Advancing Patient-Oriented Clinical Pharmacy Education in Germany: Evaluation and Application of Objective Structured Clinical Examination-Based Training on Counseling for Pharmacy Students

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I. Eidesstattliche Erklärung

Hiermit versichere ich an Eides statt, dass die vorgelegte Dissertation mit dem Titel:

Advancing Patient-Oriented Clinical Pharmacy Education in Germany: Evaluation and Application of Objective Structured Clinical Examination-Based Training on Counseling for Pharmacy Students

von mir selbstständig und ohne unzulässige fremde Hilfe unter Beachtung der Grundsätze zur Sicherung guter wissenschaftlicher Praxis an der Heinrich-Heine-Universität Düsseldorf erstellt worden ist. Die Dissertation wurde in der vorgelegten oder in ähnlicher Form noch bei keiner anderen Institution eingereicht. Ich habe bisher keinen erfolglosen Promotionsversuch unternommen.

Düsseldorf, den 05.08.2021 Imaneh Farahani

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III. Zusammenfassung

In den letzten Jahrzehnten gab es in der Apothekenpraxis einen Paradigmenwechsel von ihrem ursprünglichen Fokus auf der Abgabe von Arzneimitteln hin zu einer patientenzentrierten pharmazeutischen Versorgung. Dabei stellt die Patientenberatung einen wichtigen Bestandteil der patientenzentrierten Versorgung dar. Der Übergang zu einem patientenorientierteren universitären Pharmaziestudium wurde weltweit in unterschiedlichem Maße verwirklicht. So sind patientenorientierte Aspekte der Lehre im deutschen Pharmaziecurriculum im Vergleich zu den Vereinigten Staaten von Amerika und einigen europäischen Ländern wie den Niederlanden noch unterrepräsentiert. Patientenorientierte Kompetenzen im Pharmaziestudium können durch den Einsatz von kompetenzbasierten Methoden gefördert werden, beispielsweise durch den Einsatz von *Objective Structured Clinical Examinations* (OSCEs) als Lehrmittel zur Vermittlung von Beratungskompetenzen.

In dieser Arbeit wurde der Einsatz von OSCEs als Lehrmittel für Pharmaziestudierende in drei Studien evaluiert, wobei in zwei Studien die Beratung zum Indikationsbereich Diabetes mellitus als Beispiel für eine chronische Erkrankung behandelt wurde und in einer Studie die Selbstmedikationsberatung. Dazu wurden in allen drei Studien die Auswirkungen der OSCE-basierten Trainings auf die Beratungs- und Kommunikationsfähigkeiten der Studierenden sowie deren Selbstsicherheit beziehungsweise selbstwahrgenomme Kompetenz vor und nach dem Training erhoben. Auch die Zufriedenheit der Studierenden mit den Seminaren wurde erhoben. In der ersten Studie wurde das OSCE-basierte Training als Teil eines *Blended Learning*-Formats in einem Pre-Post-Design mit einer einzelnen Gruppe untersucht und zeigte vielversprechende Ergebnisse. Dies führte zu der Hypothese, dass ein OSCE-basierter Trainingsansatz die Beratungsfähigkeiten von Pharmaziestudierenden verbessert, die in den darauffolgenden zwei Studien untersucht wurde. Dazu wurde in der zweiten Studie diese Hypothese unter Verwendung einer Kontrollgruppe untersucht und auf die Selbstmedikationsberatung übertragen. In dieser randomisierten kontrollierten Studie mit Pre-Post-Design absolvierte die Interventionsgruppe ein OSCE-basiertes Training zur Selbstmedikationsberatung, während die Kontrollgruppe beratungsrelevante Informationen aus Fachinformationen rezeptfreier Arzneimittel sammelte. Im Allgemeinen war die Mehrheit der Studierenden mit dem Seminar zufrieden. Während die OSCE-trainierte Gruppe einen signifikant größeren Anstieg der Beratungsfähigkeit und der Selbstsicherheit beziehungsweise selbstwahrgenommen Kompetenz als die Kontrollgruppe aufwies, zeigten beide Gruppen einen ähnlichen Anstieg der Kommunikationsfähigkeiten. In der dritten Studie wurde der Trainingsansatz modifiziert und es wurde untersucht, ob ein OSCE-basiertes Training im Vergleich zu einer Kontrollgruppe zu einer signifikant größeren Verbesserung der Beratungsfähigkeiten von Pharmaziestudierenden hinsichtlich der Indikation Diabetes mellitus führt. In dieser randomisierten kontrollierten Studie, durchgeführt in einem Pre-Post-Design, absolvierte die Interventionsgruppe ein OSCE-Training zur Beratung mit dem Fokus auf den Indikationsbereich Diabetes mellitus, während die Kontrollgruppe Patientenfälle zur Indikation Diabetes mellitus

nach dem *Subjective Objective Assessment Plan* Schema bearbeite und diskutierte. Die OSCE-trainierte Gruppe zeigte eine signifikant größere Steigerung der Beratungs- und Kommunikationsfähigkeiten sowie der Selbstsicherheit beziehungsweise selbstwahrgenommen Kompetenz als die Kontrollgruppe. Beide Gruppen waren im Allgemeinen mit dem Seminar zufrieden.

Der OSCE-basierte Trainingsansatz sowohl für die Beratung im Selbstmedikationsbereich als auch im verschreibungspflichtigen Bereich (mit dem Schwerpunkt Diabetes mellitus) ist ein wertvolles Werkzeug um Pharmaziestudierenden Beratungsfähigkeiten zu vermitteln. Das in dieser Dissertation untersuchte OSCE-basierte Training trägt dazu bei, die Lücke in der patientenorientierten Ausbildung im deutschen universitären Pharmaziecurriculum zu schließen.

IV. Summary

The past decades have seen a paradigm shift in pharmacy practice from its original focus on medical product distribution towards patient-centered pharmaceutical care, with patient counseling playing a key role. While the movement to a more patient-oriented pharmacy university curriculum has been achieved to varying degrees throughout the world, it is relatively lacking in Germany compared to the United States of America and some European countries, such as the Netherlands. Patient-oriented competencies in pharmacy education could be promoted using a competency-based method, such as objective structured clinical examinations (OSCEs) applied as a tool for teaching counseling.

This work evaluated the value of OSCEs as a teaching tool through 3 studies: 2 focusing on counseling for a chronic disease, specifically diabetes mellitus, and 1 concerning self-medication counseling. The impact of OSCE-based training on students' counseling and communication skills, as well as students' self-confidence or self-perceived proficiency was evaluated before and after the training for each study. The students' satisfaction with the respective seminar was also assessed for each study. In the first study, OSCE-based training integrated into a blended learning setting was evaluated in a pre-post design with a single group and showed promising results. This led to the hypothesis that an OSCE-based training approach improves pharmacy students' counseling skills, which was investigated in the subsequent 2 studies. Therefore, in the second study, this hypothesis was investigated using a control group and transferring to self-medication counseling. In this randomized controlled study using a pre-post design, the intervention group completed OSCE-based self-medication training, while the control group collected counseling-relevant information from summaries of product characteristics of non-prescription drugs. The majority of students were generally satisfied with the seminar. While the OSCE-trained group demonstrated significantly greater increases in counseling skills and self-confidence or self-perceived proficiency than the control group, both groups had similar increases in communication skills. In the third study, the training approach was modified and it was evaluated whether OSCE-based training leads to a significantly greater increase in pharmacy students' counseling skills concerning diabetes mellitus compared to a control group. In this randomized controlled study using a pre-post design, the intervention group received diabetes-focused OSCE-based training, while the control group solved diabetes-focused patient cases by preparing subjective, objective, assessment, and plan notes and discussing them. The OSCE-trained group demonstrated significantly greater increases in counseling and communication skills and self-confidence or self-perceived proficiency than the control group. In general, both groups were satisfied with the seminar.

OSCE-based training in both self-medication and prescription drug counseling (with the focus on diabetes mellitus), is a valuable tool for teaching pharmacy students counseling skills. The OSCE-based training examined in this dissertation contributes to closing the gap in patient-oriented education in the university's pharmacy curriculum.

V. Table of Contents

VI. List of Abbreviations

AAppO	Licensing Regulations for Pharmacists (*Approbationsordnung für Apotheker*)
ApBetrO	Ordinance on the Operation of Pharmacies (*Apothekenbetriebsordnung*)
APhA	American Pharmacists' Association
approx	Approximately
ASHP	American Society of Health-System Pharmacists
BPhD e.V.	Federal Association of Pharmacy Students in Germany (*Bundesverband der Pharmaziestudierenden in Deutschland e. V.*)
CoDia-study	Randomized controlled study on OSCE training for diabetes counseling
CoSeMed-study	Randomized controlled study on OSCE training for self-medication counseling
COVID-19	Coronavirus disease 2019
DRP	Drug-related problem
eg	*Exempli gratia*, for example
FIP	International Pharmaceutical Federation
GOSCE	Group objective structured clinical examination
GPP	Good pharmacy practice
ie	*Id est*, that is
IPSF	International Pharmaceutical Students' Federation
IQR	Interquartile range

ITOSCE	Interprofessional team objective structured clinical examination
NA	Not applicable
NPM	Non-prescription medicine
OSATS	Objective structured assessment of technical skill
OSCE	Objective structured clinical examination
OSPE	Objective structured practical examination
OSPVE	Objective structured practical veterinary examination
OTC	Over-the-counter
PCE	Patient Counselling Event
PrOSCE	Practice OSCE
pp	Percentage points
SD	Standard deviation
SiGDia-study	Single group study on OSCE training for diabetes counseling integrated into a blended learning setting
SmPC	Summary of product characteristics (*Fachinformation*)
SOAP	Subjective, objective, assessment, and plan
SP	Standardized/simulated patient
TOSBA	Team objective structured bedside assessment
TOSCE	Team objective structured clinical examination
USA	United States of America
USP	United States Pharmacopeia
WHO	World Health Organization

VII. List of Tables

VIII. List of Figures

1. Introduction

1.1 The Role of Pharmacists in Health Care

Pharmacists are experts in drug therapy and well-accessible health care professionals.[1-3] A review by Tsuyuki et al suggested that "primary care pharmacists see their patients somewhere between 1.5 and 10 times more frequently than they see primary care physicians."[4] In Germany, it is estimated that community pharmacies have 1 billion patient contacts per year.[5] The role of pharmacists has expanded over time beyond dispensing medicines.[3,6,7] Indeed, their role has transformed to a rather patient-centered focus and they are confronted with diverse health issues such as poor adherence to prescribed medicines and prescribing errors.[7-9] Although the literature indicates that pharmacists' interventions have the potential to improve patients' health outcomes,[10-12] the scope of pharmaceutical services and activities provided in pharmacies varies from country to country depending on their legislation and regulations.[13,14] The World Health Organization (WHO) and the International Pharmaceutical Federation (FIP) have published a joint guideline on good pharmacy practice (GPP) to provide guidance for national pharmacy professional associations worldwide on how pharmacists can contribute to the improvement of access to health care, health promotion and the use of drugs for their patients. They outlined 6 major components of pharmacy practice*:* "being readily available to patients with or without an appointment"; "identifying and managing or triaging health-related problems"; "health promotion"; "assuring the effectiveness of medicines"; "preventing harm from medicines; and" "making responsible use of limited health-care resources."[15] Moreover, the GPP guideline delineates important roles and functions of pharmacists in community and hospital settings encompassing "1. [p]repare, obtain, store, secure, distribute, administer, dispense and dispose of medical products"; "2. [p]rovide effective medication therapy management"; "3. [m]aintain and improve professional performance"; and "4. [c]ontribute to improve effectiveness of the health-care system and public health."[15]

This wide spectrum of pharmaceutical activities and services has also been implemented to a large extent on the national level in Germany and has the legal

basis in the "Ordinance on the Operation of Pharmacies" (*Apothekenbetriebsordnung*, ApBetrO). According to this ordinance, the pharmaceutical activities comprise along with dispensing of and counseling on medicines, the development and manufacture of medicines, testing of starting materials or drugs, observation, collection, and evaluation of drug risks and medication errors, and medication management.[16] Furthermore, services customarily rendered by a pharmacy are for example counseling on health and nutrition issues, health education and information, preventive measures, and medical devices as well as performing simple health tests, patient-individual adjustment of medical devices, and conveying health-related information.[16]

In the scope of pharmacists' extensive range of tasks in health care, patient counseling is one of the pharmacists' key tasks.[17,18] In the joint FIP/WHO GPP guideline, it is emphasized that pharmacists "should provide advice to ensure that the patient receives and understands sufficient written and oral information to derive maximum benefit for the treatment" when dispensing medicines.[15] In pharmacy literature, different definitions of the term counseling can be found,[18] with some being more detailed and comprehensive than others.[18-22] For example, Palaian et al defined patient counseling based on the "United States Pharmacopeia (USP) Medical Counseling Behavior Guidelines"[23] as "providing medication related information orally or in written form to the patients or their representatives, on topics like direction of use, advice on side effects, precautions, storage, diet and lifestyle modifications"[19] and thus, referring to the content of counseling. Puspitasari et al outlined in their review the content of counseling[18] based on various guidelines including the "Omnibus Budget Reconciliation Act of 1990,"[24] "Guidelines for Pharmacists on Providing Medicines Information to Patients" (1996) of the Pharmaceutical Society of Australia,[25] "USP Medication Counseling Behavior Guidelines" (1997),[23] "ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling" (1997) of the American Society of Health-System Pharmacists (ASHP),[26] and "Guidelines for Pharmacist Counseling of Geriatric Patients" (1998) of the American Society of Consultant Pharmacists.[27] Puspitasari et al found agreement between the guidelines on the following counseling contents: "name and description of the medicine, indications, route of administration, dose and dosage

form, directions for use, duration of therapy, special directions, precautions, side effects, and contraindications." Additionally, they emphasized that pharmacists need to determine patients' understanding of their medications by posing a number of questions to the patient.[18] Patient counseling by pharmacists is vital as it serves as the final check for the prescription before the medication is handed over to the patient.[28] Regarding counseling on non-prescription medicines (NPMs), the pharmacist is responsible for deciding whether a patient can be self-treated or referral to a physician is necessary because it is beyond the pharmacist's scope of practice (triaging).[29] Adequate patient counseling helps to improve patients' adherence[30] and to identify and resolve drug-related problems for prescription and NPMs.[28,31-34]

Adherence is vital for achieving therapy success and is defined as "the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider."[35] Poor adherence can be associated with a higher economic burden, poor health outcomes, adverse clinical events, and mortality.[35-37] Although the consequences of nonadherence can be devastating, adherence to long-term therapy for chronic diseases is not always present. For example, the WHO states that adherence to long-term therapy for chronic diseases is around 50% in developed countries and even lower in developing countries.[35] However, that number, which is frequently cited in the literature, should be interpreted cautiously.[38] In particular, Mathes et al followed the cited references, the WHO statement is based on, and found that the cited studies "are not suitable to assume such generalized adherence estimation."[38] Nevertheless, adherence is a factor in therapy that should not be treated lightly. The possible reasons for poor adherence are manifold and can be unintentional and/or intentional.[39,40] Intentional nonadherence arises from patients' beliefs and is based on an active decision whether to take or not to take medications.[39,40] Among others, concerns about adverse events or doubts about the necessity of medication might lead to patients adjusting doses or taking "drug holidays."[40] Unintentional nonadherence is associated with the patients' "demographics, primarily age, and clinical variables."[39] For example, forgetfulness, misunderstanding of instructions, cognitive impairments, visual impairments, or reduced manual dexterity can

result in unintentional nonadherence.[35,39,40] Literature suggests that pharmacists have the potential to improve patients' adherence to long-term therapy.[30,35,36,41,42] For example, pharmacists' interventions for addressing adherence of patients with diabetes can include "education, consultation, medication review, printed/digital material, telephone calls, daily record books, training and group discussions, or other (referrals, blood glucose meters, and pillbox)."[42]

A drug-related problem (DRP) is defined as "an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes."[43] Several studies support pharmacists' potential in detecting and resolving DRPs,[28,31-34] with some of them conducted in Germany.[31,32,34] For example, a study by Nicolas et al analyzed DRPs in prescribed drugs, which were identified by community pharmacists in German pharmacies at the time of dispensing. Their investigation revealed "0.23 DRPs per patient and 0.13 DRPs per prescribed medicine."[34] The most frequent causes for DRPs in the study were "[p]otential drug–drug interaction," "dose not known to patient," "patient insecure due to generic substitution," and "insufficient patient knowledge of correct drug use."[34] The DRPs were mainly addressed by pharmacists' counseling in the study.[34] In another study by Eickhoff et al focusing on DRPs in self-medication in Germany at the time of drug dispensing, community pharmacists found DRPs in 17.6% out of 12567 self-medication requests (ie, approximately 1 out of 5 encounters) with "inappropriate self-medication, inappropriate requested drug, duration of drug use too long (including abuse), and wrong dosage" being the most frequent. Moreover, according to the pharmacists participating in that study, approximately 90% of the DRPs could partially or completely be solved.[31] These results support the importance of patient counseling by pharmacists on both prescription and non-prescription medicines.

However, the literature indicates room for improvement in community pharmacy staff's counseling skills.[44-47] For example, a study by Langer et al explored the quality of counseling on acute diarrhea in German pharmacies and revealed the potential for optimization regarding counseling on acute diarrhea in almost all investigated pharmacies. They found an overall rather poor quality of counseling in pharmacy staff. In addition, they investigated the difference in counseling quality between a symptom-based request and a direct product-based request

and found that the symptom-based requests achieved significantly higher scores as compared to the direct product-based requests. The authors assumed that the patients' wish for specific active ingredients leads to the pharmacy staff seeing little need for counseling and not differentiating them according to different user groups. In addition, they state that appropriate training is a prerequisite for adequate counseling and suggest training and assessing patient counseling as an example to improve the quality of counseling.[44] Watson et al indicated poor consultation performance in community pharmacies mostly due to "inadequate information gathering or advice provision."[48] It is vital to gather pertinent details from patients and disclose relevant information to them to address their conditions and therapy appropriately.[49,50] Besides poor quality of counseling, other researchers indicated also a lack of counseling.[18,51] For example, an observational study in swiss community pharmacies revealed that counseling was provided to 66.0% of the patients with prescription medicines.[51] A review on an international level by Puspitasari et al indicated that counseling rates ranged from 8% to 100% depending on the research method used (eg, observational studies or self-reported pharmacist studies) and type of prescription (eg, repeat prescription or new prescription).[18] Adequate training might address deficiencies in counseling performance, as indicated in the literature.[52]

1.2 Current Pharmacy Education in Germany

The past decades have seen a paradigm shift in pharmacy practices from its original focus on medical product distribution towards patient-centered pharmaceutical care, with patient counseling playing a key role.[7,53] This movement in pharmacy practice should be also addressed in academic pharmacy education to ensure successful pharmaceutical care of patients by pharmacists.[7,13] The movement to clinical pharmacy and clinical pharmacy education began in the United States of America (USA) between the 1960s and 1970s, with some mentions prior to that.[54-56] Clinical pharmacy is described by the American College of Clinical Pharmacy as “a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention.”[57] Over the years, reports from organizations across the world reinforced or suggested the movement to patient-oriented education.[7,58-60] For example, in their year 2000 Statement of Policy on Good Pharmacy Education Practice, the FIP emphasized that patient-focused pharmaceutical care should be a mandatory part of the curriculum.[58] While the movement to a more patient-oriented pharmacy curriculum has been achieved to varying degrees throughout the world, it is relatively lacking in Germany compared to the USA and some European countries, such as the Netherlands.[13,61-63] The “Licensing Regulations for Pharmacists“ (*Approbationsordnung für Apotheker*, AAppO), which legally regulates the German pharmacy curriculum, established clinical pharmacy as a teaching and examination subject with the second regulation for the revision of the AAppO in 2000 (*Zweite Verordnung zur Änderung der Approbationsordnung für Apotheker*).[64,65] This regulation was entered into force in 2001[65] and implemented clinical pharmacy aspects, such as pharmaceutical care, patient cases, and drug therapy assessment, into pharmacy education.[64] The current university pharmacy curriculum is comprised of 2 phases: phase 1 (semesters 1 to 4) focuses mainly on the natural sciences (eg, chemistry, biology, mathematics, physics, and pharmaceutical technology) and introduces few medical subjects (eg, anatomy and physiology) while phase 2 (semesters 5 to 8) deepens the knowledge acquired in those disciplines and introduces biopharmacy, pharmacology, and clinical pharmacy.[64] After completing the academic portion of the degree,

students must complete a practical year, with at least 6 months performed in a community pharmacy.[64] Notably, clinical pharmacy in Germany accounts for a minor fraction of the total pharmacy curriculum compared to drug-centered subjects, such as pharmaceutical chemistry.[63,66] The German pharmacy curriculum is still deemed drug-oriented, with continued demands for more patient-oriented pharmacy education and fostering clinical content.[13,61,67]

The pharmacy curriculum, as well as the extent of clinical pharmacy services, varies between countries.[13] A survey by Rose et al involving experts from 12 countries indicated that there might be a linear correlation between aspects of education/research and the implementation of clinical pharmacy services. For example, the pharmacy curriculum in Germany, Austria, and Bosnia-Herzegovina was drug-oriented while in some other countries, including Canada, the USA, Belgium, Switzerland, Australia, Netherlands, Japan, Kosovo, and Thailand, had curriculums that were patient-oriented, both patient- and drug-oriented, or were shifting from drug- to patient-oriented.[13] Rose et al concluded that education and research need to be addressed to ensure the successful implementation of clinical pharmacy services.[13] Importantly, patient-oriented aspects in German pharmacy education are not only demanded from a scientific standpoint[13,61] but also by the German "Federal Chamber of Pharmacists" (*Bundesapothekerkammer*).[67,68]

Apart from therapy recommendations being treated on the basis of patient cases, the German AAppO provides no further information concerning teaching methods for conveying clinical pharmacy skills.[64] In 2017, the German Federal Chamber of Pharmacists published a competency-oriented catalog of learning objectives, which are regarded as recommendations, to further develop pharmacy education. Concerning the field of community pharmacy, this document emphasized the implementation of competency-oriented teaching, learning (eg, problem-based learning), and examination formats, such as objective structured clinical examinations (OSCEs).[68] Based on the document "*Apotheke 2030*"[69] they derived 6 pharmacist competency areas: pharmaceutical expertise ("*Pharmazeutisches Fachwissen*"), scientific work and research ("*Wissenschaftliches Arbeiten und Forschen*"), communication ("*Kommunikation*"), intra- and interprofessional collaboration ("*Intra- und*

interprofessionelle Zusammenarbeit"), pharmacist attitude and ethics ("*Apothekerliche Haltung, Ethik*"), and management ("*Management*").[68] In 2020, the "Federal Association of Pharmacy Students in Germany" (*Bundesverband der Pharmaziestudierenden in Deutschland e.V.*, BPhD e.V.) published a position paper on pharmacy education and licensing regulations for pharmacists, demanding changes to the German pharmacy curriculum and offering recommendations. Among these, the BPhD e.V. suggested that pharmacy studies be extended by 2 semesters and demanded that this extra time be used to deepen and expand clinical pharmacy and pharmacology.[70] These reports indicate that the pharmacy curriculum in Germany might need educational approaches to promote patient-oriented education. The need for patient-oriented education in Germany is further supported by the fact that the majority of the pharmacists in Germany work in community pharmacies.[71] One method to implement these changes in a competency-based and practice-oriented way could be the use of OSCEs.

