs agreed within three weeks. After a reminder, one additional Austrian center replied positively. The chairpersons of the six reluctant centers were contacted via telephone. By mid-July, three German centers confirmed their participation. One center refused participation because of the formalities pertaining to the ethics commission, while one center did not fulfill the inclusion criteria as it undertook solely short time monitoring over 48 h. Another center refused participation without giving any reason. Later, one German center withdrew its consent. Finally, five (68%) of the German and four (80%) of the Austrian centers, including the Salzburg EMU, agreed to join the study. Four of them were four-bed EMUs; two were five-bed EMUs; one was a nine-bed EMU, one a six-bed EMU, and another one a three-bed EMU. They were asked to collect 30–33 questionnaire sets each. As the research received no funding and was financed privately by the first author, it was only possible to provide them with chocolates. However, one center made it clear that it would have preferred a financial donation.

3.5. Ethics commissions

The first author contacted all the ethics commissions and prepared the necessary documents. Apart from the Salzburg ethics commission, the study was checked for ethical issues by three more Austrian and German commissions each. Two German ethics commissions followed the decision of another commission without taking any on their own. Basically, the ethics commissions met monthly. Applications had to be filed two to three weeks ahead of the meeting. While some of the

Table 2
Descriptive statistics of EMUCQ-items (N = 44).