1.3 Objective Structured Clinical Examinations

1.3.1 Definition and Characteristics of Objective Structured Clinical Examinations

Objective structured clinical examinations, abbreviated OSCEs, were firstly described by Ronald Harden and colleagues in 1975 as a practice-based approach to assess students' clinical competencies.[72,73] OSCEs were developed at the University of Dundee for medical students with the intention to replace the traditional clinical examinations which are associated with some drawbacks such as potential subjectivity or bias associated with examiners' assessment of students.[72] In particular, Harden defined OSCEs as "an approach to the assessment of clinical competence in which the components of competence are assessed in a planned or structured way with attention being paid to the objectivity of the examination."[74] During an OSCE, examinees interact, for example, with a patient and are observed and scored by an examiner who fills out checklists and/or rating scales.[72-75] Besides procedure stations, where examinees perform a clinical task on someone, question stations are possible, where examinees' task is to answer questions, usually based on information obtained at the previous station.[72,73,75] The examinees rotate around a series of stations within a predetermined period of time and each station focuses on 1 or more elements of clinical competence.[72-75] Variables in an OSCE, but also in other clinical examinations, are the student (examinee), the patient, and the examiner.[72-75] However, in an OSCE the variables examiner and patient are more controlled.[72-75]

During OSCEs, patients can be represented, for example, by real patients, simulated patients, standardized patients, manikins, video recordings of a patient, results of patient investigations, patient medical records, or text descriptions of patients.[72,74] The OSCE encounter is not limited to 1 person and a patient can be accompanied by a relative such as a husband/wife or parent.[72,74,75] Moreover, OSCEs can also include other health care professionals in addition to or instead of patients, for example, to assess students' competencies in interprofessional collaboration.[72,74,76] Although in the literature the terms "standardized patient" and "simulated patient" are extensively discussed, inconsistent definitions can be

found,[77-82] with some researchers using the terms interchangeably[80-82] and others differentiating between both terms with heterogeneous definitions.[77-79] In the interest of simplification in this work, the terms “standardized/simulated patient” (SP) are considered interchangeable and refer to an individual (faculty member or student) who plays patient and is instructed to adhere to the script in order to achieve ideally standardized conditions. Generally, the role of SPs can be performed by actors, faculty members, or students depending on their availability with each having advantages and disadvantages. For example, actors as SPs have the advantage of being unfamiliar to the students and thus, contributing to the fidelity of the encounter.[83,84] However, they may be expensive, and their ability to provide feedback on some skills, if required, may be limited.[83,84] Faculty members as SP can provide extensive feedback, if required, are accepted by students, and benefit from the SP experience by getting insights into students' abilities.[83,84] However, they may deviate from scripts, provide clues to students, and might intimidate students as they are familiar to them.[83] Students performing the SPs regard this experience as a contribution to their own learning and student SPs might be less intimidating to students as compared to faculty members.[83] Nevertheless, Mavis et al reported that student examinees regard peer SPs as the least valuable patient encounter.[83]

The role of the examiner can be performed by faculty members,[85,86] health professionals,[72] students[72,85] or SPs[72,86-88]. In this work, the terms “examiner”, “rater”, “assessor” and “observer” are used interchangeably. Performing the role of examiner provides students a useful learning activity.[89,90] Furthermore, Moineau et al suggested that student assessors seem to be capable of rating students’ performance regarding completing checklists and providing feedback. They found a higher correlation between faculty assessors and student assessors for checklists as compared to global rating scales.[85] The use of SPs as assessors is considerably debated in the literature.[86,88,91,92] SPs as assessors can have some drawbacks. The combination of acting and assessing simultaneously can be challenging and Newlin-Canzone et al emphasized that “[t]he need to simultaneously portray a character and assess a learner may affect the ability of standardized patients to accurately observe the learner’s nonverbal behaviors especially when they are required to improvise responses to

unexpected questions."[88] Moreover, the literature indicates that SPs' ratings can differ from faculty assessors.[86,91,92] The literature describes different explanations for this deviation. For example, the assessment of the SPs is dependent upon their memories as they usually have to wait until the end of students' performance to complete the grading rubric, while a faculty member with the sole task of observing can assess the student throughout the performance.[86] Additionally, the SPs are more involved in the students' performance which might affect the SPs' perception of the performance.[86]

As the name implies, further pivotal elements of OSCEs are the objectivity, structure, and clinical aspects.[74] The use of checklists and/or rating scales, in which it is predefined what is going to be assessed, contributes to the objectivity of OSCEs.[74,75,93,94] Checklists state "what is expected of the student at the station."[72] With checklists assessors observe students' performance in OSCEs and the individual checklist scores achieved at a station reflect the proportion of actions carried out by the student during the performance.[95] A rating scale serves as an overall assessment instrument, in which the performance is usually rated on a continuum (eg, from "poor" to "excellent").[72] A global rating scale may assess students' general performance or a specific aspect such as communication skills.[86,94,96] When using a global rating scale for assessing communications skills, verbal and non-verbal communication skills, such as "body language, empathy, and organization of speech," can be addressed.[86] In the literature, the application of analytical checklists versus global rating scales or in combination is discussed.[72,91,95-97] The objectivity of OSCEs is also supported by other aspects such as the assessment of a wide range of skills over a number of stations.[72,74] The structured aspects of OSCEs are promoted by the prior planning of the objectives and content of the OSCEs as well as the competencies which are going to be assessed, for example, by preparing an OSCE blueprint.[72,74] The clinical aspect of OSCEs is reflected by the fact that OSCEs are clinical or practical-based examination which addresses how students put their theoretical knowledge into practical use rather than only "knowing".[72,74,75]

Miller outlined different levels of clinical assessment in education setting and ranked them in the Miller's pyramid[98,99] (Figure 1-1):

- "knows," which represents the baseline level;
- "knows how," which includes, but is not limited, to gathering information from different sources, analyzing and interpreting these data, and the translation into a plan;
- "shows how," which represents the performance in an artificial examination setting;
- "does," which addresses the clinical practice.[98]

OSCEs address the "show how" domain. With an increasing level in the Miller pyramid the professional authenticity increases.[99]

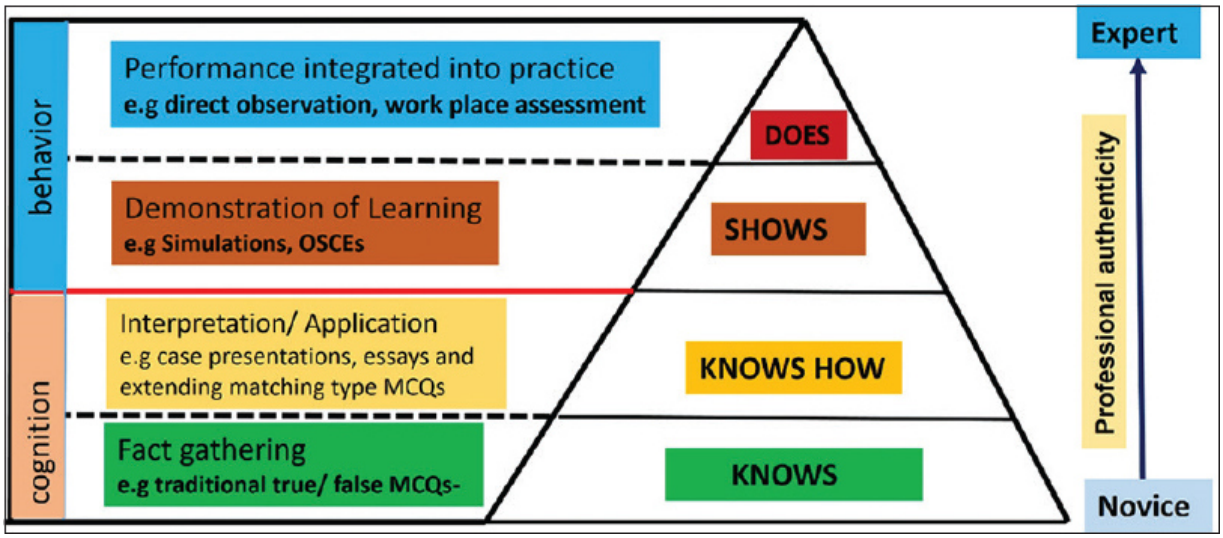

Figure 1-1: Miller's Pyramid

Reproduction from "Best practices to impart clinical skills during preclinical years of medical curriculum", by Sahu PK, Chattu VK, Rewatkar A, Sakhamuri S, 2019, *J Edu Health Promot*; 8:57. Copyright 2019 by Wolters Kluwer – Medknow.[99]

OSCEs have the potential to bridge the gap between academic knowledge and practical application[29] and provide a safe environment for students to apply clinical skills without risk to patients.[100-102] One goal of OSCEs described in the literature "is to provide a reasonably accurate real-world simulation of situations that students may face in order to understand how they will perform in similar circumstances."[76] OSCEs can encompass advantages as well as disadvantages, examples are depicted in Table 1-1.

Table 1-1: Examples of Advantages and Disadvantages of Objective Structured Clinical Examinations as Described in the Literature

Advantages	Disadvantages
• Assessment of a wide range of skills[73-75,101,103] • Flexible[74] • Safe environment for students to apply clinical skills without risk to patients[100-102] • Encouraging students to participate actively in their learning process[102] • Considered as more objective than traditional approaches of clinical examinations (eg, due to predefined decisions about content and competence going to be assessed) by some researchers[73-75] • Considered as more reliable than traditional approaches of clinical examinations by some researchers[75] • Considered as more valid than traditional approaches of clinical examinations by some researchers[75] • Opportunity for feedback[73,75]	• Time-consuming and increased preparation and organization required[73,75,102-104] • Costly[101,103,104] • Tendency to split student's knowledge and skills into compartments with possibly discouraging them to consider the patient as a whole[73,75] • Possibility of observer and SP fatigue[75,105]

SP = standardized/simulated patient.

Regarding the purposes of OSCEs, a distinction can be made between formative and summative OSCEs.[106] Formative OSCEs function as a learning tool[106] and enable the identification of deficiencies in students' skills,[97] while summative OSCEs are used for evaluation of clinical skills or knowledge, mostly as part of the end-of-year or final examinations.[106] Feedback, defined as "[s]pecific information about the comparison between a trainee's observed performance and a standard, given with the intent to improve the trainee's performance,"[107] is not only an essential part of formative assessment but should also be included in summative assessment.[108] Feedback can also be provided by peers. In this context, a randomized controlled study by Krause et al with dental students found improved communication after video-based feedback intervention, with no significant difference being observed between feedback provided by experts or peers.[109] Adequate feedback is discussed to be a crucial part of the learning process.[110,111] For example, Ende emphasized that "[w]ithout feedback, mistakes go uncorrected, good performance is not reinforced, and clinical competence is achieved empirically or not at all."[111] The power of feedback depends on different factors including, but not limited to, the skill addressed with feedback, type of feedback, feedback channel, and feedback direction.[112,113]

1.3.2 Variants of Objective Structured Clinical Examinations

After the "traditional" OSCE approach by Harden and colleagues was published,[73-75] variations of the OSCE came along over time and were described in the literature,[72,89,114-122] which might have the potential to address some obstacles of traditional OSCEs, as indicated in the literature.[89,114-117,120,122] An example is the group OSCE (GOSCE), in which the students complete the stations in small groups instead of individually.[114] GOSCEs are often used as a learning tool in a formative setting.[114,116,122] In GOSCEs, the students can observe each other executing the clinical task, discuss their performance and provide each other feedback.[114-116,122] GOSCEs have the potential to reduce costs, allow participants to benefit from the experience and expertise of the group members, and offer the opportunity to assess social skills.[114] For example, in the formative GOSCEs by Sulaiman et al, medical students were divided into groups of 4 to 5 and 1 student was assessed on the station task while being observed by the other

students and the clinical tutor. Following feedback from the tutor and peers, the students took turns in performing the tasks as they move around the stations.[116] In the interprofessional team objective structured clinical examination (ITOSCE) described by Symonds et al, formative OSCEs were used for interprofessional education in mixed groups of medical students and student midwives, with all members of the group participating at each station.[118] In addition, Brazeau et al modified OSCEs to a teaching tool. For these teaching OSCEs, clerkship students were divided into groups of 6 to 8 students with a faculty facilitator assigned to each group. During these teaching OSCEs, each student performed an OSCE station while being observed by the faculty facilitator and the remaining group members via a video monitor. Subsequently, a feedback session followed.[123] Similarly, Bevan et al applied their OSCE approach for practicing purposes as "totally peer-led multi-role practice OSCEs (PrOSCEs)." In these PrOSCEs, medical students took over the roles of student, examiner, and patient in 6 simulated stations designed by peers, and after each station, peer feedback was provided.[120] Further variations of the traditional OSCE are, for example, team objective structured bedside assessment (TOSBA),[72,119] team objective structured clinical examination (TOSCE),[72,117] objective structured practical examination (OSPE),[72] objective structured practical veterinary examination (OSPVE),[72] and objective structured assessment of technical skill (OSATS).[72] Moreover, the International Pharmaceutical Students' Federation (IPSF) organizes "Patient Counselling Events" (PCEs) in their annual world congresses as well in IPSF regional symposiums. The PCEs were "innovated by student organizations in United States pharmacy schools in the 1980s and supported by American Pharmacists' Association (APhA) and the United States Pharmacopeia (USP)".[53] PCEs are events in which students roleplay patient counseling scenarios and "compete in their patient counseling skills."[53] Similar to OSCEs, judges usually use checklists to evaluate students' performance and to provide feedback.[53]

Generally, the inclusion of peer learning in OSCEs, for example, in the format of peers as assessors or patients also contributes to the reduction of costs and simultaneously induces a learning experience[85,89,90] as mentioned above. Topping defines peer learning as "the acquisition of knowledge and skill through

active helping and supporting among status equals or matched companions."[124] Having this definition in mind, some of these above-mentioned variations of OSCEs with formative purpose can also be considered having elements of peer learning.

1.3.3 Objective Structured Clinical Examinations in Pharmacy Education

OSCEs were firstly introduced in the education of medical students,[73] but over time they were adopted in the education of other health care professionals, such as in pharmacy education. Countries such as the USA and Canada widely use OSCEs in pharmacy education.[125,126] Interviews conducted by Sturpe between 2008 and 2010 revealed that from 87 pharmacy schools in the United States included in their analysis, 32 reported using OSCEs. While almost all of the schools used summative OSCEs (n = 30), 18 used formative OSCEs.[125] Several publications describe the application of OSCEs in pharmacy education,[29,91,127-131] with the majority rather focusing on OSCEs as an assessment tool. Based on literature and internet search, in Germany, only a few of 22 universities with pharmacy studies apply OSCEs in pharmacy education. For example, at Johannes Gutenberg University Mainz, OSCEs with examination purposes are obligatory for pharmacy students according to their study regulations as of 2018,[132,133] while at the Ruprecht Karl University of Heidelberg OSCEs for pharmacy students were optional according to a publication as of 2018.[132] Moreover, the Rhenish Friedrich Wilhelm University of Bonn temporarily offered voluntary OSCEs from 2008 to 2013, but due to the resource intensity of OSCEs, the project was suspended after the university study fees have been eliminated, according to the publication mentioned above.[132] At the Philipps University of Marburg, a project on OSCEs for pharmacy students was implemented and evaluated in the summer semester 2018 after conducting a pilot project prior to that.[134] In addition, at Friedrich–Alexander University Erlangen–Nürnberg, a teacher-practitioner-project on bedside-teaching for pharmacy students was conducted which used OSCEs as an evaluation tool[135] and the research was published in 2017.[136]

OSCEs in pharmacy education differ from OSCEs in other health care professions' education, such as medicine.[91] Unlike other health care professions, community pharmacists' scope of practice regarding physical patient assessment is often limited to performing simple health tests.[16,91] Moreover, one of community pharmacists' key role is conducting patient counseling.[17,18] Pharmacists' performance within their scope of practice refers more to "verbal and non-verbal communication, observation, and review and management of patient information and medical information databases, for the purpose of identifying and resolving clients' drug-related problems or other health care needs."[91] Consequently, "questioning, listening, observing and problem-solving" are pivotal components of pharmacists' practice.[91] Therefore, pharmacy OSCEs should address these skills. For example, Hastings et al applied OSCEs to assess pharmacy students' counseling skills on NPMs.[29] In the study by Simansalam et al, OSCEs assessed students' counseling skills on smoking cessation and the correct usage of the peak flow meter and inhalers.[137] OSCEs as an assessment tool in pharmacy education have been frequently studied.[29,91,128-131] However, there is a lack of studies investigating the effect of OSCEs as a teaching tool for training pharmaceutical skills such as counseling on prescription drugs or NPMs in pharmacy students.

1.4 Diabetes Mellitus

Diabetes mellitus is defined as “a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both.”[138,139] Deficient action of insulin on target tissues leads to abnormalities in carbohydrate, fat, and protein metabolism.[138-140] Symptoms of hyperglycemia can include, but are not limited to, polyuria, polydipsia, weight loss, and blurred vision.[138-140] Moreover, hyperglycemia with ketoacidosis or the nonketotic hyperosmolar syndrome constitute acute and life-threatening consequences of uncontrolled diabetes.[138,139] Long-term consequences of diabetes mellitus are, for example, microvascular complications related to eyes, kidneys, and nerves, as well as a grown risk for cardiovascular, peripheral vascular, and cerebrovascular diseases.[138-141] Generally, diabetes mellitus can be classified into type 1 diabetes mellitus, type 2 diabetes mellitus, other specific types of diabetes mellitus, and gestational diabetes mellitus,[138,139,142] with type 2 diabetes mellitus accounting for 90% of cases.[143] Type 1 diabetes mellitus results from the destruction of β-cells of the pancreas and usually leads to an absolute insulin deficiency. A subdivision can be made into immune-mediated and idiopathic type 1 diabetes mellitus.[138,139,142] In type 1 diabetes mellitus, therapy is based on insulin therapy, blood glucose self-measurement, diabetes training, nutrition, and psychosocial care as well as the therapy of complications.[144] Also, comorbidities should be considered in the therapy.[144] Type 2 diabetes mellitus “may range from predominantly insulin resistance with relative insulin deficiency to a predominantly secretory defect with insulin resistance.”[138,139] The type 2 diabetes mellitus therapy comprises lifestyle modifications (including nutrition, physical activity, weight management, and smoking cessation), diabetes education, blood glucose self-measurement (particularly in situations recommended by guidelines), and pharmacotherapy as well as the therapy of comorbidities and complications.[145,146]

The worldwide diabetes prevalence was estimated to be 463 million people (9.3% of the global adult population) in 2019 and expected to increase to 700 million (10.9%) in 2045.[147] Nonadherence in diabetes patients is associated with poor glycemic control, increased risk of hospitalization, increased mortality, and higher costs.[148-151] Despite these consequences, poor adherence still occurs in patients

with type 1 diabetes mellitus[152] and 2 diabetes mellitus.[153] Several investigations have shown the benefits of involving pharmacists in the therapy management of diabetes mellitus patients.[10,154-156] The pharmacist interventions in the management of diabetes mellitus described in the literature are diverse and comprise among others counseling and education on the disease, medications, adherence, lifestyle modifications, and self-management.[156]

1.5 Self-Medication

The term “self-care” describes “what people do for themselves to establish and maintain health, prevent and deal with illness”[50] and comprises “self-medication, non-drug self-treatment, social support in illness, and first aid in everyday life” based on “health activities and health-related decision-making of”, for example, “individuals, families, friends,” and “colleagues at work.”[157] Self-medication, a part of self-care, is defined as “the selection and use of medicines […] by individuals to treat self-recognized illnesses or symptoms”[50] and represents a meaningful part of health care by providing patients direct and rapid access to treatment.[157] Access to NPMs, also referred to as over-the-counter (OTC) medications,[158] differs by law from country to country, and may, for example, be offered at pharmacies as well as retail outlets in some countries.[159,160] “Responsible self-medication” is present when “individuals treat their ailments and conditions with medicines which are approved and available without a prescription, and which are safe and effective when used as directed.”[50] Thus, self-medication enables patients to assume an active role in their health care with self-reliant management of minor ailments by using NPMs supported by health care professionals such as pharmacists.[157,158] Appropriate self-medication practices may be associated with economic advantages, including decreasing the need for medical consultations and the costs of community-funded health care programs.[157] Nevertheless, self-medication could be subject to risks including, but not limited to, incorrect self-diagnosis or choice of therapy, inadequate administration, inappropriate dosages, excessively prolonged use, dependence, abuse, improper storage, double medications, contraindications, or interactions, which could result in a rise in drug-induced diseases as well as wasteful public expenses.[157] Moreover, self-medication may cause a postponement in the diagnosis and treatment of serious medical conditions or mask the symptoms of a serious condition.[161] However, patients are not always mindful of the potential hazards of NPMs.[162] To ensure the safe, appropriate, and effective application of self-medication, pharmacists play an important role.[31]

Pharmacists can provide adequate counseling to ensure self-medication is performed appropriately by educating patients about a healthy lifestyle, recommending and advising about NPM-treatments, and referring patients to

physicians when symptoms indicate a potentially serious condition.[163] Ample research supports the beneficial impact of pharmacist intervention in NPM therapy.[31,164,165] When counseling patients on NPMs, the pharmacist has the responsibility to assess whether a patient can be self-treated within the pharmacist's scope of practice or a referral to a physician is necessary.[29] With their counseling, pharmacists can monitor the use of NPMs, detect DRPs, and intervene, if necessary, to achieve the safe, appropriate, and effective use of medicines.[31] To make appropriate decisions, the pharmacist needs to elicit the necessary information from the patient.[166] Among other things, the patient interview portion of counseling is also considered in the guideline for quality assurance for providing information and counseling to patients on the dispensing of self-medication drugs published by the German Federal Chamber of Pharmacists[167] (Figure 1-2). Moreover, the literature describes the use of different mnemonics for self-medication counseling intending to provide guidance for counseling.[49,168] An example is the WWHAM method with "W" for "What are the symptoms?", "W" for "Who is it for?", "H" for "How long have they had them?", "A" for "Action already taken?" and "M" for "Medicines being taken for other problems?".[169] The indications regarding self-medication are diverse. A systematic review by Limaye et al identified cough and cold, body pain, gastrointestinal complaints as the top reported self-medicated health complaints in the investigated studies.[170]

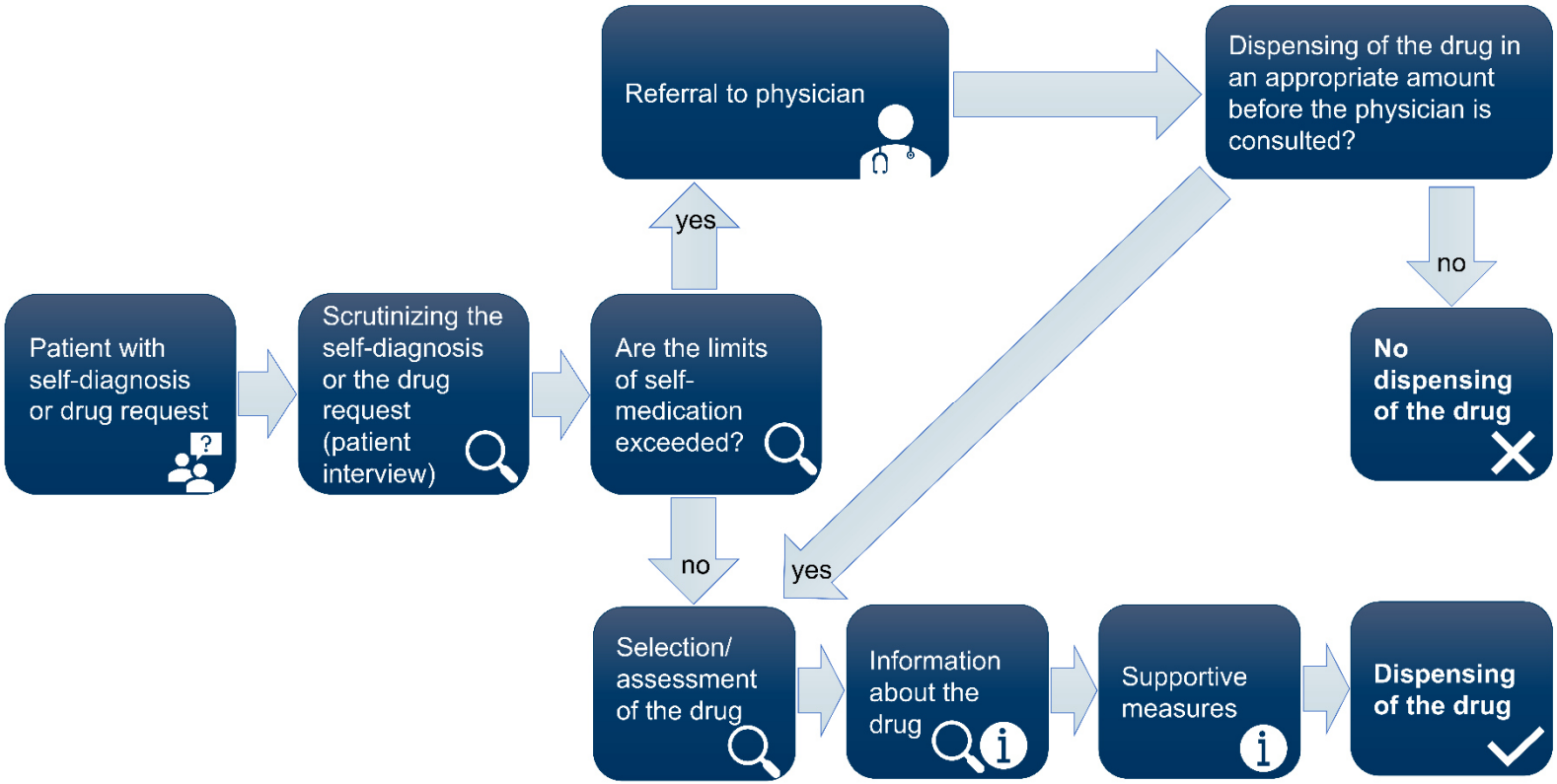

Figure 1-2: Simplified Process of Self-Medication Counseling

Based on the guideline of the German Federal Chamber of Pharmacists on quality assurance: information and counseling of patients when dispensing medicines – self-medication 2019, (*Leitlinie der Bundesapothekerkammer zur Qualitätssicherung: Information und Beratung des Patienten bei der Abgabe von Arzneimitteln – Selbstmedikation 2019*)[167] modified for the present work.

1.6 Aims

Demands for increased patient-oriented education in the German pharmacy curriculum have been made by the academic community[13,61] and the German Federal Chamber of Pharmacists.[67,68] This dissertation seeks to address this need by promoting the use of OSCEs as a teaching tool for patient-oriented and competency-based pharmacy education, particularly patient counseling. The impact of new educational approaches should be evaluated in educational research and the broad application of the approaches should be evidence-based.[171,172] Therefore, the overall aim of this dissertation was the evaluation of OSCEs as a tool for imparting pharmacy students with counseling skills in the scope of clinical pharmacy education. For that purpose, 3 studies involving OSCEs were performed and OSCEs were implemented in the clinical pharmacy course at Heinrich Heine Univerisity Düsseldorf (Figure 1-3). The aims of this dissertation were particularly:

1. Investigating the impact of OSCE training integrated into a blended learning setting to teach pharmacy students **diabetes mellitus** counseling.[173] (single group study on OSCE training for diabetes counseling integrated into a blended learning setting, abbreviated as **SiGDia-study**; chapter 2)
2. Investigating the efficacy of an OSCE-based approach to train pharmacy students in **self-medication** counseling using a randomized controlled design.[174] (randomized controlled study on OSCE training for self-medication counseling, abbreviated as **CoSeMed-study**; chapter 3)
3. Investigating the efficacy of an OSCE-based approach to train pharmacy students in **diabetes mellitus** counseling using a randomized controlled design.[175] (randomized controlled study on OSCE training for diabetes counseling, abbreviated as **CoDia-study**; chapter 4)
4. Implementation of OSCEs in clinical pharmacy education at Heinrich Heine University Düsseldorf. (chapter 5)

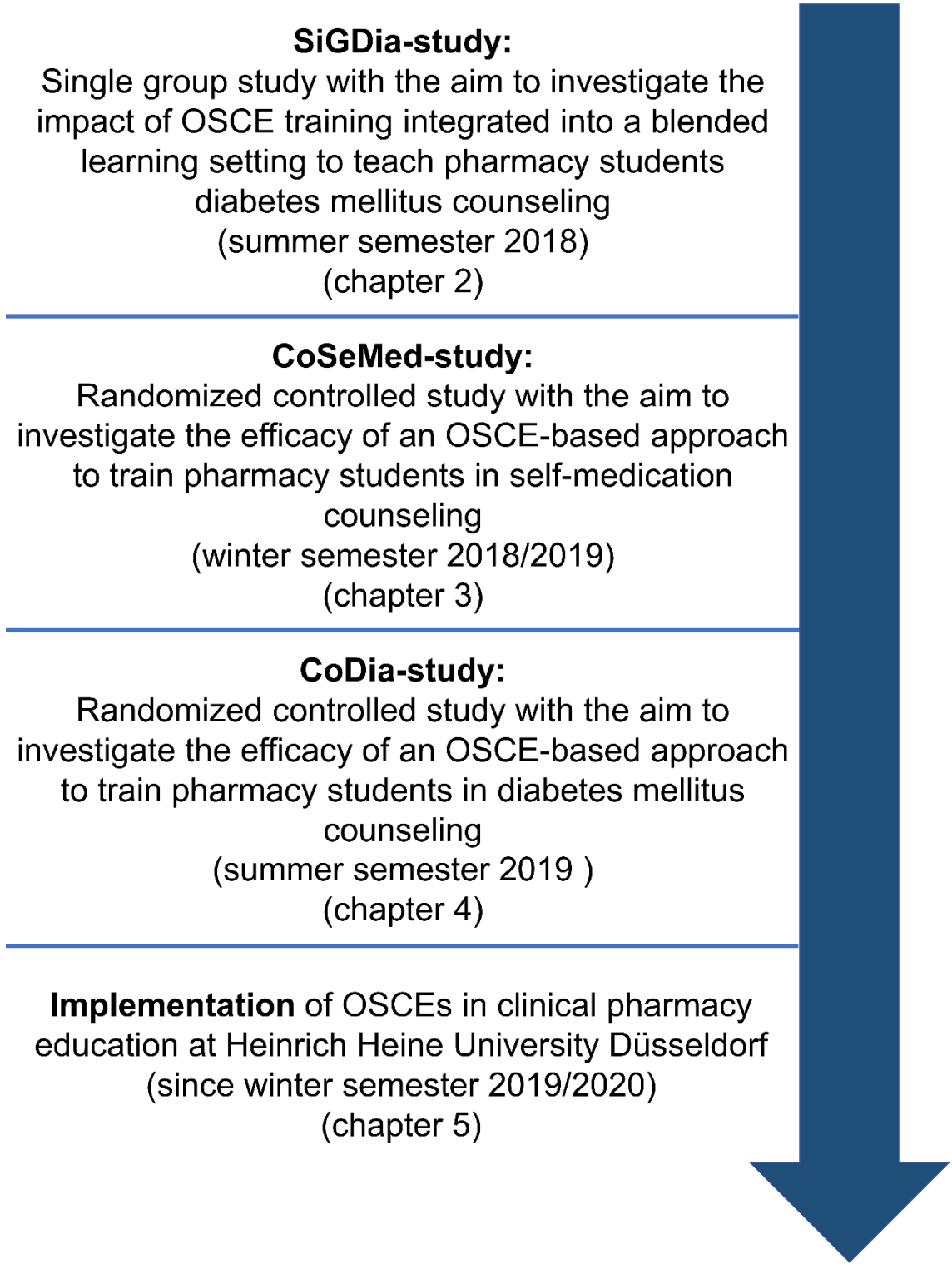

Figure 1-3: Timeline of Milestones in this Work

OSCE = objective structured clinical examination; SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling; CoDia-study = randomized controlled study on OSCE training for diabetes counseling.

2. Evaluation of OSCE Training Integrated into a Blended Learning Setting for Improving German Pharmacy Students' Diabetes Mellitus Counseling Skills (SiGDia-Study)

2.1 Background and Aim

One of community pharmacists' key tasks is to counsel patients and physicians on medicines.[16-18] Several investigations have shown the benefits of involving pharmacists in the therapy management of patients with chronic diseases such as diabetes mellitus.[10,154-156] The worldwide diabetes prevalence was estimated to be 463 million people in 2019[147] and nonadherence in diabetes patients is associated with adverse consequences including poor glycemic control, increased risk of hospitalization, increased mortality, and higher costs.[148-151]

Generally, community pharmacists, as well-accessible health care professionals and experts in drug therapy,[1-3] have the potential to contribute to patients' adherence[30,35] and to identify and resolve DRPs.[28,32-34] As the majority of pharmacists work in community pharmacies,[71,176] pharmacy students should be prepared appropriately to provide adequate counseling right from the beginning of their working life. The literature indicates that in Germany, there is a need for more patient-oriented education and fostering clinical content in the pharmacy curriculum.[13,61,67] OSCEs integrated into a blended learning setting may have the potential to address counseling skills in a patient-oriented and competency-based way. In the literature, different definitions of the term "blended learning" can be found.[177-179] For instance, Garrison and Kanuka describe blended learning as "the thoughtful integration of classroom face-to-face learning experiences with online learning experiences."[178] Research suggests that blended learning has positive effects on health care professionals' and health care professional students' knowledge and skills.[180-183] For example, the single group study PharmAdhere used a blended learning program including e-learning and OSCEs for training community pharmacists in Germany in conducting consultations in chronic diseases and found improvement of knowledge and skills after the training.[180] E-learning can be defined as "the use of electronic devices and Internet

technologies to deliver a variety of solutions to enable learning and improve performance."[184] Regarding OSCEs, the literature indicates the potential of OSCEs as a teaching tool.[123,180]

This study, abbreviated SiGDia-study, aimed to assess whether OSCE training integrated into a blended learning setting could enhance pharmacy students' counseling performance regarding diabetes mellitus.

2.2 Methods

2.2.1 Operational Definitions

For the purpose of this work, the term “formative OSCEs” describes OSCEs used for training. The term “summative OSCEs” refers to OSCEs for assessing the participants' performance at baseline (summative pre-training OSCE) as well as after training (summative post-training OSCE). In this study, the summative OSCEs did not affect the students’ passing of the course and served as a measurement instrument for the study.

2.2.2 Study Design and Participants

The blended learning intervention, based on a study with community pharmacists (PharmAdhere),[180] was conducted between April and June 2018 during a clinical pharmacy course at Heinrich Heine University Düsseldorf in the German language. The ethics committee of the medical faculty of Heinrich Heine University Düsseldorf approved the study protocol (study number: 5705). For the investigation, a pre-post design was applied with the baseline performance being assessed before the training and compared with the post-training performance. In April 2018, 65 students in their eighth and final semester of university pharmacy studies were invited to participate in this study. During an introductory lecture, students were informed about the study. Moreover, written participant information and an informed consent form were handed out to them. Students were eligible to participate in the study once they voluntarily signed the informed consent form. As the blended learning approach was completed as a part of the clinical pharmacy course, students who did not sign the informed consent form took part in the seminar as supportive staff without their data being collected.

2.2.3 Study Procedure

At first, the participants completed an online baseline knowledge test (pre-e-learning online test) consisting of 15 multiple-choice questions. The test was composed automatically out of a question pool. The participants were given 15 minutes for the test. After that, the participants had a maximum of 1 week to use the e-learning, consisting of online educational texts on the basics, pharmacological therapy, and clinical aspects of diabetes mellitus, as well as multiple-choice tests for training purposes. Following this period, the participants' level of knowledge was re-evaluated by a second online knowledge test (post-e-learning online test) consisting of 15 multiple-choice questions out of the question pool. The educational texts could be downloaded and read offline. Therefore, no statement can be made about the time participants spent reading the material.

Three weeks after the second online knowledge test, the counseling skills of the participants were evaluated. For this purpose, each participant completed a summative pre-training OSCE consisting of 1 case depicting the baseline measurement of the participants' skills. About 3 weeks after the summative pre-training OSCE, the participants watched a counseling video in-class and were offered a link to watch online videos showing counseling scenarios.[185] Afterward, the participants trained their skills through formative OSCEs. Three weeks after the formative OSCEs, the participants completed a summative post-training OSCE.

2.2.4 Instruments

OSCE Cases

A pharmacist and a senior scientist (pharmacist) with additional skills in behavioral psychology and experience in conducting blended learning programs prepared a total of 16 cases about type 2 diabetes mellitus. A total of 8 OSCE cases dealt with the initiation of antidiabetic medication therapy while the other 8 cases dealt with the implementation of antidiabetic medication therapy. In this work, “initiation” of antidiabetic medication therapy implies that the medication was prescribed for the first time to the patient. The “implementation” of

antidiabetic medication therapy implies that the patient received a follow-up prescription. Eight cases (4 OSCE cases on initiation of therapy and 4 OSCE cases on implementation of therapy) were used for the summative pre-training OSCE (first summative OSCE) and the formative OSCEs. The other 8 cases were used for the summative post-training OSCE (second summative OSCE). Each OSCE case represented a complete clinical case in a community pharmacy and began with the SP handing over a prescription for an antidiabetic drug to the participant. Every case was designed to be accomplished within a maximum of 10 minutes. Cases 1 to 4 and cases 9 to 12 dealt with a patient getting acarbose, dapagliflozin, sitagliptin, nateglinide, glimepiride, liraglutide, insulin detemir, or insulin lispro for the first time (“initiation” of antidiabetic treatment). Cases 5 to 8 and cases 13 to 16 dealt with the patient handing over a follow-up prescription for insulin detemir, glimepiride, dapagliflozin, insulin lispro, nateglinide, a combination drug consisting of metformin and sitagliptin, liraglutide, or metformin (“implementation” of antidiabetic treatment). The participant's task was to counsel an SP on the prescription.

Analytical Checklist for OSCEs

Two scoring instruments were used to assess the performance during the summative OSCEs: an analytical checklist and a global rating scale. To evaluate the participants' counseling skills regarding the content of counseling during the OSCEs, a case-specific analytical checklist was filled out by the observers for each participant. For that purpose, a global analytical checklist for OSCEs was provided by authors of the PharmAdhere study,[180] and adapted for the present study. The adapted global analytical checklist was then adjusted to every diabetes OSCE case (case-specific analytical checklist) so that the case-specific analytical checklists only included the items relevant for the respective case. Unlike the PharmAdhere study, this analytical checklist did not have weighted items. The weighting of checklist items allows for their differential contribution to the overall score and emphasizes particular items.[186,187] Sandilands et al “found no appreciable differences in reliability” by weighting checklists items.[187] Overall, the literature suggests “that the benefit of weighting items is not worth the extra

effort."[72] Based on these counterarguments it was decided against weighting. In the case-specific analytical checklist, exemplary dialogues were given below every item to facilitate the observers' task. Items that could have been addressed wrongly (such as the dosage) included one additional checkbox to specify not only that the item was addressed, but also that it was addressed correctly. The analytical checklists encompassed the sections "greeting," "medical history," "drug information" (initiation or implementation), "prevention," "goal setting," "risk communication," and "patient involvement", with each section comprising 1 or more items. For the analysis of "items addressed," 1 point was given for the respective item if the item was addressed; if not, 0 points were given. Regarding the analysis of "items addressed correctly," 1 point was given if the item was addressed correctly; if not, 0 points were given. For items which could not be addressed wrongly, 1 point was given if the item was addressed; if not, 0 points were given. Maximum achievable scores varied among the case-specific analytical checklists. With the analytical checklists used for the summative pre-training OSCEs, the observers also surveyed the participants' demographic characteristics including age, gender, and additional education as pharmaceutical technical assistants.

Global Rating Scale for OSCEs

To assess the participants' communication skills during the OSCEs, a global rating scale was filled out by the observers for each participant. The global rating scale for OSCEs provided by authors of the PharmAdhere study[180] was shortened and used to assess the behavior and communication skills of the participants during the OSCEs. The modified global rating scale comprised the 3 domains "verbal communication skills," "non-verbal communication skills," "patient-centered communication" assessing each domain with a 6-point Likert scale ranging from 0 ("poor behavior") to 5 points ("optimal behavior").[180] Consequently, a maximum of 15 points was achievable.

Self-Assessment Questionnaire

After the completion of each summative pre- and post-training OSCE encounter, the participants filled out a self-assessment questionnaire, which was provided by authors of the PharmAdhere study.[180] The self-assessment questionnaire, adapted for the use in this study, consisted of 11 items (Appendix 1). The assessment was based on a 6-point Likert scale ranging from 0 (“very bad”) to 5 points (“very good”). With the self-assessment questionnaire, it was aimed to assess participants’ self-confidence or self-perceived proficiency.

Satisfaction Survey

Participants filled out a survey for assessing their satisfaction with the seminar (Appendix 2) after the formative OSCEs but before summative post-training OSCEs. The survey comprised 7 items rated on a 6-point Likert scale ranging from “strongly disagree” to “strongly agree.” The items addressed, for example, participants' interest in the seminar content, whether the OSCE seminar conveyed security in dealing with patients in the pharmacy, and whether the OSCE seminar should be implemented in future clinical pharmacy courses. Participants were also asked in 3 free-text items about what they particularly liked, what they would suggest changing, and additional comments. For analysis, the comments on the free-text items were categorized into topics.

2.2.5 Summative OSCEs

For an adequate, timely process and in respect of the room situation at the university, 6 to 8 students, all of them working on a different case, simultaneously took part in the summative OSCEs in one lecture hall. Each OSCE consisted of a 5-minute pre-encounter phase in which the participant, for example, had the opportunity to read the respective instruction (example in Appendix 3) and the respective summary of product characteristics (SmPC, *Fachinformation*, expert information) of the particular antidiabetic drug used in the OSCE case, a maximum 10-minute patient encounter phase in which the participant counseled the SP and the observer evaluated the participant’s counseling using a case-

specific analytical checklist and the global rating scale, and a maximum 10-minute post-encounter phase where the participant filled out the self-assessment questionnaire and the observer had the opportunity to complete the analytical checklist and global rating scale, if necessary. The timeframe of 10 minutes for the patient encounter phase was based on the PharmAdhere study[180] and a pilot testing of the blended learning approach in pharmacy students in the scope of an elective course. Eight faculty members (pharmacists) played the role of the SPs and received written instructions on their roles before the summative OSCEs. Eight students who participated in a pilot testing of the blended learning approach with OSCEs, and thus, were not invited to participate in the study (7 students from the semester the study took place and 1 student who completed the clinical pharmacy course the prior semester), served as observers and were trained on how to fill out the analytical checklists and the global rating scale. One SP, 1 observer, and 1 participant attended each OSCE encounter. Additionally, after the summative post-training OSCE students received feedback on their performance.

2.2.6 Blended Learning

The blended learning comprised e-learning aiming to bring the participants' knowledge on diabetes mellitus to the same level and OSCE training aiming to convey diabetes counseling skills. The PharmAdhere course materials[180] for the e-learning on diabetes knowledge (provided by the first author of the PharmAdhere study[180]) were reviewed according to at that time current national diabetes guidelines.[188,189] These materials encompassed 3 e-learning modules: basics, pharmacological therapy, and clinical aspects of diabetes mellitus. Each module comprised an educational text and online tests for training purposes consisting of multiple-choice questions. Furthermore, before and after the e-learning, participants completed an online test consisting of 15 multiple-choice questions to assess the change in diabetes knowledge. Correctly answered questions were scored with 1 point while incorrectly answered questions or not answered questions were scored with 0 points. The modules and questions were offered on a Moodle platform.

The OSCE training in this study was mainly based on formative OSCEs. Besides, the participants watched a counseling video in class and were offered online videos showing counseling scenarios, provided by Pharmabrain.[185] During the formative OSCEs, conducted at 1 afternoon, 7 to 8 participants in 8 groups trained 1 OSCE case, which they had completed in their summative pre-training OSCEs, and were provided with analytical checklists and the global rating scale. Consequently, each group trained different OSCE cases. The students who did not sign the informed consent form played the role of the SPs. The study participants assumed the role of the pharmacists. The observers in the groups were portrayed by 7 student observers of the summative pre-training OSCEs and in 1 case by a faculty member as 1 of the 8 student observers was not present. The assigned observers provided feedback to the participants. The participants and SPs incorporated the feedback and from each group, 1 pair of pharmacist and SP presented their trained counseling encounter to the other groups and 2 instructors (faculty members). Immediately after the performance, the groups received feedback from the other groups and instructors.

2.2.7 Data Analyses and Statistical Methods

Maximum achievable scores varied among the analytical checklists for the OSCE cases. Therefore, the point-based scores of the analytical checklists were converted into percentages and the analysis was carried out in percentages or percentage points to enable comparison across the different OSCE cases. The analytical checklist scores were analyzed first regarding “items addressed” and second regarding “items addressed correctly.” Also, for the analyses of the online test, global rating scale, and self-assessment questionnaire, point-based scores were converted into percentages and the analyses were carried out in percentages or percentage points. A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores was used to evaluate whether the respective scores increased significantly from summative pre- to post-training OSCEs. Also, regarding the online test, a one-sided Wilcoxon signed rank test applied to the differences between pre- and post-e-learning online test scores was used to evaluate whether the scores increased

significantly from pre- to post-e-learning online tests. The significance level was considered to be alpha = 0.05 and *p*-values were not adjusted for multiple testing. Asymptotic *p*-values are considered in the following. Participants who did not complete both the pre- e-learning online test and post-e-learning online test were excluded from the data analysis of the e-learning on diabetes knowledge. Equally, participants who did not complete both pre- and post-training OSCEs were excluded from the respective data analysis of the OSCEs. Microsoft Excel 2016[190] was used for data entry and Microsoft Excel 2019[191], OriginPro 2019[192], and OriginPro 2021[193] were used for analyses. All data were collected in pseudonymous form, with the exception of the anonymous satisfaction survey. After analysis, all data were rendered anonymous. All applied materials were in the German language (eg, analytical checklists, global rating scale, self-assessment questionnaire, satisfaction survey, e-learning, video).

2.3 Results

2.3.1 Participants

Fifty-eight students signed the informed consent form. Participants' demographics, which were collected during the summative pre-training OSCE, were obtained from 57 participants. Therefore, demographic data was based on 57 participants. Table 2-1 shows the demographic characteristics. The age of the participants ranged from 21 to 33 years with a mean age of 24.39 years (standard deviation [SD] = 2.65 years) and a median age of 24 years (interquartile range [IQR] = 3 years). The majority of the participants (70.18%) were female. Moreover, 7.02% of the participants were additionally trained as pharmacy technicians. Seven students did not sign the informed consent form and were assigned a supporting role such as starting each OSCE session in time, tracking time during the OSCE, collecting the checklists from the stations, and typing analytical checklist and global rating scale scores on the faculty laptop.

Table 2-1: Demographic Characteristics of Participants in the SiGDia-Study

Characteristics	Participants (N = 57 [a])
Age in years	
Mean (SD)	24.39 (2.65)
Median (IQR)	24 (3)
Range [b]	21 to 33
Gender	
Female, n (%)	40 (70.18)
Male, n (%)	17 (29.82)
Additional education as a pharmaceutical technical assistant	
Yes, n (%)	4 (7.02)
No, n (%)	53 (92.98)

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; SD = standard deviation; IQR = interquartile range.
[a] Fifty-seven participants completed the summative pre-training OSCE, thus, demographics from 57 participants could be obtained. [b] Rage refers to minimum to maximum.