Number and Stem	Item	Missing (%)	Mean	Quartile (25/50/75)	SD	Range	Skewness	Strongly disagree %	Strongly agree %	Item difficulty
#01	My body is relaxed right now.	0	3.91	3/4/5	1.41	1–6	−0.25	4.5	13.6	58
#02	I have enough privacy in this ward.	0	3.52	2/4/5	1.64	1–6	−0.11	13.6	11.4	49
#03	There are those I can depend on when I need help.	0	5.39	5/6/6	0.99	1–6	−2.35	2.3	61.4	88
#04	I would like to do physical exercises with a therapist more often.	0	3.57	3/4/4	1.35	1–6	−0.03	6.8	9.1	51
#05 – R	My present condition gets me down.	0	3.55	2.25/3/5	1.63	1–6	0.08	13.6	18.2	51
#06	I am confident that an appropriate therapy will be found for me.	0	4.55	4/5/5.75	1.28	1–6	−0.80	2.3	25	71
#07 – R	I feel dependent on others here.	0	3.68	2/4/5	1.74	1–6	−0.15	15.9	20.5	54
#08	I feel my life is worthwhile right now.	0	4.93	4.25/5/6	1.27	1–6	−1.38	2.3	40.9	78
#09	These surroundings are pleasant.	0	3.48	2/3.5/4	1.50	1–6	0.15	9.1	13.6	50
#10 – R	There are sounds here that bother me.	1 (2.3)	4.47	3/5/6	1.49	1–6	−0.73	4.5	31.8	67
#11 – R	I feel misunderstood.	0	5.45	5/6/6	0.76	3–6	−1.33	0	59.1	89
#12 – R	The itching of the scalp is difficult to endure.	0	4.73	4/5/6	1.33	1–6	−1.07	2.3	34.1	75
#13	I am inspired to do my best.	0	5.11	4.25/5.5/6	1.13	2–6	−1.26	0	50	82
#14	My faith helps me to not be afraid.	2 (4.5)	2.88	1/3/4	1.67	1–6	0.23	31.8	4.5	35
#15 – R	I do not like it in this ward.	1 (2.3)	5.12	5/5/6	1.12	1–6	−1.64	2.3	45.5	80
#16 – R	I am constipated right now.	3 (6.8)	5.15	4/6/6	1.37	1–6	−1.44	2.3	61.4	76
#17 – R	I do not feel healthy right now.	1 (2.3)	3.86	3/4/5	1.54	1–6	−0.21	6.8	18.2	55
#18 – R	This room makes me feel scared.	0	5.02	4/6/6	1.25	1–6	−1.25	2.3	52.3	80
#19 – R	I am afraid of what is next.	0	4.5	4/5/6	1.56	1–6	−1.05	9.1	31.8	70
#20 – R	I am hungry.	1 (2.3)	4.63	4/5/6	1.63	1–6	−1.05	6.8	40.9	70
#21 – R	I would like to talk to a doctor more often.	1 (2.3)	4.35	4/5/5	1.41	1–6	−0.82	4.5	20.5	65
#22	The temperature in this room is fine.	0	3.8	2.25/4/5	1.52	1–6	−0.05	4.5	15.9	57
#23 – R	I am very tired.	0	3.84	3/4/5	1.54	1–6	−0.12	6.8	20.5	57
#24	I can rise above my pain.	3 (6.8)	4.15	2.5/4/6	1.71	1–6	−0.43	6.8	29.5	57
#25	The mood around here uplifts me.	2 (4.5)	3.24	2/3/5	1.51	1–6	0.19	13.6	6.8	42
#26	I am content regarding the situation here.	1 (2.3)	4.23	3/4/6	1.54	1–6	−0.45	4.5	27.3	63
#27	This bed is comfortable.	1 (2.3)	4.4	4/5/5	1.38	1–6	−0.71	2.3	22.7	64
#28	I see things out of my window which inspire me.	1 (2.3)	1.93	1/1/3	1.40	1–6	1.32	61.4	2.3	18
#29	I can reach my personal belongings easily.	1 (2.3)	4.12	3/4/6	1.55	1–6	−0.28	4.5	25	60
#30 – R	I feel out of place here.	2 (4.5)	4.83	4/5/6	1.48	1–6	−1.59	9.1	40.9	73
#31	Nice people are thinking of me and are in contact with me.	0	5.2	5/6/6	1.27	2–6	−1.48	0	63.6	84
#32	I have enough information about my current health condition.	0	4.61	4/5/6	1.26	2–6	−0.52	0	31.8	72
#33 – R	I feel out of control.	0	4.66	4/5/6	1.36	1–6	−0.90	2.3	34.1	73
#34 – R	This room smells terrible.	1 (2.3)	5	4/5/6	1.19	1–6	−1.40	2.3	43.2	78
#35 – R	I am depressed.	0	4.82	4/5/6	1.30	2–6	−0.85	0	40.9	76
#36	I feel good.	0	3.84	3/4/5	1.40	1–6	−0.08	4.5	13.6	64
#37 – R	I feel tense because I am waiting for a seizure.	0	4.45	3.25/5/6	1.70	1–6	−0.82	9.1	40.9	69
#38 – R	I feel observed.	0	3.27	1/3/5	1.98	1–6	0.20	29.5	22.7	45
#39 – R	It is boring.	0	3	2/3/4	1.58	1–6	0.37	22.7	9.1	40
#40 – R	I am afraid of a seizure/its aftermath.	0	4.20	3.25/5/6	1.82	1–6	−0.82	18.2	29.5	64
#41	I have enough fresh air.	0	3.02	2/2.5/4	1.62	1–6	0.44	18.2	9.1	40
#42	I feel clean.	0	2.93	2/3/4	1.40	1–6	0.38	18.2	4.5	37
#43	The light in this room is pleasant.	0	2.5	1/2/3	1.41	1–6	0.92	29.5	6.8	34
#44	This room is nicely decorated.	1 (2.3)	3.47	3/3/4	1.29	1–6	0.22	4.5	6.8	48

R = reverse coded.

commissions accepted the documents electronically, others needed paper documents and sometimes compact discs. In Austria, students may apply for full discounts on the commission fee by sending a confirmation form that the study was for scientific reasons only. In Germany, either no fees or reduced fees were charged. Although it was a nursing study in eight of the nine applications, it needed to appoint a medical principal investigator. The nursing director's signature was demanded by one Austrian commission. One German commission wanted the patient code to be randomly generated as pure numeral code by the researcher concerned and not by the patients themselves. The first ethics vote was received in August 2018 and the last in January 2019. As planned, data collection started at six centers in October 2018. Two centers began collecting data in January 2019 and another in February 2019.