2.3.2 E-learning on Diabetes Knowledge

For 56 participants, data for both online tests in the scope of the e-learning on diabetes knowledge were available and therefore could be included in the analysis of the e-learning. Results regarding the online tests are depicted in Figure 2-1 and Table 2-2. In the pre-e-learning online test (first online test), 16 of the 56 participants answered more than half of the questions correctly. In the post-e-learning online test (second online test), 53 participants answered more than half of the questions correctly. The scores of the online tests increased significantly ($p < 0.001$) from the pre-e-learning online test (mean = 43.33% [SD = 16.13%] and median = 40% [IQR = 20%]) to the post-e-learning online test (mean = 77.5% [SD = 17.69%] and median = 80% [IQR = 26.67%]).

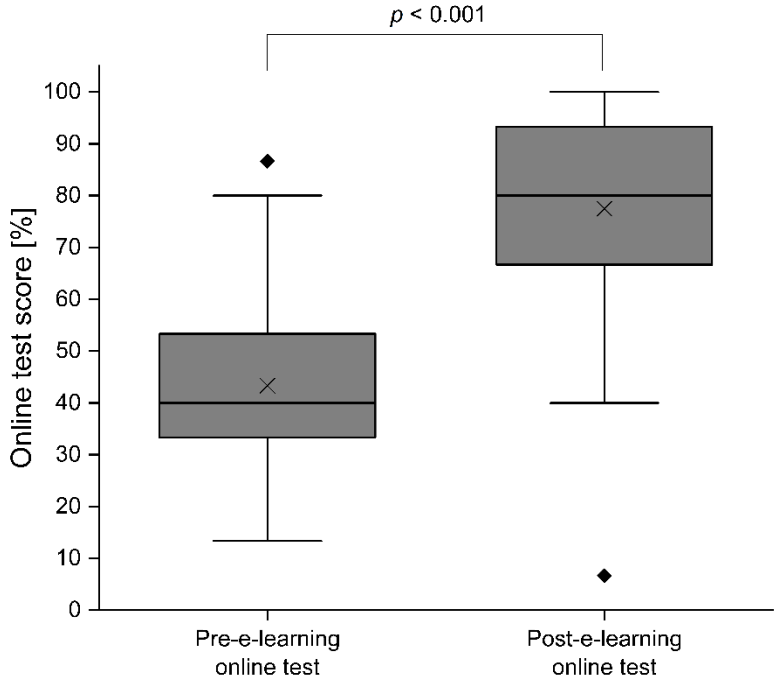

Figure 2-1: Online Test Scores in the SiGDia-Study

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting.
Cross mark (**x**) = mean; horizontal line = median; black diamond (♦) = outlier.
N = 56. Results are depicted as box plots.
A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-e-learning online test scores with a significance level of alpha = 0.05 was used.

Table 2-2: Results of Knowledge Online Test in the SiGDia-Study

Evaluation type	Pre-e-learning online test score in %		Post-e-learning online test score in %		*p*-value [a]	Score difference in percentage points	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		Mean (SD)	Median (IQR)
Online test (N = 56)	43.33 (16.13)	40 (20)	77.5 (17.69)	80 (26.67)	$p < 0.001$	34.17 (20.02)	33.33 (23.33)

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; SD = standard deviation; IQR = interquartile range.

[a] A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-e-learning online test scores with a significance level of alpha = 0.05 was used.

2.3.3 Analytical Checklist for OSCEs

Fifty-three students, who attended the summative pre-training OSCE, formative OSCEs, and summative post-training OSCE, were included in the analysis of the analytical checklist. Thus, 5 participants were excluded from the analysis as they did not attend 1 of the 3 appointments. To determine the participants' change in counseling skills from summative pre-training OSCE to summative post-training OSCEs, the analytical checklist was filled out by the observers for each participant. The results regarding the analytical checklist score are shown in Figure 2-2 and Table 2-3. For both analyses the “items addressed” and the “items addressed correctly,” the analytical checklist scores increased significantly from the summative pre- to post-training OSCEs (for both analyses $p < 0.001$).

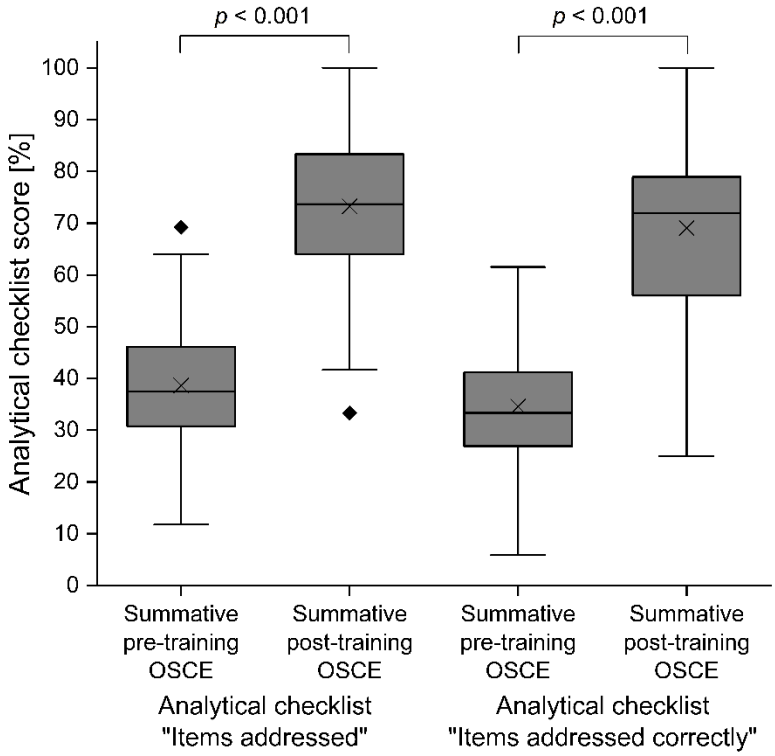

Figure 2-2: Analytical Checklist Scores in the Summative OSCEs in the SiGDia-Study

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; OSCE = objective structured clinical examination.
Cross mark (**x**) = mean; horizontal line = median; black diamond (♦) = outlier.
N = 53. Results are depicted as box plots.
A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.

Table 2-3: Results of the Analytical Checklist in the Summative OSCEs in the SiGDia-Study

Evaluation type	Pre-training score in %		Post-training score in %		*p*-value [a]	Score difference in percentage points	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		Mean (SD)	Median (IQR)
Analytical checklist “items addressed” (N = 53)	38.66 (12.25)	37.5 (15.38)	73.24 (13.19)	73.68 (19.33)	$p < 0.001$	34.58 (14.35)	33.34 (20.45)
Analytical checklist “items addressed correctly” (N = 53)	34.58 (12.08)	33.33 (14.25)	69.05 (14.36)	72 (22.95)	$p < 0.001$	34.48 (15.60)	33.34 (18.84)

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; OSCE = objective structured clinical examination; SD = standard deviation; IQR = interquartile range.

[a] A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.

2.3.4 Global Rating Scale for OSCEs

Equally to the analysis of the analytical checklist, 53 participants were included in the analysis of the global rating scale. To assess the participants' change in communication skills from summative pre- to post-training OSCEs, the global rating scale was completed by the observer for each participant. Results regarding the global rating scale score are depicted in Figure 2-3 and Table 2-4. Participants' global rating scale score increased significantly from summative pre- to the post-training OSCEs ($p < 0.001$).

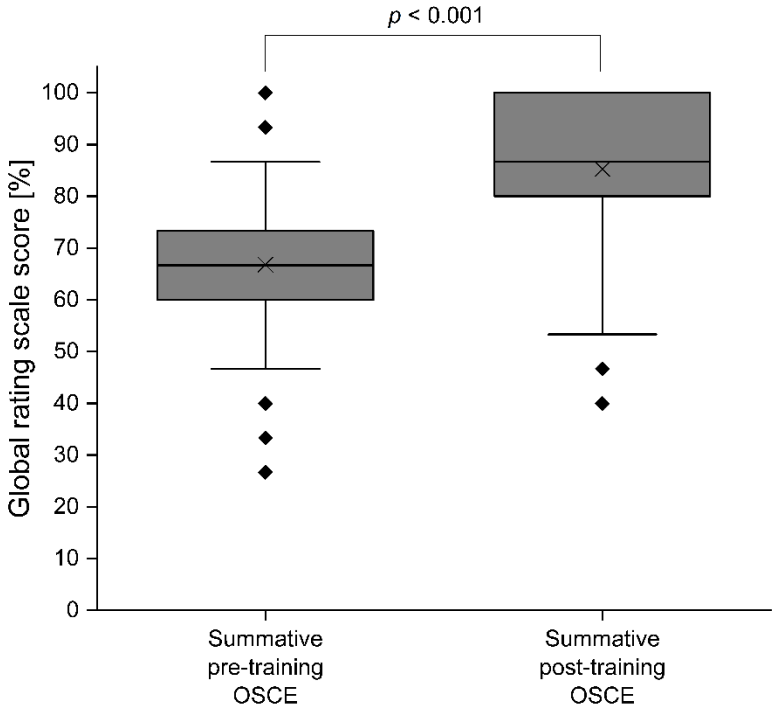

Figure 2-3: Global Rating Scale Scores in the Summative OSCEs of the SiGDia-Study

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; OSCE = objective structured clinical examination.
Cross mark (**x**) = mean; horizontal line = median; black diamond (♦) = outlier.
N = 53. Results are depicted as box plots.
A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.

Table 2-4: Results of the Global Rating Scale in the Summative OSCEs in the SiGDia-Study

Evaluation type	Pre-training score in %		Post-training score in %		*p*-value [a]	Score difference in percentage points	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		Mean (SD)	Median (IQR)
Global rating scale (N = 53)	66.79 (16.77)	66.67 (13.33)	85.28 (16.14)	86.67 (20)	$p < 0.001$	18.49 (17.72)	20 (20.00)

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; OSCE = objective structured clinical examination; SD = standard deviation; IQR = interquartile range.

[a] A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.

2.3.5 Self-Assessment Questionnaire

All of the 53 participants, who attended the summative pre-training OSCE, formative OSCEs, and summative post-training OSCE, were included in the analysis of the self-assessment questionnaire, with missing data in the self-assessment questionnaire imputed with the median of the respective item. The analysis of the self-assessment questionnaire showed a significant increase in the score from pre-training assessment to post-training assessment ($p < 0.001$). In Figure 2-4 and Table 2-5, the results regarding the self-assessment questionnaire score are depicted (N = 53). In an additional analysis of the self-assessment questionnaire, 10 participants, who did not fill out the self-assessment questionnaire completely (some items were not answered), were excluded from the additional analysis of the self-assessment questionnaire, resulting in 43 participants being included. Also, this analysis showed a significant increase in the self-assessment questionnaire score from pre-training assessment to post-training assessment ($p < 0.001$). Appendix 4 shows the results of the additional analysis regarding the self-assessment questionnaire score (N = 43).

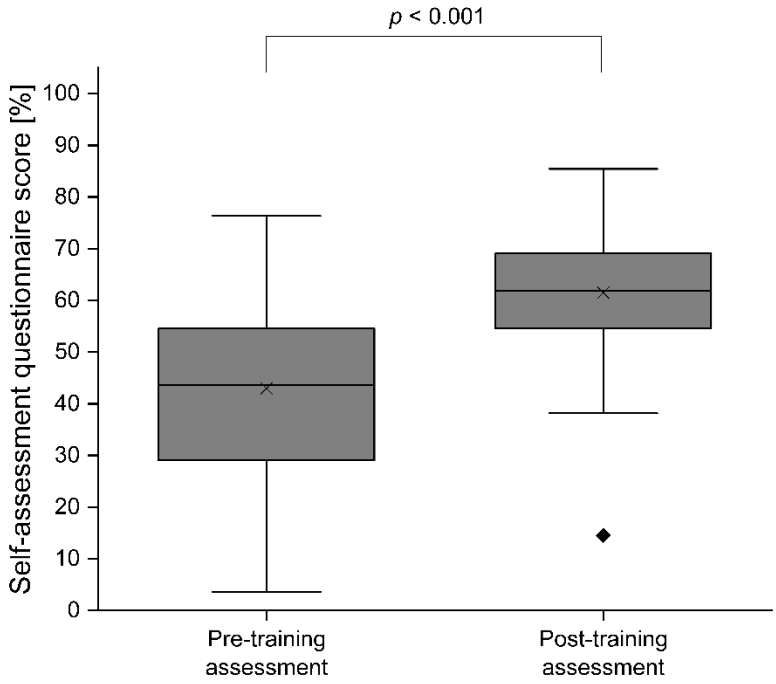

Figure 2-4: Self-Assessment Questionnaire Scores in the SiGDia-Study

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting.
Cross mark (**x**) = mean; horizontal line = median; black diamond (♦) = outlier.
N = 53. Results are depicted as box plots.
A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.

Table 2-5: Results of the Self-Assessment Questionnaire in the SiGDia-Study

Evaluation type	Pre-training score in %		Post-training score in %		*p*-value [a]	Score difference in percentage points	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		Mean (SD)	Median (IQR)
Self-assessment question-naire (N = 53 [b])	42.98 (17.52)	43.64 (25.45)	61.51 (12.43)	61.82 (14.55)	$p < 0.001$	18.52 (20.05)	18.18 (25.45)

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; SD = standard deviation; IQR = interquartile range.

[a] A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.

[b] All participants who participated in both the summative pre- and post-training OSCEs were included in the analysis, with missing data in the self-assessment questionnaire imputed with the median of the respective item.

2.3.6 Satisfaction Survey

Fifty-four participants completed a satisfaction survey. Table 2-6 shows the results of the survey. For example, 57.41% of participants (strongly agree, agree, slightly agree summarized) agreed to some extent that they enjoyed dealing with the seminar content, 75.93% (strongly agree, agree, slightly agree summarized) agreed to some extent that their clinical skills improved, 79.63% (strongly agree, agree, slightly agree summarized) agreed to some extent that their communication skills improved. Moreover, 81.48% (strongly agree, agree, slightly agree summarized) agreed to some extent that the OSCE seminar should be implemented in future clinical pharmacy courses. Students commented, for example, that they particularly liked training or simulating counseling. The students criticized, for example, that the course was focused on diabetes (Table 2-7). As the study was conducted in the scope of the clinical pharmacy course with other seminars, it cannot be excluded that some of the comments or opinions might also be attributed to other seminars, although students were informed that the survey only refers to the study.

Table 2-6: Results of the Satisfaction Survey in the SiGDia-Study

Item	Proportions of responses in %					
	Strongly disagree	Disagree	Slightly disagree	Slightly agree	Agree	Strongly agree
I enjoyed dealing with the seminar contents.	3.70	14.81	24.07	37.04	16.67	3.70
I enjoyed the OSCE seminar [a].	3.70	9.26	14.81	37.04	27.78	7.41
The OSCE seminar improved my clinical skills.	3.70	7.41	12.96	18.52	37.04	20.37
The OSCE seminar improved my communication skills.	0	11.11	9.26	24.07	27.78	27.78
The OSCE seminar conveyed much practical knowledge.	1.85	9.26	7.41	22.22	38.89	20.37
The OSCE seminar conveyed security in dealing with patients in the pharmacy.	0	3.70	11.11	40.74	27.78	16.67
The OSCE seminar should be implemented in future clinical pharmacy courses.	9.26	5.56	3.70	27.78	31.48	22.22

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; OSCE = objective structured clinical examination.
N = 54.
[a] The seminar, during which the blended learning approach took place, was named “OSCE seminar” in the survey.

Table 2-7: Example Topics of Comments from Free-Text Items of the Satisfaction Survey in the SiGDia-Study

Free-text item	Topic of comments	Number of comments on the topic
I particularly liked the following at the OSCE seminar:	Gaining first impressions of practice and counseling in the community pharmacy	5
	Training or simulating counseling	5
	Structured patient counseling	5
I would change the following and further comments [a]:	Additionally other diseases should be included, less diabetes	11
	More precise information about the process flow of the seminar	5
	The checklist was not always practical	3

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; OSCE = objective structured clinical examination.

[a] For analysis, the items “I would change the following” and “further comments” were summarized.

The 3 most frequent topics of comments for each item are shown. If topics of comments occurred with equal frequency, 1 of them was selected. Further topics of comments can be found in Appendix 5.

2.4 Discussion

This pre-post design study showed that the applied blended learning approach on diabetes mellitus had positive effects in 4 areas: 1. participants' knowledge in the field of diabetes mellitus increased significantly after e-learning as measured by online tests; 2. participants' counseling and communication skills improved significantly as measured by summative OSCEs; 3. participants' self-assessment questionnaire score significantly increased; and 4. the majority of participants were satisfied with the seminar based on the satisfaction survey.

This study strongly supports the use of e-learning for improving pharmacy students' knowledge. The findings of this study suggest that e-learning on diabetes knowledge as the introductory part of the blended learning approach has the potential to impart diabetes mellitus knowledge to the pharmacy students, as shown by a significant improvement from the pre-e-learning online test to the post-e-learning online test, which agrees with previous reports in the literature.[194,195] For example, Hall et al found significant improvements in pharmacy students' knowledge of diabetes and management of patients with diabetes after completing a web-based diabetes course, as measured by pre- and post-course knowledge tests.[195] E-learning is considered to be flexible.[196] In the SiGDia-study, e-learning was used to bring participants to the same level of diabetes knowledge before the summative pre-training OSCE. The e-learning on diabetes knowledge that was provided by the first author of the PharmAdhere study[180] could be used, which saved time during the preparation phase of the study. As e-learning on diabetes knowledge was conducted outside of class, the limited in-class time available for the training approach could be used for instructor-guided activities.

Using OSCE-based training has the potential to improve students' counseling and communication skills, as shown by the significant increases in the analytical checklist score and global rating scale score from summative pre- to post-training OSCEs. During OSCE training, the students were able to apply the theoretical knowledge acquired during e-learning to situations that simulated practice in community pharmacies in a safe environment, where even serious mistakes could not affect patients, which were depicted by SPs. This safe environment

provided by OSCEs is cited as 1 of its major benefits.[100-102] Nevertheless, the efficacy of formative OSCEs is still discussed controversially.[106,180,197] Also, it should be considered that the summative pre-training OSCE might have contributed to the improved learning by allowing students to identify and address potential weaknesses, as previously noted by other researchers.[198]

After completing OSCE-based training and the summative post-training OSCE with feedback, participants' self-confidence or self-perceived proficiency, as measured by a self-assessment questionnaire, were significantly increased. The improved self-confidence of students after completing OSCE training or summative OSCEs is also described in the literature.[120,199] Importantly, 81.48% of the participants agreed to some extent (strongly agree, agree, and slightly agree summarized) that the OSCE seminar should be implemented in future clinical pharmacy courses. Similarly, other researchers found that OSCEs are well accepted by students.[123,200,201]

The methods of OSCEs can vary. While in this investigation, both SPs and observers were used, the literature also describes the combination of the tasks by having only 1 person portraying the patient and assessing the student by completing checklists,[86-88,92,127] hence reducing the staff needed. However, it should be considered that the assessment of the SPs is usually dependent upon his memories since they often have to wait until the end of the participant's performance before they can fill out the checklist.[86] Also, the SP's perception of the participant's performance can be affected by the fact that he/she is more involved in the performance.[86] OSCEs usually consist of several stations to examine various activities.[72,73,75] In the present study, knowledge was assessed before the OSCEs by an online test and 1 elaborate station was applied to assess the full consultation to best imitate reality.

The findings of the SiGDia-study support the use of a blended learning approach for pharmacy students, in agreement with previous studies in the literature.[181,202] For example, Hess et al evaluated an interprofessional (medical and pharmacy students) blended learning course for patient-centered interpersonal communication skills and found a significant increase in pre- to post-course patient-centered communication skills for both medical and pharmacy

students.[181] A meta-analysis on the effectiveness of blended learning for knowledge acquisition in the health professions by Liu et al indicated that "[b]lended learning appears to have a consistent positive effect in comparison with no intervention and appears to be more effective than or at least as effective as nonblended instruction," with the notation that this conclusion should be interpreted with caution due to the large heterogeneity across the studies.[182] The blended learning approach in the SiGDia-study can be broadly divided into two parts. The first part focused on imparting diabetes mellitus knowledge by the use of e-learning on diabetes knowledge. The second part focused on counseling skills and constituted the activities of the educational approach which followed the post-e-learning online test.

Some limitations must be considered in this study. In educational research, subjects have been reported to change their behavior or performance when they are aware of being observed, which has been described as the "Hawthorne effect."[203-205]. Boet et al stated that "[a]ssessing the impact of the Hawthorne effect on one's research work is difficult, but researchers need to acknowledge its potential presence."[204] Furthermore, students, who participated in the OSCE pilot tests took on the role of observers (raters). Due to a lack of resources, no more than 1 observer could be used during an OSCE-encounter. To reduce potential inter- and intra-observer variability, these students were trained as observers before the study during their scientific elective course. To facilitate the observer's task, analytical checklists additionally included examples for adequate fulfillment of each item. These measures were intended to ensure that observers would rate the participant according to the requirements set by the instructors. Due to the limited resources available for the blended learning approach, only 1 chronic disease, diabetes mellitus, was addressed. Working on only diabetes was rather disliked by the participants, who would have preferred the inclusion of other diseases. Therefore, a broader range of indications should be considered when implementing OSCE training in the pharmacy curriculum.

This study was conducted without a control group but the evaluation was based on a pre-post comparison. A randomized controlled trial has the potential to control for confounders.[206] To assess whether the improved counseling performance from the pre-training OSCE to post-training OSCE resulted from the

OSCEs for training purposes or other aspects such as the counseling videos or a learning effect due to the experience of the summative pre-training OSCE, a randomized, controlled study design should be applied. As the study was conducted during the clinical pharmacy course, other clinical pharmacy seminars (eg, exercises on self-medication counseling) occurred between the summative pre- and post-training OSCEs. A controlled study could address possible confounders arising from seminars in parallel to the investigated training approach.

2.5 Conclusion

This study with a pre-post design demonstrated that OSCE-based training integrated into a blended learning setting can improve students' diabetes counseling and communication skills, and self-confidence/self-perceived proficiency. The e-learning on diabetes knowledge of the blended learning approach was suitable to convey diabetes mellitus knowledge. A controlled study design is needed to confirm that the improvement in counseling performance resulted from the OSCEs for training purposes. Consequently, the following 2 chapters of this dissertation investigate OSCEs as a teaching tool for patient counseling using a randomized controlled design. Chapter 3 describes a randomized controlled study evaluating the effect of OSCE-based training on pharmacy students' self-medication counseling skills (CoSeMed-study). In the CoSeMed-study, the OSCE-based training approach focused on self-medication counseling to evaluate whether the positive impact of the OSCE-based training from the SiGDia-study was transferable to other indications. The topic self-medication was chosen because it is relevant[157] and part of the university's clinical pharmacy curriculum. The blended learning aspect (e-learning and video) was removed from the educational approach to focus on the impact of OSCEs as a teaching tool.

2.6 Disclosure

Parts of this chapter were previously published as “Farahani I, Laeer S, Farahani S, Schwender H, Laven A. Blended learning: improving the diabetes mellitus counseling skills of German pharmacy students. *Curr Pharm Teach Learn*. 2020;12(8):963-974. doi:10.1016/j.cptl.2020.04.016.” The author of this dissertation had substantially contributed to the methodology, formal analysis, investigation, data curation, visualization, writing - original drafts, as well as writing - review and editing.

3. Training Pharmacy Students in Self-Medication Counseling Using an Objective Structured Clinical Examination–Based Approach (CoSeMed-Study)

3.1 Background and Aim

To investigate the hypothesis set up in the SiGDia-study that OSCE training improves the counseling and communication skills of pharmacy students and their self-confidence or self-perceived proficiency, for this study a control group was included. To evaluate the transferability of the findings of the previous study (chapter 2) regarding the impact of OSCE-based training on students' counseling to other indications, it was decided to investigate the impact on self-medication counseling.

Self-medication, defined as “the selection and use of medicines by individuals to treat self-recognized illnesses or symptoms”,[50] plays an important role in the health care system.[157] Although adequate self-medication is associated with potential benefits such as direct and rapid access to treatment, patients’ active role in their health care, and potential economic benefits, it comes also with risks including, but not limited to, incorrect self-diagnosis or choice of therapy, inadequate administration, inappropriate dosages, excessively prolonged use, dependence, abuse, and contraindications or interactions, which can lead to “an increase in drug-induced diseases and wasteful public expenditures.”[157] Self-medication may lead to a delay in the diagnosis and treatment of serious medical conditions or mask the symptoms of a serious condition.[161] Nevertheless, patients are not always aware of the potential risks of NPMs.[162] The literature supports the beneficial effect of pharmacists’ intervention in NPM therapy.[31,164,165] With adequate counseling pharmacists have the potential to address some of these risks, for example, by identifying DRPs[31] or referring patients to physicians if necessary.[29,31] However, studies indicate room for improvement in pharmacists’ self-medication counseling.[44-46] For example, Watson et al described poor consultation performance in community pharmacies mostly due to “inadequate information gathering or advice provision.”[48] During self-medication counseling, a pharmacist bears the responsibility to assess whether a patient can be self-

treated within the pharmacists' scope of practice or a referral to a physician is required.[29] Given the potential risks of self-medication[157] and the room for improvement in pharmacists' counseling skills,[44-46] pharmacy students should receive adequate training during their academic education. A possible strategic teaching approach could be the application of objective structured clinical examinations (OSCEs) for training pharmacy students in counseling.

The aim of this randomized controlled study, abbreviated CoSeMed-study, was to evaluate the effect of an OSCE-based training approach on self-medication counseling performance of pharmacy students, focusing on conditions frequently treated by self-medication: headache, heartburn, and diarrhea.[31,170] In particular, the impact of the OSCE-based training approach on participants' counseling skills as measured by analytical checklists, communication skills as measured by a global rating scale, self-confidence/self-perceived proficiency as measured by a self-assessment questionnaire, and satisfaction as measured by a satisfaction survey were aimed to be assessed.

3.2 Methods

3.2.1 Operational Definitions

For the purpose of this work, the term “formative OSCEs” refers to OSCEs for training purposes, which were used for the intervention group’s training in this study. The term “summative OSCEs” refers to OSCEs for assessing the participants' performance at baseline (summative pre-training OSCE) and after training (summative post-training OSCE). In this study, the summative OSCEs did not affect the students’ passing of the course and served as a measurement instrument for the study.

3.2.2 Study Design and Participants

This randomized controlled trial with a pre-post design was approved by the ethics committee of the medical faculty of Heinrich Heine University Düsseldorf (study number: 2018-246-ProspDEuA). The study was conducted between October 2018 and January 2019 during a clinical pharmacy course at Heinrich Heine University Düsseldorf. The clinical pharmacy course and investigation were conducted in the German language. Students in the eighth and final semester of their university pharmacy studies were invited to participate in the study in October 2018. Students were eligible to participate in the study if they signed voluntarily the informed consent form. It was necessary to limit the sample size to 20 participants per group as the study was conducted as part of a self-medication seminar during the clinical pharmacy course in which the time and staff available were limited. Thus, of the students who signed the informed consent form, 40 students were randomly selected, with 20 randomized into the intervention group and 20 into the control group using the statistical software R.[207] Non-participating students of the eighth semester (students who did not sign the informed consent form or were not randomly selected to participate in the study) served as support staff typing the self-assessment questionnaires scores on the faculty laptop or as timekeepers during summative OSCEs.

3.2.3 Study Procedure

The study procedure (Figure 3-1) began with recruitment, during which students were informed about and invited to the study. Students were provided with written participant information and an informed consent form. After collecting the informed consent forms, the lots were drawn for determining 40 participants who were randomized into the intervention group or control group. All the students listened to a lecture on self-medication, covering definitions, relevance, legal basis, and clinical aspects focused on headache, heartburn, and diarrhea, to establish comparable basic knowledge. For each of the 3 indications, the following aspects were addressed:

- an overview of the limits of self-medication
- examples of medicines used for self-medication, for which contraindications, interactions, adverse drug reactions, and a table with 1. information on dosage; 2. (maximal) duration of intake; and 3. additional important information about the respective medicine (eg, in the case of headache: “prolonged use of any type of pain reliever for headaches can make them worse”) based on the Laven counseling trio[208] were stated
- additional recommendations

On the same day, after the lecture, the participants completed a summative pre-training OSCE evaluating their baseline counseling performance. Five weeks after the summative pre-training OSCE, the participants underwent their assigned training. The intervention group completed formative OSCEs on self-medication, while the control group collected counseling-relevant information from SmPCs of OTC drugs (see sections 3.2.6 and 3.2.7 for further details). Immediately following training, participants completed the summative post-training OSCE evaluating the change in their counseling and communication skills (see section 3.2.5 for further details on summative pre- and post-training OSCEs). Also, participants’ self-confidence or self-perceived proficiency was surveyed before the respective summative OSCE. Finally, the participants completed an anonymous satisfaction survey.

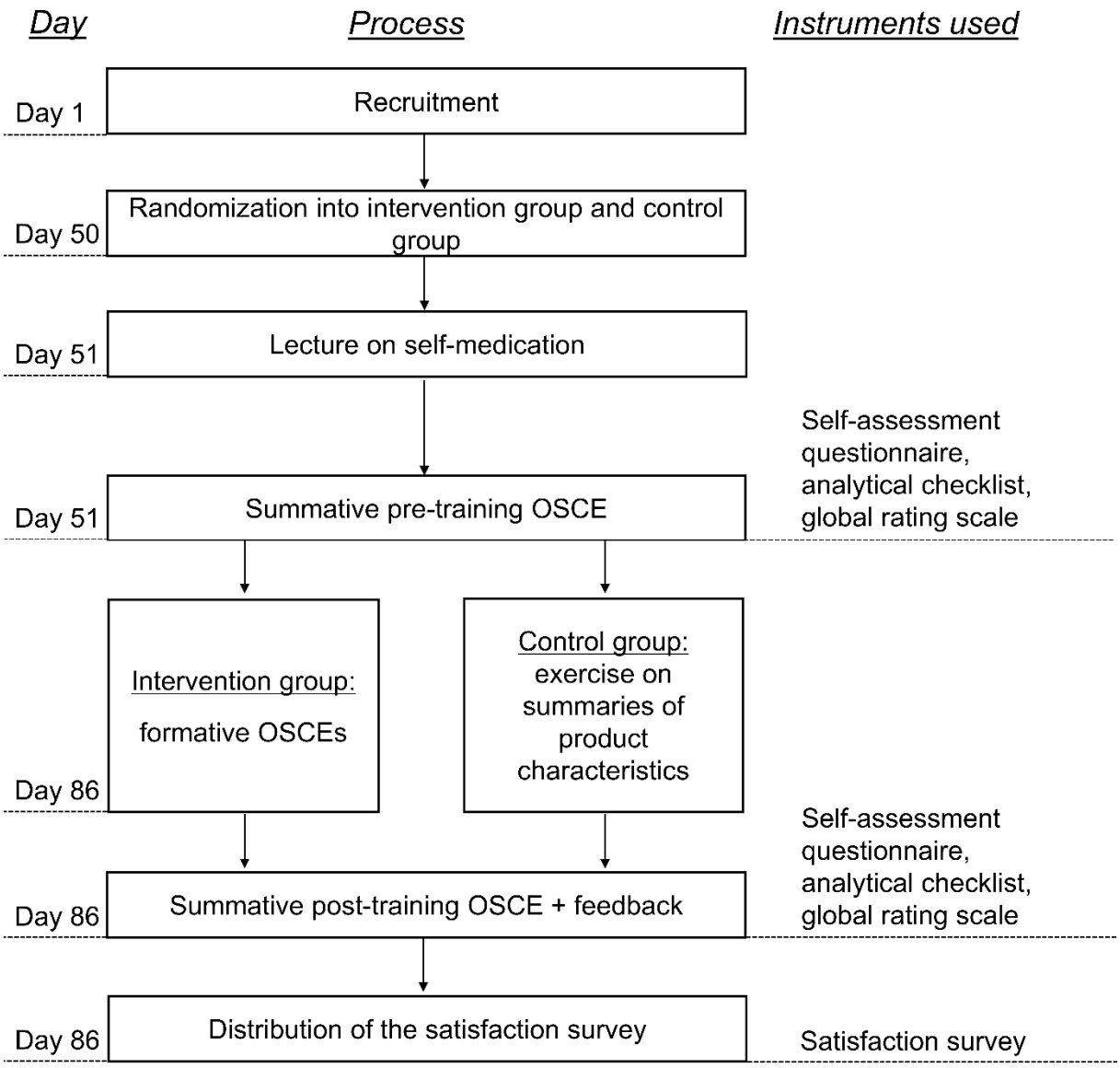

Figure 3-1: Overview of the Study Procedure of the CoSeMed-Study

CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling; OSCE = objective structured clinical examination.

3.2.4 Instruments

Analytical Checklist for OSCEs

The analytical checklists were used to assess the participants' counseling skills. For that purpose, a global analytical checklist was modified from previous studies (PharmAdhere study[180] and SiGDia-study in chapter 2) based on the at that time current German Federal Chamber of Pharmacists' national guidelines for self-medication[209-211] to account for self-medication counseling requirements. The global analytical checklist (Appendix 6) was adapted on a case-specific basis so that the case-specific analytical checklists only included the items relevant for the respective case. Consequently, the maximum achievable score in case-specific checklists varied among the OSCE cases. The analytical checklists encompassed the sections "greeting," "medical history," "drug information" (initiation or implementation), "supportive measures," "risk communication," "goal setting," "patient involvement," and where necessary, "additional questions that are necessary in the specific case." Each section was comprised of 1 or more items. For every correctly performed item in the case-specific analytical checklist 1 point was awarded; if the item was not performed correctly, 0 points were awarded. Items that could not be performed wrongly (did only have the checkbox "addressed" and did not have the checkbox "correctly") were awarded 1 point if the item was addressed; if not 0 points were awarded.

Global Rating Scale for OSCEs

A global rating scale adapted from literature[180] and previously applied in the SiGDia-study (described in chapter 2) was used to evaluate participants' communication skills employing a 6-point Likert scale ranging from 0 ("poor behavior") to 5 points ("optimal behavior"). The global rating scale comprised 3 domains covering "verbal communication skills," "non-verbal communication skills," and "patient-centered communication." Consequently, a maximum of 15 points was achievable.

Self-Assessment Questionnaire

Each participant filled out a self-assessment questionnaire immediately preceding the summative pre- and post-training OSCEs. The questionnaire comprised 7 items intending to rate students' self-confidence or self-perceived proficiency using a 6-point Likert scale ranging from 0 ("very bad") to 5 points ("very good"). The self-assessment questionnaire comprised the following items:

1.) How do you rate your competence in self-medication counseling?
2.) How do you rate your competence in motivating a patient to carry out the therapy?
3.) How do you rate your competence in actively listening?
4.) How do you rate your competence to lead through questions?
5.) How do you rate your competence in structuring a counseling encounter according to the time available?
6.) How do you rate your competence in providing correct, relevant and useful information to the patient during the counseling?
7.) How do you rate your competence in transferring specialist knowledge in lay language?

The content of the self-assessment questionnaire applied in this study was based on studies prior (PharmAdhere study[180] and SiGDia-study in chapter 2). The self-assessment questionnaire for the post-training OSCE also surveyed demographic characteristics, including age, gender, additional education as a pharmaceutical technical assistant, and whether the pharmacy student works in a community pharmacy counseling patients.

Satisfaction Survey

After the post-training OSCE, a satisfaction survey (Appendix 7) was distributed to the participants. The satisfaction survey comprised 8 items rated on a 6-point Likert scale ranging from "strongly disagree" to "strongly agree" and 2 open-ended questions (free-text items) concerning what they particularly liked about the seminar and what they would suggest changing. For analysis, the comments on the free-text items were categorized into topics.

3.2.5 Summative OSCEs

The participants completed summative OSCEs before (summative pre-training OSCE) and after (summative post-training OSCE) training. The summative pre-training OSCE assessed the participants' baseline performance, while the summative post-training OSCE evaluated changes in their OSCE performance after the respective training. Participants filled out a self-assessment questionnaire before each summative OSCE encounter. A pharmacist with experience in community pharmacy developed 20 cases focused on self-medication for headache, heartburn, or diarrhea, 10 each for the summative pre- and post-training OSCEs. All cases were reviewed by another pharmacist. An SP, 1 observer, and 1 participant attended each OSCE encounter. Two participants completed each 1 OSCE simultaneously in a single lecture hall. Each OSCE was limited to a maximum of 7 minutes comprising a 1-minute pre-encounter phase, during which the participant had the possibility to read the instruction (Appendix 8) and the respective SmPC, and a patient encounter phase of a maximum of 6 minutes during which the participant assumed the role of the pharmacist and had the task to counsel the SP. The SP initiated each case by directly requesting a product from the participant. The observer evaluated the participant's performance using the respective case-specific analytical checklist and the global rating scale during the OSCEs. To reduce the risk of inter-observer variability due to 2 different observers involved in the study, the same observer was allocated to each participant for both the summative pre- and post-training OSCEs. The 2 SPs and 2 observers were portrayed by faculty members (pharmacists) who were instructed specifically on their tasks. An additional faculty member (pharmacist) was present during the summative OSCEs and coordinated the pre- and post-training OSCEs. Additionally, immediately after the summative post-training OSCE students received individual feedback from their respective observer on their performance. The content-related aspects to be considered in self-medication counseling regarding the indications tested in the summative OSCEs were presented to both groups prior to the pre-training OSCEs in the above-mentioned lecture.

3.2.6 Training for the Intervention Group

The intervention group was divided into 5 groups, each of which trained for approximately 1 hour on 2 summative pre-training OSCE cases concerning the indication the respective student completed in the pre-training OSCE. In each group, one case focused on counseling about a drug new to the patient (“initiation”) and the other about a drug known to the patient (“implementation”). The cases used for the summative pre-training OSCE were reused for the OSCE training in the intervention group. Each group was provided for the 2 respective cases the following material: respective SmPCs, the case-specific analytical checklists with the actor description, and the global rating scale. Within these groups, each study participant was instructed to portray the pharmacist. In each group, students not participating in the study played the role of the SP and/or observer, providing feedback using the respective case-specific analytical checklist and global rating scale. The intention of involving the non-participating students as SPs and/or observers in the formative OSCEs was to let them experience OSCEs as well since the study participants of both groups at least experienced summative OSCEs. Moreover, the participating students had the chance to listen focused on each other’s counseling and provide feedback without simultaneously performing the role of SP. Two instructors were present during training and moved from group to group to answer questions and give feedback.

3.2.7 Training for the Control Group

The control group worked for approximately 1 hour on handling SmPCs for OTC drugs indicated for the treatment of conditions not covered in the OSCEs (obstipation, athlete's foot, cough, and sore throat) in groups. Different indications were used for the control group’s training than in the intervention group’s training because those handled by the intervention group during their training and by both groups in the summative pre- and post-training OSCEs were already presented in the lecture to both groups and thus had already been discussed. Participants were required to process the information in the SmPCs in a structured approach by collecting information on each drug, including active ingredients, contraindications, patient situations requiring prior consultation or monitoring by

a physician, examples of interactions and adverse drug reactions, dosage and (maximal) duration of application in the scope of self-medication, important administering information, and approved age groups in the scope of self-medication. Additionally, they were required to collect examples of additional recommendations the pharmacist could provide for the assigned condition. The control group's activity on handling SmPCs intended, first, to facilitate students' ability to filter out autonomously relevant information on OTC-drugs from the SmPCs as a preparation for the summative post-training OSCE in which the SmPCs were provided as supporting materials. Second, it purposed to raise the awareness for important elements of self-medication counseling such as contraindications or dosage which need to be considered during counseling by the pharmacist.

3.2.8 Data Analyses and Statistical Methods

This study analyzed the effects of OSCE-based training on the analytical checklist, global rating scale, and self-assessment questionnaire scores and surveyed students' satisfaction. Point-based scores of the analytical checklists were converted into percentages and the analysis was carried out in percentages or percentage points to enable comparison across the different OSCE cases. Also, for the analyses of the global rating scale and self-assessment questionnaire, point-based scores were converted into percentages and the analyses were carried out in percentages or percentage points. A two-sided Mann-Whitney test was applied for a baseline comparison of the respective scores between the 2 groups. A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores was used to evaluate whether the respective scores increased significantly from pre-training assessment to post-training assessment. A one-sided Mann-Whitney test was used to assess whether score increases from pre-training assessment to post-training assessment in the respective scores were significantly greater in the intervention group as compared to the control group. In all statistical tests, the significance level was considered to be alpha = 0.05. Asymptotic *p*-values are considered in the following. The *p*-values were not adjusted for multiple testing.

All data were collected in pseudonymous form, except the anonymous satisfaction survey. After analysis, all data were rendered anonymous. The statistical software R[207] was used for randomization, Microsoft Excel 2019[191] was used for data entry, and Microsoft Excel 2019[191], OriginPro 2019[192], and OriginPro 2021[193] were used for analyses. All applied materials were in the German language (eg, analytical checklists, global rating scale, self-assessment questionnaire, satisfaction survey).

3.3 Results

3.3.1 Participants

Forty-six pharmacy students in the eighth semester signed the informed consent form and 40 of them were randomly selected for the study. All the 40 participants attended the summative pre-training OSCE. Participants who did not attend the training and/or summative post-training OSCE were excluded from the analyses. Additionally, 1 participant was excluded from the analyses due to non-standardized conditions during the summative post-training OSCE but could not be excluded from the satisfaction survey due to its anonymous character. Finally, 16 participants in the intervention group and 14 in the control group were included in the analyses of demographics, OSCE performance, and the self-assessment questionnaire. The demographic characteristics of the participants are depicted in Table 3-1.

Table 3-1: Demographic Characteristics of Participants in the CoSeMed-Study

Characteristics	Intervention group	Control group
Age in years	n = 16	n = 12 [a]
Mean (SD)	25.75 (2.84)	24.08 (1.73)
Median (IQR)	25 (4.5)	24 (3)
Range [b]	22 to 32	22 to 27
Gender	n = 16	n = 14
Female, n (%)	13 (81.25)	10 (71.43)
Male, n (%)	3 (18.75)	4 (28.57)
Additional education as a pharmaceutical technician assistant	n = 16	n = 14
Yes, n (%)	4 (25)	5 (35.71)
No, n (%)	12 (75)	9 (64.29)
Pharmacy student working in a community pharmacy (counseling patients)	n = 16	n = 13 [c]
Yes, n (%)	3 (18.75)	3 (23.08)
No, n (%)	13 (81.25)	10 (76.92)

CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling; SD = standard deviation; IQR = interquartile range.

[a] Two participants did not provide information about their age.

[b] Rage refers to minimum to maximum.

[c] One participant did not provide information about his/her work in a community pharmacy.

3.3.2 Analytical Checklist for OSCEs

The analytical checklist score reflects the participants' counseling skills, particularly regarding content. At baseline, there was no significant difference in the analytical checklist scores between the 2 groups ($p = 0.884$). Following respective training, significantly higher scores were observed for both groups in the summative post-training OSCE as compared to the summative pre-training OSCE (intervention group: $p < 0.001$; control group: $p = 0.007$) with the intervention group showing a significantly greater improvement than the control group ($p = 0.007$) in the analytical checklist score. Figure 3-2 and Table 3-2 show the results regarding the analytical checklist score.

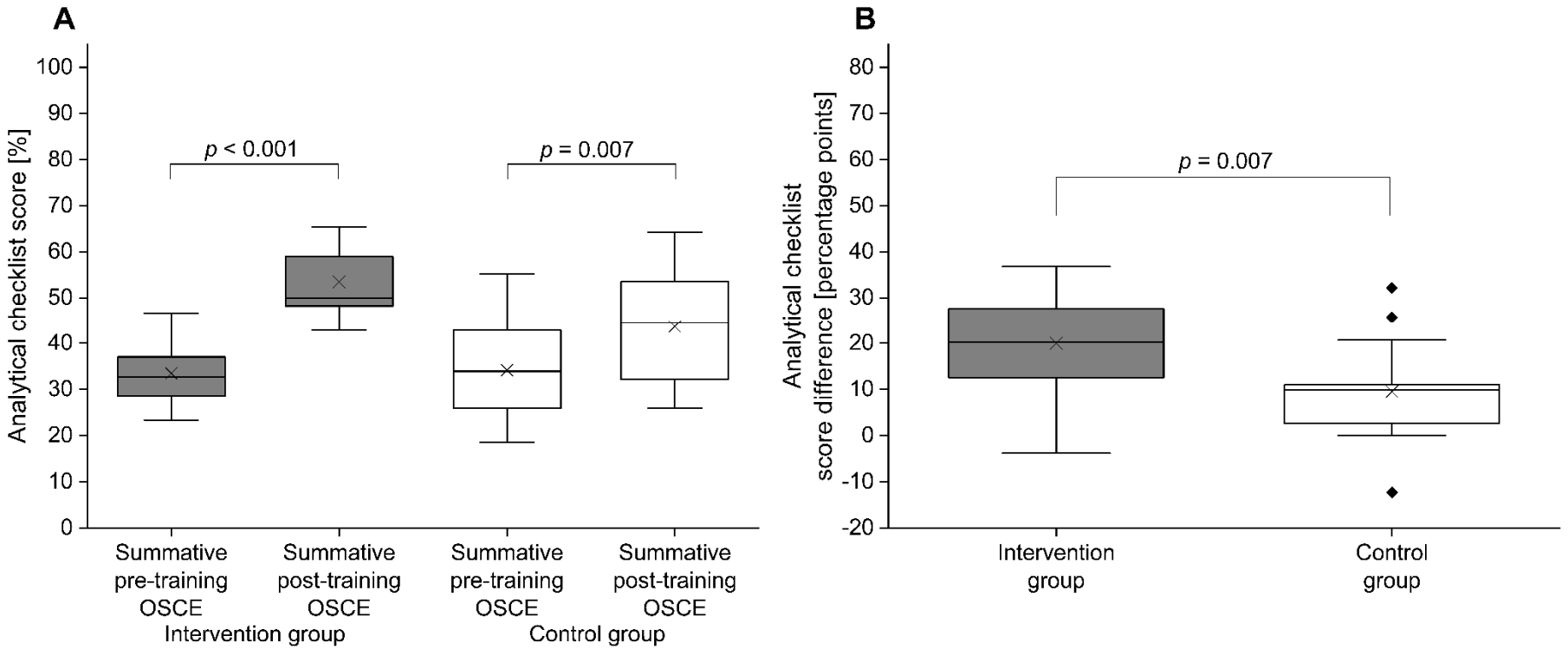

Figure 3-2: Analytical Checklist Scores in the Summative OSCEs in the CoSeMed-Study

CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling; OSCE = objective structured clinical examination.
Gray box = intervention group; white box = control group; cross mark (**x**) = mean; horizontal line = median, black diamond (♦) = outlier.
n = 16 in the intervention group and n = 14 in the control group. Results are depicted as box plots.
A: Depiction of pre- and post-training scores in the analytical checklist in percentage. A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.
B: Depiction of the differences between pre- and post-training scores in the analytical checklist in percentage points. A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used.