4. Discussion

One aim of this pilot study was to get a first impression of the item properties of the EMUCQ. Incidentally, there was no intention to modify the questionnaire. This may be seen as a limitation. It was carefully discussed to make changes in the questionnaire as this was the last opportunity prior to validation. Taking into account the small, nonrepresentative sample size and the psychometric properties of the original GCQ, which provide the EMUCQ with preliminary validity [12], changes based on the results of this pilot study could threaten validity and reliability of the new questionnaire. Therefore, no changes were applied to the instruments. Statistical results may be considered informative and interpreted cautiously. There were only 12 items that performed well. A total of 32 items showed problems. In all of them, either a floor or a ceiling effect had occurred. There is no consensus in the literature about the criteria pertaining to relevant floor and ceiling effects. While Skirko and colleagues [37] consider values higher than 50% to be relevant, others use stricter cutoffs such as 25% [38] or 15% [39]. As several researchers did (e.g., [40–42]), in this study the approach of Holmes, Bix, and Shea [31] was followed to assume a floor or ceiling effect if at least 20% of the responses ranged within the highest or lowest area of the scale. In five items, very noticeable ceiling or floor effects of ≥50% as well as item difficulty indices could be observed. These items may probably turn out to be problematic in the use of the EMUCQ. The questionnaire was designed to detect changes in comfort. Therefore, responsiveness is necessary. However, floor or ceiling effects restrict responsiveness. If the patients answer on the lowest or on the highest option at the baseline, it will be impossible to detect changes that go beyond the extremes after an intervention [16]. In only two

items, the relevant missing values could be observed—this demonstrates good face validity of the EMUCQ. During the development stage, the questionnaire was tested for content validity by expert ratings [43] and face validity through cognitive interviewing with EMU patients [23]. This rigorous procedure may have contributed to the high acceptance of the questionnaire and ensured the willingness of the patients to participate in questioning [16].

This pilot study was conducted mainly to detect the feasibility of a multicenter validation study of the EMUCQ. The aim was to find out how long it would take to collect 300 complete questionnaire sets. Based on the scheduled time span for the validation study of six months, the number of EMUs to include and the number of questionnaires to collect by each of the centers were calculated. Like most of the EMUs, the Salzburg EMU is a four-bed ward. On average, two patients per week were recruited. Almost all the patients who were asked were willing to participate. However, 58 patients (55.24%) did not fulfill the inclusion criteria because of age, language barriers, or cognitive impairment. As Polit and Yang [16] report random sampling in validation studies is difficult. Therefore, they suggest conducting a multicenter study. In this way, it is possible to include the participants of different places to enhance the sample's variation in demographic characteristics. Furthermore, the sample size needed to validate the scale might be reached earlier [16]. Several EMUs were approached via the e-mail and telephone: eight, out of 11 eligible centers, confirmed their participation. It took four months (April–July, 2018) until all the centers agreed, and another six months (until January, 2019) until all the ethics votes were granted. The need to submit applications to any competent ethics commission and the differences in application formalities resulted in a time-consuming procedure. In Germany, a project for coordinated counseling in ethics issues with a limited number of participating ethics commissions is running [44]. Despite a coordination commission, applicants have to send the documents to each of the commissions involved. This does not really simplify the procedure. It would be preferable to name one coordinating ethics commission for a multicenter study with its decision being valid for all participating study centers.

4.1. Lessons learned

When planning a multicenter study, it is essential to perform intensive networking and staying in contact with research partners [45,46]. Ideally, one is familiar with the chairperson of the center that is planned to be included. Well-known supervisors with good connections within the scientific community are helpful for PhD students. However, for a future career in research, it is necessary for students to know the essentials of networking. Socializing on different occasions—e.g., congresses and conferences—and cultivating these contacts must be practiced. To improve these skills, it is obligatory to attend scientific events when in doctorate study programs. In this study, differences could be observed in how applications for ethics votes had to be made and how the ethics commissions handled fees for their votes. While some ethics commission did not charge a fee for nonfunded PhD research projects, others preferred (reduced) fees. It is advisable to ask in advance if there would be any fee to pay and how much discount could be expected because fees might be quite high. Furthermore, enough time must be arranged because ethics commissions usually meet just once a month and mostly demand amendments in the study protocol.

5. Conclusion

Conducting a pilot study turned out to be inevitable to assess the feasibility of a multicenter study and to estimate the time required. Trends regarding item properties can be detected. Being careful in developing a questionnaire by including content validity rating as well as cognitive interviewing will pay off while using the questionnaire in a field study. Low rates in missing values and dropouts are proof of that. Networking and cultivating contacts is important when establishing a research group. Enough time must be provided for because it may last months until the required centers have joined the group and all ethics votes are gained.

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Declaration of Competing Interest

None.

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