Table 3-2: Results of the Analytical Checklist in the Summative OSCEs in the CoSeMed-Study

Evaluation type: analytical checklist							
Group	**Pre-training score in %**		**Post-training score in %**		**Score difference in percentage points**		***p*-value [a]**
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Intervention group (n = 16)	33.47 (7.00)	32.74 (8.47)	53.46 (7.49)	50 (10.73)	19.98 (10.93)	20.19 (15.10)	$p = 0.007$
Control group (n = 14)	34.16 (10.95)	33.91 (16.93)	43.66 (11.36)	44.51 (21.43)	9.51 (11.16)	9.88 (8.34)	

CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling; OSCE = objective structured clinical examination; SD = standard deviation; IQR = interquartile range.

[a] A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used to assess whether the score increase from pre- to post-training OSCEs was significantly greater in the intervention group as compared to the control group.

3.3.3 Global Rating Scale for OSCEs

The global rating scale score represents the participants' communication skills. At baseline, there was no significant difference in the global rating scale scores between the 2 groups (p = 0.342). These scores significantly increased from pre- to post-training OSCEs for both the intervention group (p = 0.002) and the control group (p = 0.015). The intervention group tended to have a greater score increase in communication skills than the control group (intervention group: mean change = 20.83 pp [SD = 23.08 pp] and median change = 20 pp [IQR = 40 pp]; control group: mean change = 11.90 pp [SD = 17.77 pp] and median change = 13.33 pp [IQR = 26.67 pp]), although the increase was not significantly greater in the intervention group as compared to the control group (p = 0.157). Results regarding the global rating scale score are depicted in Figure 3-3 and Table 3-3.

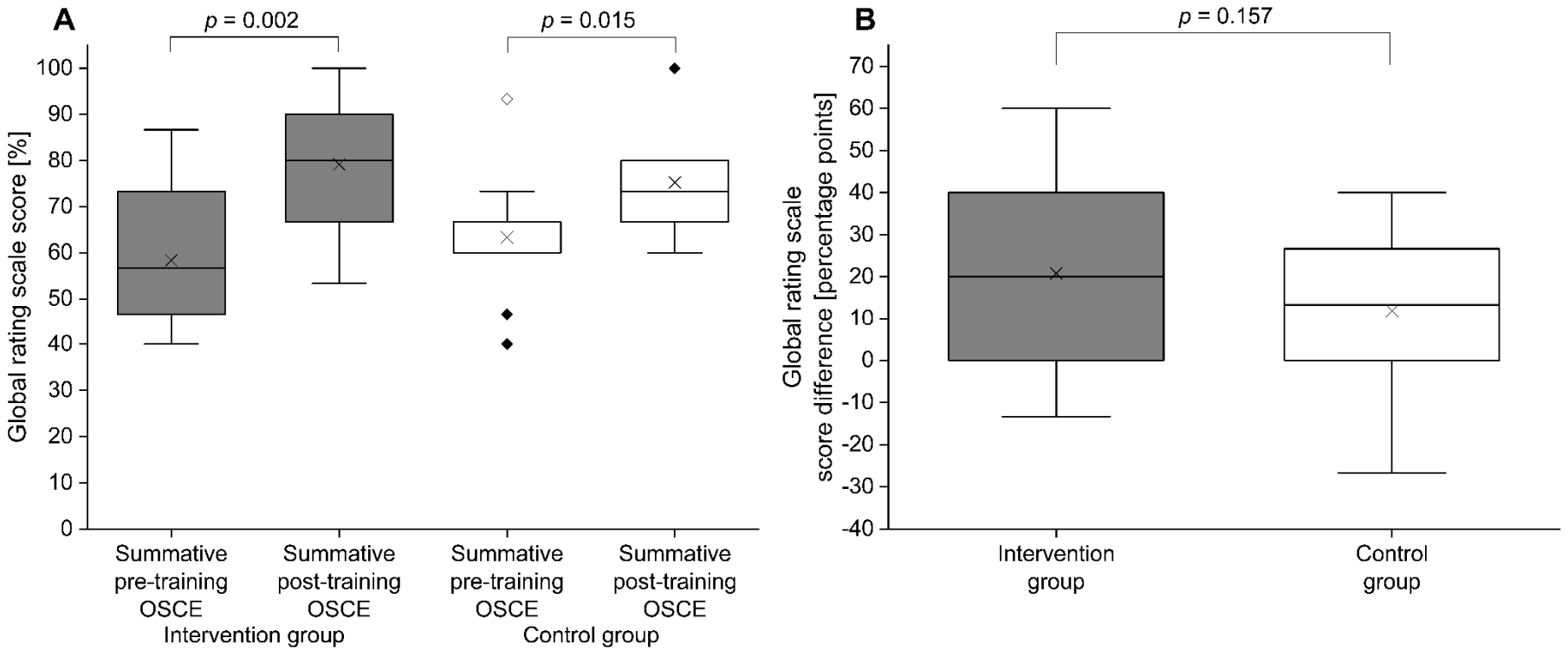

Figure 3-3: Global Rating Scale Scores in the Summative OSCEs in the CoSeMed-Study

CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling; OSCE = objective structured clinical examination.
Gray box = intervention group; white box = control group; cross mark (**x**) = mean; horizontal line = median; black diamond (♦) = outlier; white diamond (◊) = extreme value. n = 16 in the intervention group and n = 14 in the control group. Results are depicted as box plots.
A: Depiction of pre- and post-training scores in the global rating scale in percentage. A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.
B: Depiction of the differences between pre- and post-training scores in the global rating scale in percentage points. A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used.

Table 3-3: Results of the Global Rating Scale in the Summative OSCEs in the CoSeMed-Study

Evaluation type: global rating scale							
Group	**Pre-training score in %**		**Post-training score in %**		**Score difference in percentage points**		***p*-value [a]**
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Intervention group (n = 16)	58.33 (14.50)	56.67 (26.67)	79.17 (14.58)	80 (23.33)	20.83 (23.08)	20 (40)	$p = 0.157$
Control group (n = 14)	63.33 (14.02)	66.67 (6.67)	75.24 (9.58)	73.33 (13.33)	11.90 (17.77)	13.33 (26.67)	

CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling; OSCE = objective structured clinical examination; SD = standard deviation; IQR = interquartile range.

[a] A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used to assess whether the score increase from pre- to post-training OSCEs was significantly greater in the intervention group as compared to the control group.

3.3.4 Self-Assessment Questionnaire

The self-assessment questionnaire score reflects the participants' self-confidence or self-perceived proficiency. At baseline, there was no significant difference in the self-assessment questionnaire scores between the 2 groups ($p = 0.787$). While both groups showed a significant increase in the self-assessment questionnaire scores from the pre- training assessment to post-training assessment (intervention group: $p < 0.001$; control group: $p = 0.007$), the improvement was significantly higher for the intervention group as compared to the control group ($p = 0.022$). Figure 3-4 and Table 3-4 depict the results regarding the self-assessment questionnaire score.

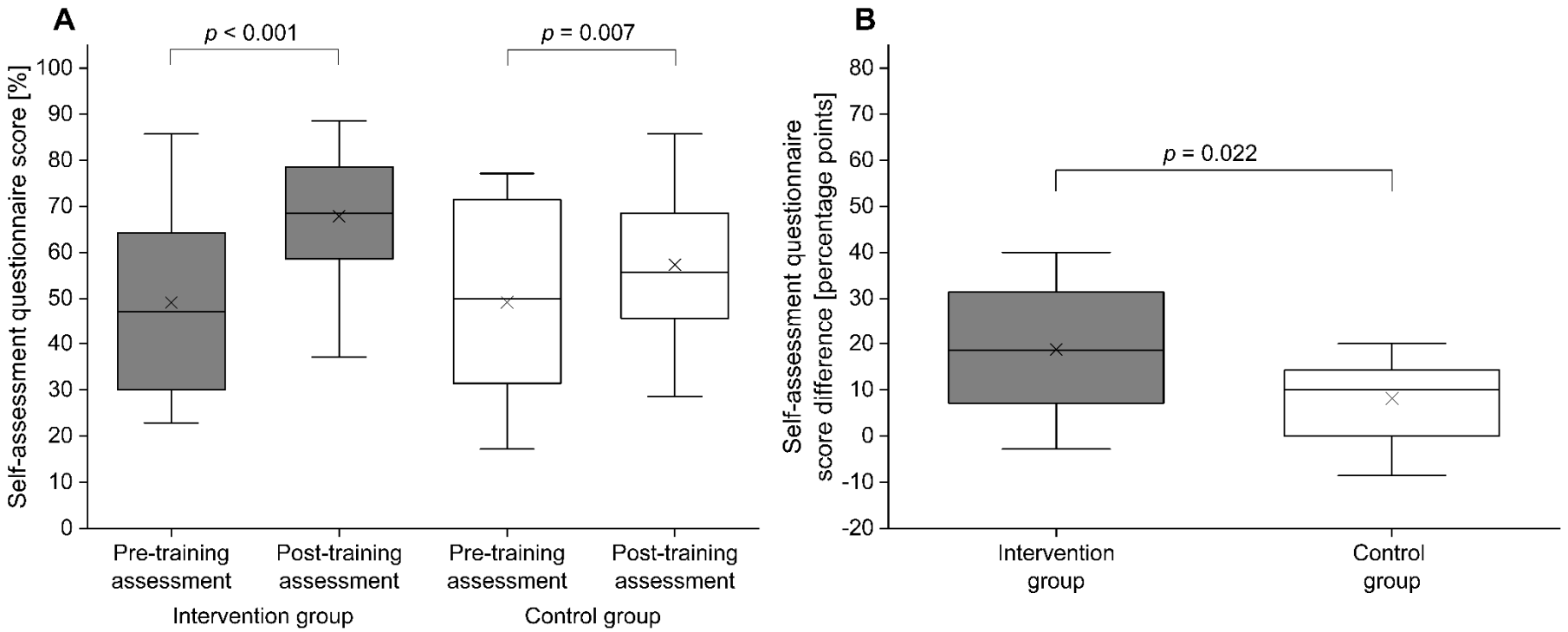

Figure 3-4: Self-Assessment Questionnaire Scores in the CoSeMed-Study

CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling.
Gray box = intervention group; white box = control group; cross mark (**x**) = mean; horizontal line = median.
n = 16 in the intervention group and n = 14 in the control group. Results are depicted as box plots.
A: Depiction of pre- and post-training scores in the self-assessment questionnaire in percentage. A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.
B: Depiction of the differences between pre- and post-training scores in the self-assessment questionnaire in percentage points. A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used.

Table 3-4: Results of the Self-Assessment Questionnaire in the CoSeMed-Study

Evaluation type: self-assessment questionnaire							
Group	**Pre-training score in %**		**Post-training score in %**		**Score difference in percentage points**		***p*-value [a]**
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Intervention group (n = 16)	49.11 (20.05)	47.14 (34.29)	67.86 (13.98)	68.57 (20)	18.75 (14.00)	18.57 (24.29)	$p = 0.022$
Control group (n = 14)	49.18 (19.51)	50 (40)	57.35 (15.47)	55.71 (22.86)	8.16 (9.43)	10 (14.29)	

CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling; SD = standard deviation; IQR = interquartile range.
[a] A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used to assess whether the score increase from pre-training assessment to post-training assessment was significantly greater in the intervention group as compared to the control group.

3.3.5 Satisfaction Survey

A total of 22 participants, who attended both summative OSCEs and the respective training, completed the satisfaction survey, which did not distinguish between the 2 groups. The results of the survey are depicted in Tables 3-5 and 3-6. The majority of participants approved of the “OSCE seminar,” with 72.73% (slightly agree, agree, and strongly agree summarized) agreeing to some extent that OSCEs should be implemented in future clinical pharmacy courses to train counseling skills.

Table 3-5: Results of the Satisfaction Survey in the CoSeMed-Study

Item	Proportions of responses in %					
	Strongly disagree	Disagree	Slightly disagree	Slightly agree	Agree	Strongly agree
I enjoyed the OSCE seminar.	4.55	13.64	4.55	27.27	45.45	4.55
During the OSCEs, I was able to determine my strengths and weaknesses.	0	4.55	31.82	22.73	31.82	9.09
The OSCE seminar conveyed safety in dealing with patients in the community pharmacy.	4.55	18.18	22.73	22.73	18.18	13.64
The OSCE cases were practice-oriented.	0	4.55	18.18	31.82	40.91	4.55
The OSCE cases were too easy.	0	9.09	27.27	27.27	22.73	13.64
The OSCE cases were too difficult.	36.36	31.82	27.27	4.55	0	0
Two days for the OSCE seminar were sufficient.	4.55	13.64	27.27	18.18	13.64	22.73
OSCEs should be implemented in future clinical pharmacy courses to train counseling skills.	4.55	9.09	13.64	13.64	40.91	18.18

CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling; OSCE = objective structured clinical examination.
N = 22 (from the intervention group and the control group).

Table 3-6: Example Topics of Comments from Free-Text Items of the Satisfaction Survey in the CoSeMed-Study

Free-text item	Topic of comments	Number of comments on the topic
I particularly liked the following at the OSCE seminar:	Patient counseling	4
	Receiving feedback after summative post-training OSCE	4
	Friendly faculty members	3
I would change the following:	Long waiting times for the summative OSCEs	8
	OSCE cases were too easy or not realistic	5
	Training on the summary of product characteristics was unnecessary (control group's training)	4

CoSeMed-study = randomized controlled study on OSCE training for self-medication counseling; OSCE = objective structured clinical examination.
The 3 most frequent topics of comments for each item are shown. Further topics of comments can be found in Appendix 9.

3.4 Discussion

This randomized controlled study showed that the applied OSCE-based training approach provides an effective approach for teaching self-medication counseling. The OSCE-based training in the intervention group resulted in a significantly greater increase in students' self-confidence or self-perceived proficiency, as well as their counseling skills, compared to a non-OSCE-trained control group. However, OSCE-based training did not result in a significantly greater increase of communication skills in the intervention group as compared to the control group. The majority of students were generally satisfied with the seminar.

The findings in the CoSeMed-study strongly support the use of OSCEs as a method for training self-medication counseling skills to pharmacy students, with the applied OSCE-based training resulting in significantly greater improvements in counseling performance in the intervention group compared to the control group. However, there is still controversy regarding the efficacy of formative OSCES in the literature.[106,180,197] Moreover, only a few investigations focus on the use of NPM-related OSCEs. For example, Hastings et al investigated the effect of summative NPM OSCEs on students' final grades. They refined the NPM elective course for pharmacy students by including case-based small group periods, which incorporated role-playing (which can be considered to be similar to the formative OSCEs in the present study) and other tasks, and added a final summative OSCE. They found similar overall grades compared to previous years where summative OSCEs were not part of the overall grade. However, they did not report further results regarding the efficacy of their refined elective course on their summative OSCEs.[29] The CoSeMed-study evaluated the efficacy of a peer learning–based OSCE training approach in a randomized controlled design and found a significantly greater improvement of the analytical checklist score from summative pre- to post-training OSCEs for the OSCE-trained intervention group compared to the control group, although there is still room for improvement (analytical checklist score in the post-training OSCE: mean = 53.46% [SD = 7.49%] and median = 50% [IQR = 10.73%] for the intervention group). In contrast to that, Hastings et al reported an average grade of 78% in the 3-case OSCE final, where students had completed a 2-credit-hour elective course on NPMs (after a core course on NPMs).[29] It may be hypothesized that longer or

more frequent training will lead to higher analytical checklist scores and better counseling performance. Moreover, more instructor-guided activities such as students presenting OSCE counseling encounters in front of the plenum with feedback might also lead to higher analytical checklist scores.

The use of formative OSCEs in this study did not lead to a significantly greater increase in the communication skills of the intervention group as compared to the control group, although both groups displayed significant improvement from the summative pre- to post-training OSCEs regarding the global rating scale score. It might be possible that longer and more frequent OSCE training sessions would result in a significantly higher increase in the intervention group's global rating scale score as compared to the control group. This assumption is also indicated by findings in the literature.[212] For example, a randomized controlled study by Cannick et al investigating a brief 2-hour communication skills training for dental students assessed by OSCEs found no significant differences from baseline to post-test between the intervention and control group. They concluded that the brief training was insufficient and that comprehensive training with frequent reinforcements might be more beneficial.[212] However, it should be considered that in the CoSeMed-study, the final scores (post-training scores) of the global rating scale in the intervention group show small room for further improvement.

In this study, increases in self-assessment questionnaire scores reflect increases in participants' self-confidence or self-perceived proficiency. This study found significant increases in self-confidence or self-perceived proficiency through the application of OSCE-based training as indicated in the literature[120] and the SiGDia-study (chapter 2). Moreover, the majority of students in the CoSeMed-study agreed to some extent (strongly agree, agree, slightly agree summarized) that OSCEs should be implemented in future clinical pharmacy courses for training counseling skills. These findings support students' acceptance of OSCEs, which is in line with the findings of previous studies.[123,200,201] Hastings et al reported a similar positive attitude from pharmacy students regarding the use of NPM-focused OSCEs for assessing their clinical skills.[29] Although the control group's training with the SmPCs was rather disliked by the students, the positive results, in particular, the significant increase in the analytical checklist score, global rating scale score, and self-assessment questionnaire score from pre- to

post-training OSCEs/assessments indicate a potential beneficial effect of the control group's training. Nevertheless, regarding the analytical checklist and self-assessment questionnaire, the OSCE-trained group was superior.

It may be possible that using a pre-test/post-test design might have led to underestimating the effect of the intervention (OSCE-based training). The pre-training OSCE might have caused a learning effect as the students were faced with their weaknesses as previously suggested by other researchers.[198] As such, it is possible that removing the pre-training OSCE from this study would better reveal the effects of the intervention, including in the participants' communication skills. Thus, the control group's improvement in analytical checklist score, global rating scale score, and self-assessment questionnaire score from pre- to post-training OSCEs might be affected not only by their training but also by experiencing the pre-training OSCE. Nevertheless, it might be assumed that also the intervention group might have a learning effect to some extent from the pre-training OSCE. Despite that, it was decided to apply a pre-post design and refrain from applying a post-course design with an assessment only at the end of an educational intervention as it is difficult to account for observed changes due to the missing baseline data.[204]

This study is not without limitations. The analytical checklists and global rating scale were only available to the intervention group during their training to enable the students to provide each other adequate feedback and were collected again after the approximately one-hour training. The checklists were not provided to the control group. Although a potential impact of the provision of the checklists cannot be completely excluded, it may be assumed that knowledge of the checklists would probably not substantially affect the performance of the intervention group compared to the control group during the summative post-training OSCEs. This assumption is supported by the findings of Cole and colleagues. In particular, they compared the OSCE scores of students who attended a peer-taught training session to the scores of students who did not attend the session. Both groups were provided with scoring rubrics during the semester. Although differences in student scores for each skill were not statistically significant between both groups, they found a significant difference in the overall OSCE score favoring the group which attended the training session.[213] The rationale of providing the checklists

to the intervention group was to set a framework for adequate peer feedback while coping with limited staff available. The decrease in participation rate at the post-training OSCE, which was the final clinical pharmacy course day in the semester, might be due to competing demands in their time at the end of the semester because of pending exams. Moreover, in educational research "contamination" can occur, such as students randomly assigned to different groups share information.[214] To mitigate this possible bias, the post-training OSCEs were conducted immediately after the training on the same day. Furthermore, due to the lack of staff, only 2 OSCE encounters could take place at 1 time. Thus, some students had long waiting times for the OSCEs which was criticized in the satisfaction survey. This might have negatively influenced the results of the satisfaction survey.

Despite these limitations, the results show benefits of applying an OSCE-based training approach in improving pharmacy students' self-medication counseling performance. Given pharmacists' role in ensuring the safe, appropriate, and effective application of self-medication,[31] and the room for improvement of pharmacists' self-medication counseling skills indicated in the literature,[44-46] an OSCE-based training is a valuable approach to support future pharmacists' education on counseling.

3.5 Conclusion

This study found that the applied OSCE-based training was widely accepted by pharmacy students and provides an effective method for training self-medication counseling. Applying OSCEs as a learning tool in pharmacy education is beneficial, improving the students' counseling skills as well as self-confidence or self-perceived proficiency. These findings support the inclusion of this strategic educational approach throughout pharmacy education and highlight its potential for bridging gaps between knowledge and practice. Nevertheless, participants showed still room for improvement in counseling skills. Consequently, these findings encouraged to conduct a further randomized controlled study described in chapter 4 with modifications of the OSCE-based training approach as well as in the study design. The study was applied on the topic of diabetes counseling as in chapter 2 to establish also a controlled study for the indication diabetes. In particular, in chapter 4, a randomized controlled study was used to investigate the efficacy of an OSCE-based approach to train pharmacy students in diabetes mellitus counseling (CoDia-study). Based on experiences from the previous studies of this dissertation, the CoDia-study design and training were developed. Compared to the CoSeMed-study, among others, the training period was extended, the instructor was more involved in the training process, the time schedule of the study was adjusted to avoid students' absence due to pending exams, participants' diabetes knowledge was assessed with multiple-choice tests, and participants were surveyed regarding their preparation for the OSCEs.

3.6 Disclosure

Parts of this chapter were previously published as “Farahani I, Farahani S, Deters MA, Schwender H, Laeer S. Training pharmacy students in self-medication counseling using an objective structured clinical examination–based approach. *J Med Educ Curric Dev*. 2021;8:1-9. doi:10.1177/23821205211016484.” The author of this dissertation had a lead role in and substantially contributed to the conceptualization, methodology, formal analysis, investigation, data curation, visualization, writing - original drafts, as well as writing - review, and editing.

4. Efficacy of an Objective Structured Clinical Examination–Based Approach for Training Pharmacy Students in Diabetes Mellitus Counseling: A Randomized Controlled Trial (CoDia-Study)

4.1 Background and Aim

Pharmacists are responsible for supplying patients and health care professionals with medicines and other health care products and counseling them concerning their proper usage.[15,16] Pharmacists should ensure that patients are aware of the correct timing of doses, drug-drug interactions, drug-food interactions, and possible adverse drug reactions, among others.[15] Additionally, patients' adherence should be supported.[15] Community pharmacists, as accessible health care professionals and experts in drug therapy,[1-3] are well positioned to contribute to patients' adherence to long-term therapy.[30,35]

The aspects of adherence and correct application are crucial issues for patients with diabetes mellitus.[153] The worldwide diabetes prevalence was estimated to be 463 million people in 2019.[147] Several investigations have shown the benefits of involving pharmacists in the therapy management of diabetes mellitus patients.[10,154-156] Poor adherence still occurs among patients with diabetes mellitus and is associated with poor glycemic control, increased risk of hospitalization, increased mortality, and higher costs.[148-151]

Proper medication counseling contributes to patients' adherence.[215,216] Furthermore, structured counseling models are found to be useful tools to improve drug use by facilitating the identification and resolution of drug-related problems.[217] Globally, the majority of pharmacists work in community pharmacies.[176] For example, it was estimated that in 2020 approximately 78% of pharmacists in Germany worked in community pharmacies.[71] As patient counseling is one of pharmacists' key tasks,[17,18] pharmacists must be able to provide optimal counseling to contribute properly to their patients' therapy. Therefore, promoting counseling and communication skills in pharmacy students

is essential to the fulfillment of their future role as community pharmacists. These patient-oriented aspects should be addressed in pharmacy education.

A possible way to address these issues could be the use of OSCEs. OSCEs provide a safe environment for students to apply clinical skills without risk to patients.[100-102] The use of OSCEs as a learning tool has been described in different settings, such as under examination-like conditions with additional feedback[106,197] or more extensive training conditions.[116,123,180] However, the effectiveness of OSCEs as a learning tool is controversial.[106,180,197] Gums et al found a significant improvement in OSCE performance after an individualized formative assessment in a laboratory session,[218] which can be considered as a formative OSCE-like approach. However, Chisnall et al reported that formative OSCEs did not result in a significant change in the overall pass rate of summative OSCEs, and found improved performance in subsequent summative OSCEs only in particular stations.[106] Alkhateeb et al found that formative OSCEs did not result in a significant difference in pass rate compared to the control group and that the group without formative OSCEs achieved even higher OSCE scores.[197] Nevertheless, OSCEs as a learning tool are well received by students[116,123] but are facility-, time-, cost-, and personnel-intense.[101,103,104,106] GOSCEs or peer-assessed OSCEs may address some of the problems encountered with using OSCEs as a learning tool.[89,114,116,120] In GOSCEs, the learners rotate in groups around the stations rather than as individuals, and learners can observe each other executing the clinical task at each station.[114-116,122] Peer-assessed OSCEs allow students to gain OSCE experience and are well received by assessed and assessors.[89,120,121]

The previous studies of this dissertation showed a beneficial effect of OSCE-based training on pharmacy students' diabetes mellitus and self-medication counseling. This study, abbreviated CoDia-Study, investigated the efficacy of an OSCE-based training approach for training pharmacy students in counseling on diabetes mellitus compared to a control group. In particular, the impact of the OSCE-based training on participants' counseling skills as measured by analytical checklists, communication skills as measured by a global rating scale, self-confidence or self-perceived proficiency as measured by a self-assessment

questionnaire, and satisfaction as measured by a satisfaction survey were assessed.

4.2 Methods

4.2.1 Operational Definitions

For the purpose of this work, the term “formative OSCEs” describes OSCEs for training purposes, which were used for the intervention group’s training in the study. The term “patient cases” refers to the training of the control group, in which patient cases were solved by the preparation and discussion of subjective, objective, assessment, and plan (SOAP) notes. Moreover, in this work, the term “summative OSCEs” refers to OSCEs for assessing the participants' performance at baseline (summative pre-training OSCE) as well as after training (summative post-training OSCE). In this study, the summative OSCEs did not affect the students’ passing of the course and served as a measurement instrument for the study.

4.2.2 Study Design and Participants

This study assessed the effect of an OSCE-based training approach using a randomized controlled trial with a pre-post design. The investigation was conducted in the April–June 2019 period during the clinical pharmacy course at Heinrich Heine University Düsseldorf. The language of the investigation was German. Approval for this study was granted by the ethics committee of the medical faculty of Heinrich Heine University Düsseldorf (study number 2019-467-ProspDEuA). Students in the eighth and final semester of their university pharmacy studies were invited to participate in the study in April 2019. The students were informed about the study and were provided with written participant information and an informed consent form. Participants who signed the informed consent form were randomized to either the intervention group or control group using the statistical program R.[207] The students were requested not to share information between the groups until the end of the study to avoid possible bias by “contamination” due to sharing information.[214] The study procedure is illustrated in Figure 4-1.

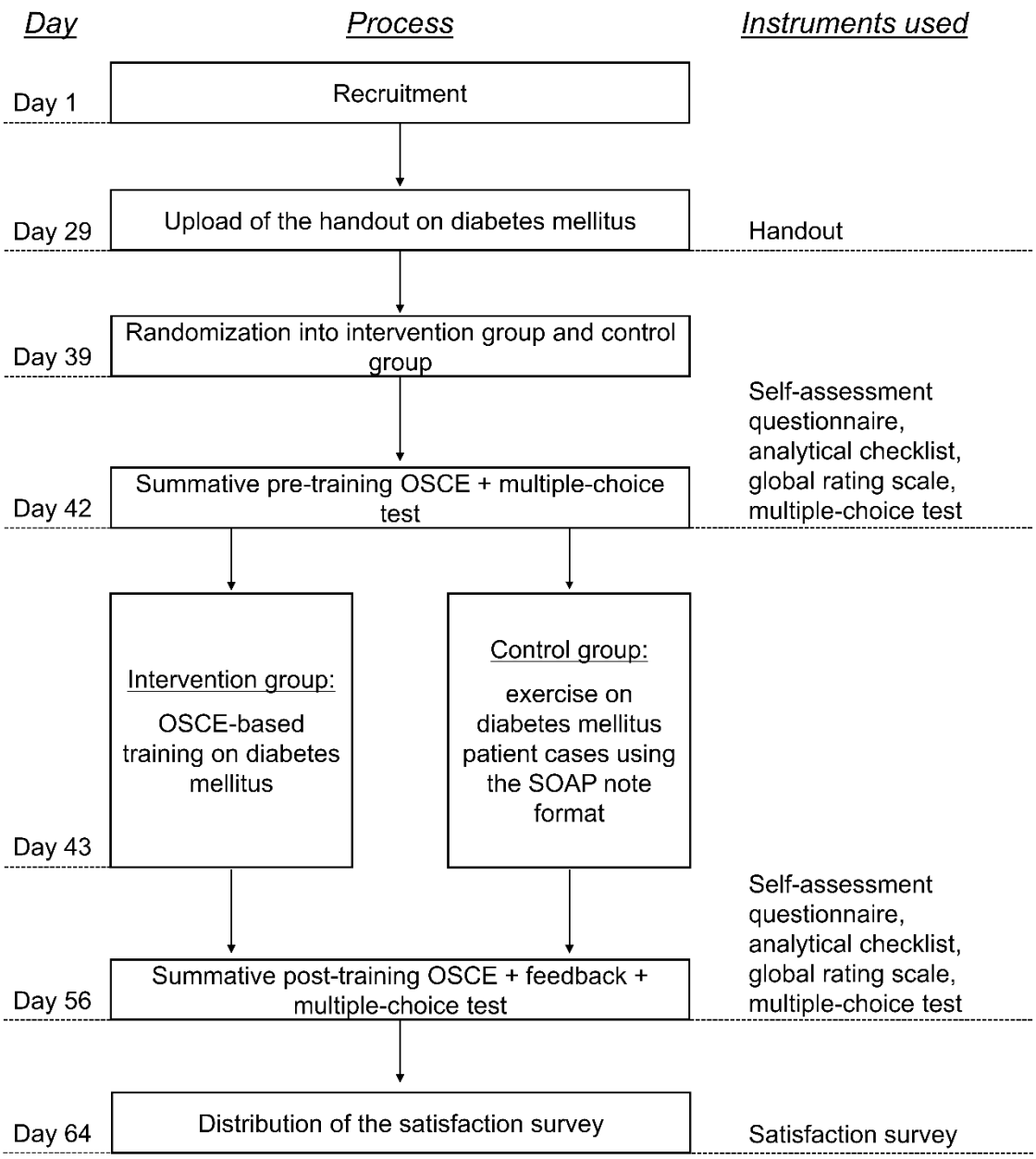

Figure 4-1: Overview of the Study Procedure of the CoDia-Study

CoDia-study = randomized controlled study on OSCE training for diabetes counseling; OSCE = objective structured clinical examination; SOAP = subjective, objective, assessment, plan.

4.2.3 Study Procedure

At the beginning of the study, a diabetes mellitus handout was uploaded online. After about 2 weeks, the participants completed a summative pre-training OSCE and the first multiple-choice test on diabetes mellitus. The next day, the participants completed training depending on their group allocation. Participants in the intervention group attended an OSCE-based training (with formative OSCEs) for approximately 2.5 hours, while the control group was trained using the university's traditional teaching method for approximately 2 hours, involving the preparation of SOAP notes to solve diabetes mellitus patient cases and discussing them. About 2 weeks after the training, participants of both groups completed a summative post-training OSCE and a second multiple-choice test on diabetes mellitus. About 1 week after the summative post-training OSCE, the participants' satisfaction with the OSCE seminar was surveyed.

4.2.4 Instruments

Handout

An about 24-page (without references) diabetes mellitus handout covering general information, therapy, and complications of diabetes mellitus based on national guidelines[188,189] was prepared by a pharmacist and reviewed by another pharmacist. The handout, aiming to bring the participants' knowledge on diabetes mellitus to the same level, was uploaded online approximately 2 weeks before the summative pre-training OSCE and was accessible to all eighth-semester pharmacy students throughout the whole semester.

OSCE Cases

The pharmacist who prepared the handout generated 12 OSCE cases on diabetes mellitus type 2 with hypertension and/or dyslipidemia comorbidities and/or NPM use, which were reviewed by the pharmacist who reviewed the handout. Half of the OSCE cases dealt with the introduction of an antidiabetic drug ("initiation" of therapy) while the other 6 cases dealt with a follow-up prescription of an antidiabetic drug ("implementation" of therapy). The OSCE

cases were designed to be completed within a maximum of 10 minutes. This timeframe was deemed to be appropriate according to the PharmAdhere study,[180] the pilot testing of the OSCEs before the SiGDia-study, and the SiGDia-study (chapter 2). Six OSCE cases (3 initiation cases and 3 implementation cases) were used in the summative pre-training OSCE while the remaining cases were used in the summative post-training OSCE. The cases used for the summative pre-training OSCE were reused for the OSCE training in the intervention group.

Analytical Checklist for OSCEs

An analytical checklist and a global rating scale were used to evaluate the participants' performance. An observer filled out a case-specific analytical checklist for each participant to evaluate the participants' counseling skills in the summative pre- and post-training OSCEs. The analytical checklists focused on the content of the counseling. The global analytical checklist for OSCEs (Appendix 10) was adjusted for each OSCE case so that the case-specific analytical checklists only included the items relevant for the respective case. Consequently, 12 OSCE case-specific analytical checklists were created, with varying total scores; therefore, the analysis was carried out in percentages or percentage points. The checklists included exemplary dialogues to facilitate the observers' task. One point was given when the participant addressed the respective item correctly; if not, 0 points were awarded. Items that could not be performed wrongly (did only have the checkbox "addressed" and did not have the checkbox "correctly") were awarded 1 point if the item was addressed; if not 0 points were awarded. The analytical checklists comprised the following sections: "greeting," "medical history," "drug information" (initiation or implementation), "prevention," "goal setting," "patient involvement," and "risk communication." Each section was comprised of 1 or more items. The global analytical checklist used for this study was based on that one from the SiGDia-study (which was adapted from the PharmAdhere study[180]) with some modifications such as adding the items "Adds/corrects incorrect use of the drug/information provided by the

patient" and "Adds/corrects incorrect handling of side effects/interactions" and adding a "comment" box for each item.

Global Rating Scale for OSCEs

A global rating scale for OSCEs, modified beforehand from the PharmAdhere study[180] for the SiGDia-study (chapter 2) and used in the SiGDia-study (chapter 2) and the CoSeMed-study (chapter 3), was applied to assess the participants' communication skills during the summative pre- and post-training OSCEs. The global rating scale focused on the domains "verbal communication skills," "non-verbal communication skills," and "patient-centered communication" using a 6-point Likert scale ranging from 0 ("poor behavior") to 5 points ("optimal behavior"). Consequently, a maximum of 15 points was achievable.

Multiple-Choice Test on Diabetes Mellitus

A multiple-choice test on diabetes mellitus assessed the participants' knowledge immediately after the summative pre- and post-training OSCEs. The multiple-choice test used after the summative pre-training OSCE (first multiple-choice test) was not the same as the one after the summative post-training OSCEs (second multiple-choice test), with each of the 2 tests consisting of 4 questions. Appendix 11 and 12 show the multiple-choice tests. The test was conducted in the same lecture hall as the summative OSCEs immediately after the completion of the respective summative OSCE.

Self-Assessment Questionnaire

Participants filled out a self-assessment questionnaire before each summative OSCE to record their self-confidence or self-perceived proficiency regarding their counseling skills before and after the respective training. The self-assessment questionnaire used a 6-point Likert scale from 0 ("strongly disagree," *trifft gar nicht zu*) to 5 points ("strongly agree," *trifft voll zu*) and comprised the following 7 items:

1.) I feel competent in counseling a patient with diabetes mellitus.
2.) I feel competent to motivate patients to carry out the therapy.
3.) I feel able to actively listen during a counseling encounter.
4.) I feel able to lead the patient through questions.
5.) I feel able to structure a counseling encounter according to the available time (10 minutes).
6.) I feel competent to pass on correct, relevant, and useful information to the patient during the counseling encounter.
7.) I feel competent to convey my specialist knowledge in lay language.

The content of the questionnaire was based on the one used in PharmAdhere[180] and SiGDia-study (chapter 2). The self-assessment questionnaire at pre-training assessment also collected the participants' demographic characteristics including age, gender, additional education as pharmaceutical technical assistants, and current or former work counseling patients in a community pharmacy.

Preparation Questionnaire

Participants completed a survey after each summative OSCE to determine their preparation, which inquired whether they had prepared for the particular summative OSCE and, if yes, the tools used for preparation and duration of preparation (Appendix 13 and 14).

Satisfaction Survey

Participants completed a survey to assess their satisfaction with the seminar. The survey (Appendix 15) comprised 8 items using a 6-point Likert scale ranging from "strongly disagree" to "strongly agree." Additionally, 2 free-text items asked what they particularly liked about the seminar and what they would suggest changing. For analysis, the comments on the free-text items were categorized into topics.

4.2.5 Summative OSCEs

Participants completed a summative pre-training OSCE and about 2 weeks later a summative post-training OSCE. The summative OSCEs comprised 1 station which simulated a patient encounter. One SP, 1 observer, and 1 participant attended each OSCE encounter. The participant's task was to take over the role of the pharmacist and counsel the SP on the use of an antidiabetic drug and, where applicable, to solve and/or prevent potential drug-related problems and/or clarify the SP's questions. Each OSCE case began with a 1-minute pre-encounter phase, in which the participant could read the short instruction (example in Appendix 16) and the SmPC of the antidiabetic medication the case dealt with. After the pre-encounter period, a maximum 10-minute patient encounter period began with the SP handing over a prescription on an antidiabetic drug to the participant. If in the course of the counseling the participant found out that the patient's medication includes in addition other drugs than the drug on the prescription, the other respective SmPCs were provided. Performance in the OSCE was assessed by the observer using a case-specific analytical checklist and the global rating scale. Three pharmacists experienced in rating OSCEs performed the role of observers, allowing 3 simultaneous patient encounters regarding 3 different OSCE cases from a pool of 6 cases for the summative pre-training OSCE to occur in a single lecture hall. The summative post-training OSCEs used a different pool of 6 cases. Cases 2, 4, 6 (pre-training OSCEs) as well as 7, 9, 11 (post-training OSCEs) dealt with a patient getting dapagliflozin, acarbose, insulin glargine, sitagliptin, glibenclamide, or metformin for the first time ("initiation" of antidiabetic treatment). Cases 1, 3, 5 (pre-training OSCEs) as well as 8, 10, 12 (post-training OSCEs) dealt with the patient handing over a follow-up prescription for metformin, sitagliptin, glibenclamide, acarbose, insulin lispro, or glimepiride ("implementation" of antidiabetic treatment). The observers received instructions for filling out the analytical checklist and global rating scale. The SPs were portrayed by pharmacists (faculty members) or pharmacy students in the eighth semester who were not participants. The SPs read their scripts and received additional instructions prior to the OSCEs. Following the completion of the summative post-training OSCEs (immediately after the patient encounter),

participants additionally received individual feedback on their performance from their observer.

4.2.6 Training for the Intervention Group

Training for the intervention group consisted of a short lecture on structured pharmaceutical counseling based on the global analytical checklist and peer-assisted formative OSCEs in groups. During the training OSCEs, the participants practiced, in groups of 4 to 5, the OSCE case which they had to complete in their summative pre-training OSCEs. Consequently, each of the 6 groups trained on a different OSCE case. In each group, 1 member functioned as the pharmacist, 1 as SP, and the remaining members as observers, taking turns in each role. The participants used the global analytical checklist which was not case-specific to standardize their assessment and feedback. In this global analytical checklist, all items contained checkboxes with “addressed,” “correct,” and “comment,” unlike the global analytical checklist on which the case-specific analytical checklists used in the summative OSCEs were based. The checklist was only provided to the intervention group during the approximately 2.5-hour training and was returned at the end of that training. Moreover, the lecture slides were not made available. After practicing the OSCE cases in groups, 2 participants from each group, with one portraying the pharmacist and the other the patient, presented their practiced patient counseling to the other groups and instructors. The instructors completed the case-specific analytical checklists and global rating scale. Following the presentation, the presenters received feedback from the other groups in the intervention group and the instructors.

4.2.7 Training for the Control Group

The 5 diabetes mellitus patient cases used for the training of the control group were designed and reviewed by the pharmacists involved in developing the handout and OSCE cases. Medications and problems used in the summative pre-training OSCE were integrated into the patient cases. The students were divided into 10 groups of 3 or 4 participants, with each group assigned 1 of the 5 patient

cases. The participants prepared SOAP notes and discussed their solutions with the other groups and an instructor (a pharmacist/faculty member). The students who did not sign the informed consent form took part in the control training without their data being collected. The control group's training took about 2 hours.

4.2.8 Data Analyses and Statistical Methods

Point-based scores of the analytical checklists were converted into percentages and the analysis was carried out in percentages or percentage points to enable comparison across the different OSCE cases. Also, for the analyses of the global rating scale and self-assessment questionnaire, point-based scores were converted into percentages or percentage points. *P*-values were calculated for the analytical checklist score, global rating scale score, and self-assessment questionnaire score. A two-sided Mann-Whitney test with a significance level of alpha = 0.05 was used to compare the respective baseline scores between the groups. A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used to evaluate whether the respective scores increased significantly from pre-training assessment to post-training assessment for each group. A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used to assess whether the increase from pre-training assessment to post-training assessment in the respective scores was significantly higher in the intervention group than in the control group. In addition, a one-sided Mann-Whitney test with a significance level of alpha = 0.05 was applied to assess whether the increase in the respective scores was significantly higher in the present study (CoDia-study) as compared to the CoSeMed-study. Asymptotic *p*-values are considered in the following. The *p*-values were not adjusted for multiple testing. Microsoft Excel 2019[191] was used for data entry and Microsoft Excel 2019,[191] OriginPro 2019,[192] and OriginPro 2021[193] were used for analyses. All data were collected in pseudonymous form, with the exception of the anonymous satisfaction survey. All data were rendered anonymous following analyses. All applied materials were in the German language (eg, handout, analytical checklists, global rating scale, self-assessment

questionnaire, satisfaction survey, multiple-choice tests, preparation questionnaires).

4.3 Results

4.3.1 Participants

Of the 58 available eighth-semester pharmacy students invited for participation, 52 signed the informed consent form. From these, 3 were excluded from the analyses due to the non-attendance of the summative pre- or post-training OSCEs or the training day. Of the 6 non-participating students, 3 assisted voluntarily as SPs, and 3 participated in the control group without their data being collected. Overall, 49 participants were included in the analyses. The demographic characteristics of the intervention and the control group are described in Table 4-1.

Table 4-1: Demographic Characteristics of Participants in the CoDia-Study

Characteristics	Intervention group (n = 25)	Control group (n = 24)
Age in years		
Mean (SD)	26.2 (6.14)	24.96 (5.80)
Median (IQR)	25 (5)	23.5 (3)
Range [a]	21 to 49	20 to 50
Gender		
Female, n (%)	18 (72)	16 (66.67)
Male, n (%)	7 (28)	8 (33.33)
Additional education as a pharmaceutical technician assistant		
Yes, n (%)	5 (20)	1 (4.17)
No, n (%)	20 (80)	23 (95.83)
Currently or formerly working in a community pharmacy (counseling patients)		
Yes, n (%)	2 (8)	6 (25)
No, n (%)	23 (92)	18 (75)

CoDia-study = randomized controlled study on OSCE training for diabetes counseling; SD = standard deviation; IQR = interquartile range.
[a] Rage refers to minimum to maximum.

4.3.2 Analytical Checklists for OSCEs

The participants' counseling skills were assessed in the summative pre- and post-training OSCEs using case-specific analytical checklists. At baseline (summative pre-training OSCE), the analytical checklist scores did not differ significantly between the intervention group and the control group ($p = 0.322$). The intervention group demonstrated a significant improvement in counseling skills from the summative pre- to post-training OSCEs ($p < 0.001$). In contrast, the control group showed no significant improvement ($p = 0.242$). The intervention group showed a significantly greater increase in the analytical checklist score from the pre- to post-training OSCEs than the control group ($p < 0.001$). The results regarding the analytical checklist score are depicted in Figure 4-2 and Table 4-2.

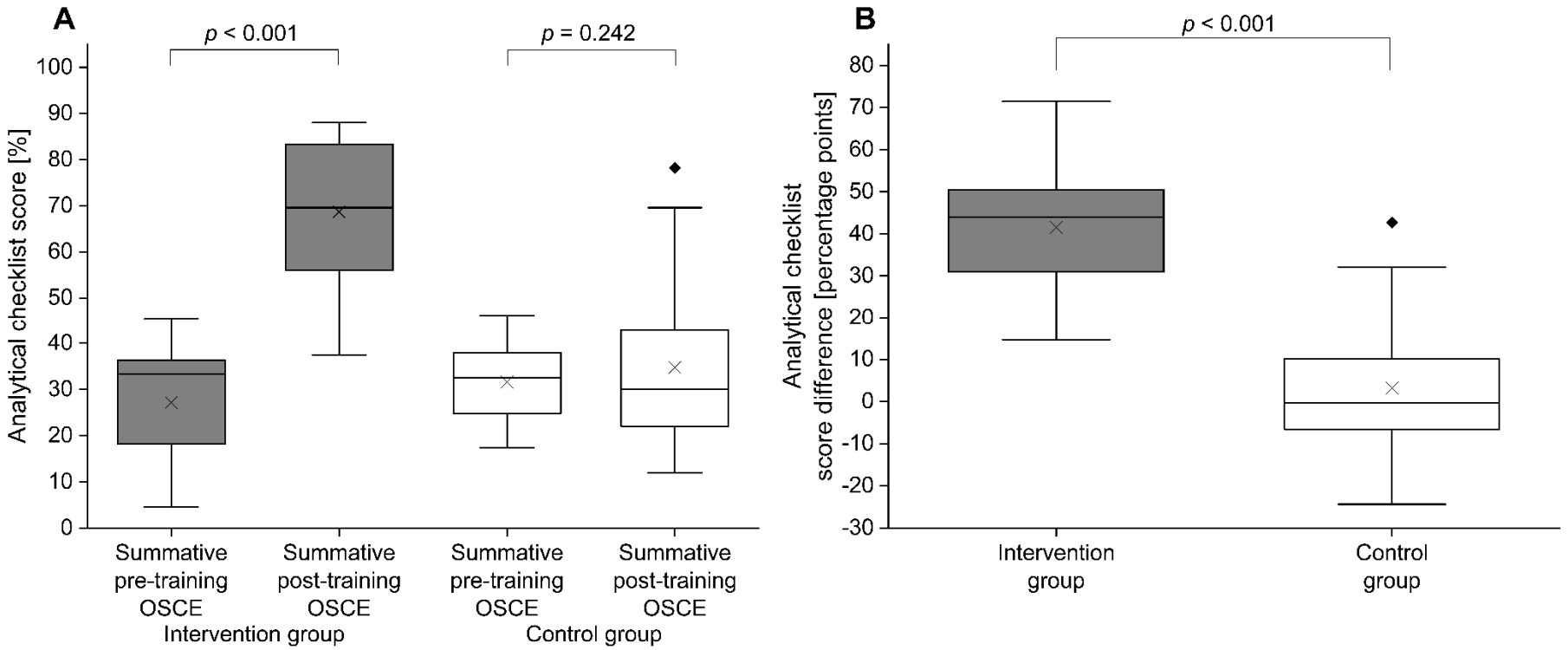

Figure 4-2: Analytical Checklist Scores in the Summative OSCEs in the CoDia-Study

CoDia-study = randomized controlled study on OSCE training for diabetes counseling; OSCE = objective structured clinical examination.
Gray box = intervention group; white box = control group; cross mark (**x**) = mean; horizontal line = median; black diamond (♦) = outlier.
n = 25 in the intervention group and n = 24 in the control group. Results are depicted as box plots.
A: Depiction of pre- and post-training scores in the analytical checklist in percentage. A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.
B: Depiction of the differences between pre- and post-training scores in the analytical checklist in percentage points. A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used.

Table 4-2: Results of the Analytical Checklist in the Summative OSCEs in the CoDia-Study

Evaluation type: analytical checklist							
Group	**Pre-training score in %**		**Post-training score in %**		**Score difference in percentage points**		***p*-value [a]**
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Intervention group (n = 25)	27.16 (12.75)	33.33 (18.18)	68.67 (14.55)	69.57 (27.33)	41.52 (14.63)	43.98 (19.54)	$p < 0.001$
Control group (n = 24)	31.61 (8.69)	32.58 (13.16)	34.76 (17.64)	30.03 (20.92)	3.16 (14.87)	−0.33 (16.73)	

CoDia-study = randomized controlled study on OSCE training for diabetes counseling; OSCE = objective structured clinical examination; SD = standard deviation; IQR = interquartile range.

[a] A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used to assess whether the score increase from pre- to post-training OSCEs was significantly greater in the intervention group as compared to the control group.

4.3.3 Global Rating Scale for OSCEs

The participants' communication skills were assessed in the summative pre- and post-training OSCEs using a global rating scale. At baseline (summative pre-training OSCE), the global rating scale scores did not differ significantly between the intervention group and the control group ($p = 0.172$). While the communication skills of the intervention group improved significantly from the pre- to post-training OSCEs ($p < 0.001$), the improvement in the control group was not significant ($p = 0.066$). The intervention group showed a significantly higher improvement of communication skills than the control group ($p = 0.007$). The results regarding the global rating scale score are shown in Figure 4-3 and Table 4-3.

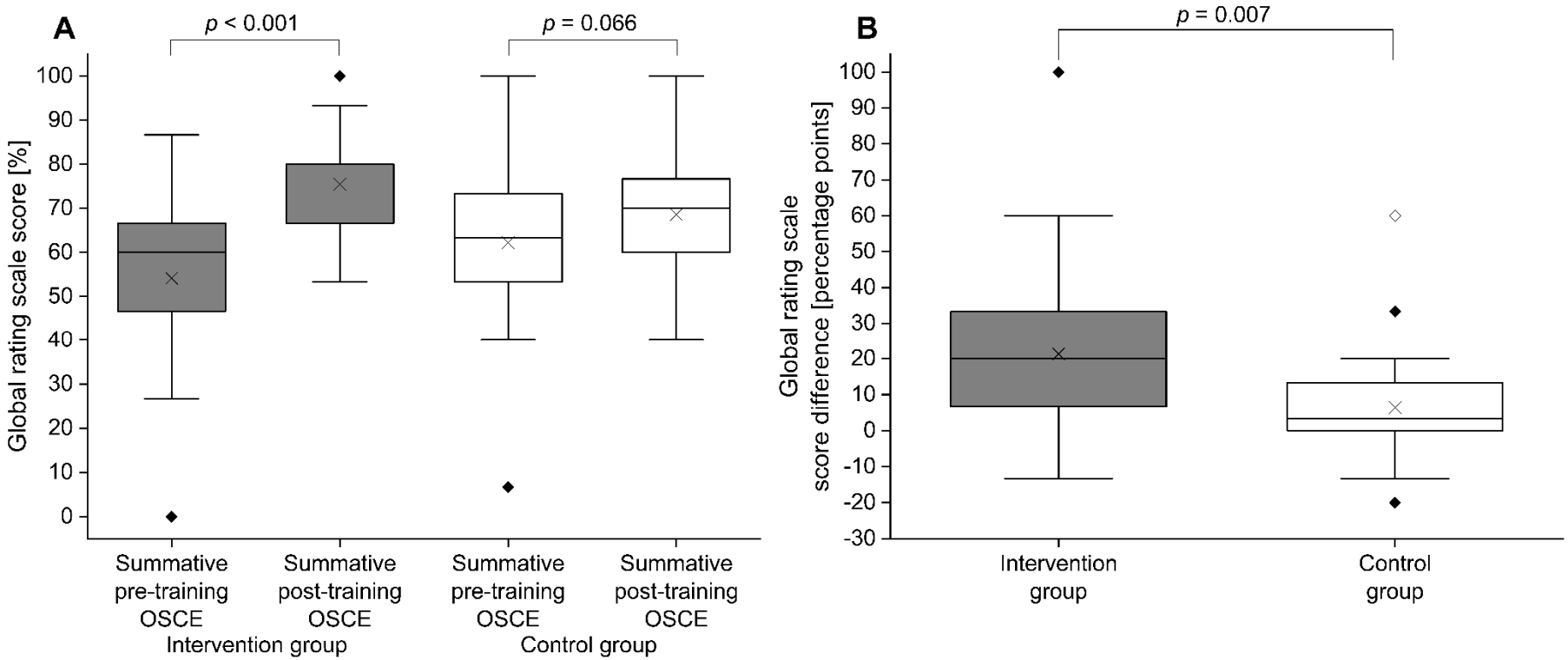

Figure 4-3: Global Rating Scale Scores in the Summative OSCEs in the CoDia-Study

CoDia-study = randomized controlled study on OSCE training for diabetes counseling; OSCE = objective structured clinical examination.
Gray box = intervention group; white box = control group; cross mark (**x**) = mean; horizontal line = median; black diamond (♦) = outlier; white diamond (◊) = extreme value. n = 25 in the intervention group and n = 24 in the control group. Results are depicted as box plots.
A: Depiction of pre- and post-training scores in the global rating scale in percentage. A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.
B: Depiction of the differences between pre- and post-training scores in the global rating scale in percentage points. A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used.

Table 4-3: Results of the Global Rating Scale in the Summative OSCEs in the CoDia-Study

Evaluation type: global rating scale							
Group	**Pre-training score in %**		**Post-training score in %**		**Score difference in percentage points**		***p*-value [a]**
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Intervention group (n = 25)	54.13 (18.69)	60 (20)	75.47 (13.84)	80 (13.33)	21.33 (24.42)	20 (26.67)	$p = 0.007$
Control group (n = 24)	62.22 (19.72)	63.33 (20)	68.61 (14.77)	70 (16.67)	6.39 (17.19)	3.33 (13.33)	

CoDia-study = randomized controlled study on OSCE training for diabetes counseling; OSCE = objective structured clinical examination; SD = standard deviation; IQR = interquartile range.

[a] A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used to assess whether the score increase from pre- to post-training OSCEs was significantly greater in the intervention group as compared to the control group.

4.3.4 Multiple-Choice Test on Diabetes Mellitus

The participants showed a decline in knowledge scores in both the intervention group and the control group from the first multiple-choice test to the second multiple-choice test. The results of the multiple-choice tests are shown in Table 4-4.

Table 4-4: Results of the Multiple-Choice Tests on Diabetes Mellitus in the CoDia-Study

	First multiple-choice test on diabetes					Second multiple-choice test on diabetes				
Score achieved in points	0	1	2	3	4	0	1	2	3	4
Proportion of the intervention group in % (n = 25)	0	0	0	8	92	0	16	4	32	48
Proportion of the control group in % (n = 24)	0	0	0	16.67	83.33	0	4.17	8.33	33.33	54.17

CoDia-study = randomized controlled study on OSCE training for diabetes counseling.
Proportions of participants in percentage achieving 0, 1, 2, 3, or 4 points in the multiple-choice tests are depicted.

4.3.5 Self-Assessment Questionnaire

The participants completed a self-assessment questionnaire on their self-confidence or self-perceived proficiency. At baseline, the self-assessment questionnaire scores did not differ significantly between the intervention group and the control group ($p = 0.157$). The self-assessment questionnaire scores for both groups significantly increased from pre-training assessment to post-training assessment (intervention group: $p < 0.001$; control group: $p = 0.031$). The increase in self-assessment questionnaire score was significantly higher in the intervention group compared to the control group ($p = 0.001$). The increase in the participants' self-assessment questionnaire score implies an improvement in self-confidence or self-perceived proficiency. The results regarding the self-assessment questionnaire score are shown in Figure 4-4 and Table 4-5.

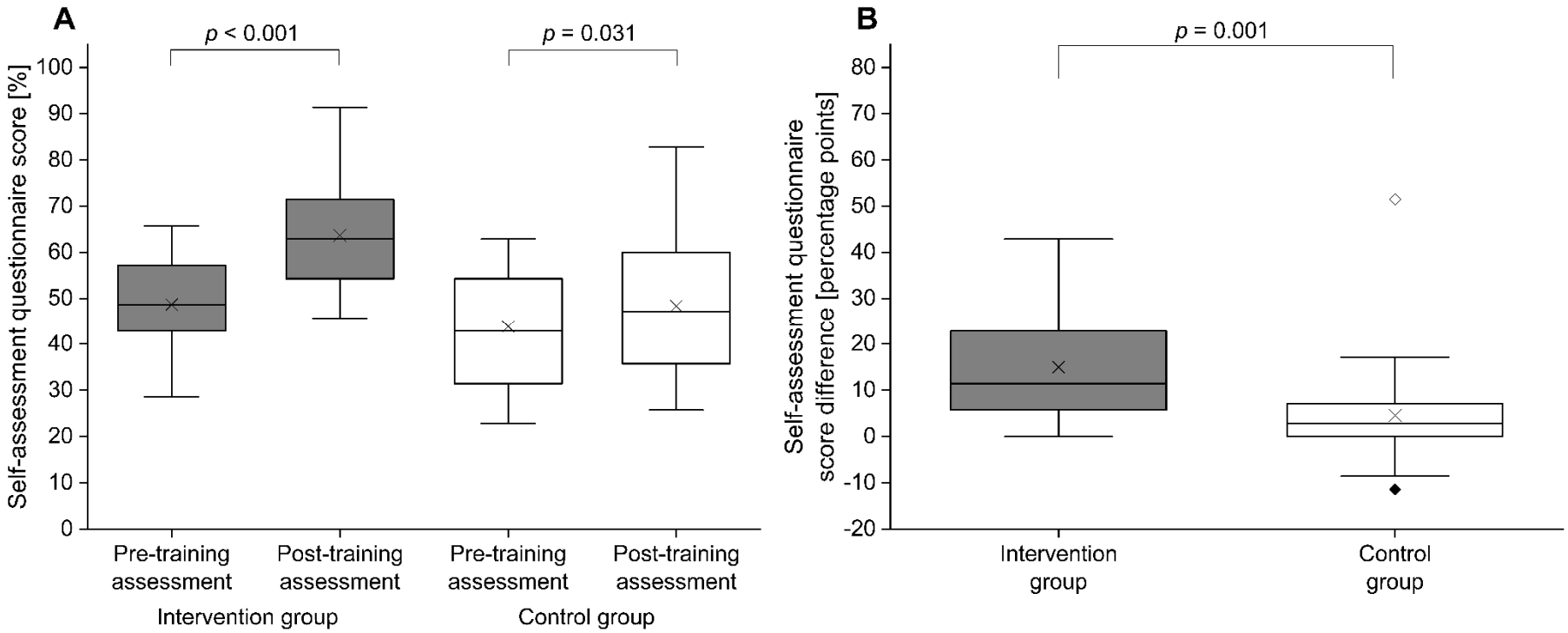

Figure 4-4: Self-Assessment Questionnaire Scores in the CoDia-Study

CoDia-study = randomized controlled study on OSCE training for diabetes counseling.
Gray box = intervention group; white box = control group; cross mark (**x**) = mean; horizontal line = median; black diamond (♦) = outlier, white diamond (◊) = extreme value. n = 25 in the intervention group and n = 24 in the control group. Resutls are depicted as box plots.
A: Depiction of pre- and post-training scores in the self-assessment questionnaire in percentage. A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.
B: Depiction of the differences between pre- and post-training scores in the self-assessment questionnaire in percentage points. A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used.

Table 4-5: Results of the Self-assessment Questionnaire in the CoDia-Study

Evaluation type: self-assessment questionnaire							
Group	**Pre-training score in %**		**Post-training score in %**		**Score difference in percentage points**		***p*-value [a]**
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Intervention group (n = 25)	48.69 (9.20)	48.57 (14.29)	63.66 (11.47)	62.86 (17.14)	14.97 (12.38)	11.43 (17.14)	*p* =0.001
Control group (n = 24)	43.81 (12.93)	42.86 (22.86)	48.33 (14.95)	47.14 (24.29)	4.52 (12.03)	2.86 (7.14)	

CoDia-study = randomized controlled study on OSCE training for diabetes counseling; SD = standard deviation; IQR = interquartile range.
[a] A one-sided Mann-Whitney test with a significance level of alpha = 0.05 was used to assess whether the score increase from pre-training assessment to post-training assessment was significantly greater in the intervention group as compared to the control group.

4.3.6 Preparation Questionnaire

The proportions of participants who prepared themselves for the summative OSCEs, the tools used for preparation, and the duration of preparation are shown in Table 4-6.

Table 4-6: Participants' Preparation for the Summative OSCEs in the CoDia-Study

	Intervention group n = 25		**Control group** n = 24	
	Summative pre-training OSCE	Summative post-training OSCE	Summative pre-training OSCE	Summative post-training OSCE
Preparation of themselves	n = 25	n = 25	n = 24	n = 24
Yes	92%	84%	91.67%	50%
No	8%	8%	8.33%	29.17%
Survey was not filled out	0%	8%	0%	20.83%
Tool used for the preparation	n = 23	n = 21	n = 22	n = 12
Handout	100%	66.67%	100%	83.33%
Internet	8.70%	0%	9.09%	8.33%
Textbooks	4.35%	4.76%	0%	0%
Own notes for other seminars [a]	4.35%	0%	9.09%	0%
Notes from training [a]	NA	71.43%	NA	16.67%
Duration of preparation	n = 23	n = 21	n = 22	n = 12
≤ 30 minutes	26.09%	61.90%	45.45%	66.67%
> 30 minutes to ≤ 1 hour	30.43%	19.05%	22.73%	16.67%
> 1 hour to ≤ 2 hours	30.43%	19.05%	13.64%	16.67%
> 2 hours to ≤ 3 hours	13.04%	0%	18.18%	0%
> 3 hours	0%	0%	0%	0%

CoDia-study = randomized controlled study on OSCE training for diabetes counseling; OSCE = objective structured clinical examination; NA = not applicable. The preparation questionnaire for the summative pre-training OSCE was filled out 1 day after the summative pre-training OSCE. The preparation questionnaire for summative post-training OSCE was filled out on the same day the summative post-training OSCE took place. [a] These topics were built out of the item "other."

4.3.7 Satisfaction Survey

The participants filled out a satisfaction survey (Table 4-7). Responses regarding free-text items are depicted in Table 4-8. In the intervention group, the greatest degree of agreement was observed for the statements “OSCEs should be implemented in future clinical pharmacy courses to train counseling skills” (100% agreement: strongly agree, agree, and slightly agree summarized), “the OSCE seminar imparted knowledge related to practice” (100% agreement: strongly agree, agree, and slightly agree summarized), and “the OSCE seminar has improved my clinical skills” (100% agreement: strongly agree, agree, and slightly agree summarized). In the control group, the greatest degree of agreement was observed for the statement “the OSCE seminar imparted knowledge related to practice” (75% agreement: strongly agree, agree, and slightly agree summarized). No participant from either group agreed with the statement “OSCEs/simulations for counseling situations are unnecessary as nothing wrong can be done during counseling.”

Table 4-7: Results of the Satisfaction Survey in the CoDia-Study

Item	Group	Proportions of responses in %					
		Strongly disagree	Disagree	Slightly disagree	Slightly agree	Agree	Strongly agree
I was interested in the OSCE seminar.	Intervention group (n = 25)	0	4	20	36	24	16
	Control group (n = 24)	0	12.5	16.67	29.17	33.33	8.33
The OSCE seminar has improved my clinical skills.	Intervention group (n = 25)	0	0	0	40	40	20
	Control group (n = 24)	0	16.67	16.67	37.5	29.17	0
The OSCE seminar has improved my communication skills.	Intervention group (n = 25)	0	4	12	44	32	8
	Control group (n = 24)	4.17	16.67	16.67	41.67	20.83	0
The OSCE seminar imparted knowledge related to practice	Intervention group (n = 25)	0	0	0	48	44	8
	Control group (n = 24)	4.17	8.33	12.5	41.67	29.17	4.17

[Continuation of Table 4-7]

The OSCE cases were too easy.	Intervention group (n = 25)	4	44	40	12	0	0
	Control group (n = 24)	0	37.5	41.67	16.67	4.17	0
The OSCE seminar conveyed safety in dealing with patients in the pharmacy.	Intervention group (n = 25)	4	8	4	60	16	8
	Control group (n = 24)	12.5	4.17	29.17	41.67	8.33	4.17
OSCEs/simulations for counseling situations are unnecessary as nothing wrong can be done during counseling	Intervention group (n = 25)	84	16	0	0	0	0
	Control group (n = 24)	50	50	0	0	0	0
OSCEs should be implemented in future clinical pharmacy courses to train counseling skills.	Intervention group (n = 25)	0	0	0	32	40	28
	Control group (n = 23 [a])	4.35	8.70	13.04	21.74	30.43	21.74

CoDia-study = randomized controlled study on OSCE training for diabetes counseling; OSCE = objective structured clinical examination.
[a] One participant did not answer the item “OSCEs should be implemented in future clinical pharmacy courses to train counseling skills.”

Table 4-8: Example Topics of Comments from Free-Text Items of the Satisfaction Survey in the CoDia-Study

Free-text item	Group	Topic of comments	Number of comments on the topic
I particularly liked the following at the OSCE seminar:	Intervention group	The practical exercise/training of counseling (simulation)	6
		Practical relevance	6
		Checklist as a good guide	3
	Control group	The practical exercise of counseling (simulation)	6
		Practical relevance	2
		Feedback	2
I would change the following:	Intervention group	Time schedules for the OSCEs should be optimized	6
		Checklists or OSCEs were not realistic	3
		All students should have the possibility to complete the OSCE training	1
	Control group	In the control group, preparing SOAP notes did not prepare for patient counseling, training counseling was demanded (as in the intervention group)	8
		Provision of guidance document (checklist)	3
		Several topics should be covered	2

CoDia-study = randomized controlled study on OSCE training for diabetes counseling; OSCE = objective structured clinical examination.
The 3 most frequent topics of comments for each item per group are shown. If topics of comments occurred with equal frequency, 1 of them was selected. Further topics of comments can be found in Appendix 17.

4.3.8 Comparison of the CoDia-Study with the CoSeMed-Study

The intervention group of the CoDia-study (the present study) showed a significantly higher increase in the analytical checklist score from pre- to post-training OSCEs as compared to the intervention group of the CoSeMed-study ($p < 0.001$). Nevertheless, regarding the global rating scale score and the self-assessment questionnaire score, there was no significantly higher increase in the intervention group of the CoDia-study as compared to the intervention group of the CoSeMed-study ($p = 0.574$ for the global rating scale score and $p = 0.829$ for the self-assessment questionnaire score). When interpreting the comparison between the studies, it should be considered that the 2 studies focused on 2 different counseling topics (diabetes mellitus and self-medication), the analytical checklists differed in parts, and the procedure of the studies differed.

4.4 Discussion

This randomized controlled study showed that the applied OSCE-based training approach (using formative OSCEs) was more effective than the non-OSCE training method for improving German pharmacy students in diabetes mellitus counseling. The OSCE training approach (intervention group) showed a significantly greater improvement in counseling and communication skills compared to the non-OSCE training method (control group). Furthermore, the OSCE training approach resulted in a significantly greater increase in self-confidence or self-perceived proficiency than the control group's training.

The results support the application of the in this study applied OSCE-based training approach to improve pharmacy students' counseling and communication skills. In line with the findings in this study, Gums et al found that pharmacy students' communications skills and clinical competency at an ophthalmic OSCE station, as measured by OSCE scores, improved after undergoing individualized formative assessments in a pharmacy skills laboratory[218] which could be considered as a formative OSCE-like approach. In contrast, Chisnall et al found that formative OSCEs as a learning tool did not improve the overall pass rate of medical students. Nevertheless, they indicated that formative OSCEs were associated with improved pass rates in subsequent summative OSCEs for stations that were identical in the formative and summative OSCEs. Additionally, they noted improved pass rates for some stations that did not appear in the formative OSCEs.[106] Alkhateeb et al found in a randomized controlled investigation with medical students that applying formative OSCEs as a learning tool in addition to a standard module did not result in a significant difference in pass rates and that the group without formative OSCEs achieved an even higher mean score than the intervention group.[197] Differences in the OSCE training approach in the CoDia-study in comparison to the studies by Alkhateeb et al[197] and Chisnall et al[106] might explain the positive results of this study. For example, the CoDia-study used a more intensive and interactive training setting than Alkhateeb et al[197] and Chisnall et al.[106] In the CoDia-study, training was conducted in groups and incorporated elements of peer-assisted learning, where counseling performances in OSCE cases on diabetes were observed and assessed by peers and trainers who provided immediate feedback. In contrast,

Alkhateeb et al and Chisnall et al applied their OSCEs under examination-like conditions and provided delayed feedback.[106,197] In the CoDia-study, the formative OSCEs and summative OSCEs required the same skill and knowledge—specifically, counseling and communication for diabetes mellitus. On the other hand, Chisnall et al and Alkhateeb et al worked on several stations and skills during their formative and summative OSCEs.[106,197] It might be assumed that these differences in the setting of the training OSCEs contributed to positive results in the CoDia-study.

For the CoDia-study, it might be conjectured that the difference between the counseling performance of the groups was not due to a difference in knowledge regarding diabetes mellitus, as the majority of both groups achieved similarly high scores on the first multiple-choice test. Surprisingly, both groups scored more poorly on the second multiple-choice test. The questions used in the multiple-choice tests were based on the diabetes mellitus handout and evaluated basic knowledge on diabetes and not counseling skills. Several reasons might explain the deterioration in the scores on the second multiple-choice test. The observed deterioration in test scores could have resulted from information from the diabetes mellitus handout being retained only for a short period and the students may not have revised it for the second multiple-choice test 14 days later as intensively as for the first multiple-choice test. Additionally, the students had little room for improvement in scores from the first multiple-choice test (92% and 83.33% of the participants in intervention and control groups, respectively, achieved 100% of the scores).

It is unlikely that participants' performance in this study was affected by additional professional education. Although a higher proportion of participants in the intervention group was additionally trained as pharmaceutical technician assistants than in the control group, a greater proportion of the control group, currently or formerly, worked in a community pharmacy in a counseling position, potentially balancing these effects. It should be considered that the information about additional professional education and work in a community pharmacy was self-reported by the students. Moreover, it should be noted that a higher proportion of participants in the intervention group reported preparing for post-training OSCEs than the control group which may also affect the participants'

OSCE performance. However, not all participants provided information about their preparation and recall bias regarding their preparation were possible.

Applying the OSCE-based training approach resulted in a significantly greater increase in self-confidence or self-perceived proficiency, as demonstrated by a significantly greater increase in the intervention group's self-assessment questionnaire score compared to the control group. This could be expected as OSCE training exposes students to a skill-based educational approach. McClimens et al revealed a significant increase in confidence once the students have completed the OSCE task.[199] Moreover, a study by Bevan et al found that practicing OSCEs contributed to students' self-confidence.[120] Additional support for implementing OSCEs in training and assessment is the high satisfaction of students in this study. The literature also shows students' acceptance of OSCEs as an assessment method[200] and as a training approach.[106,123]

Comparing the 2 randomized controlled studies in this work (ie, the CoDia-study with the CoSeMed-study), it is noteworthy that the OSCE-trained group in the CoDia-study showed a significantly greater improvement in counseling skills than the OSCE-trained group in the CoSeMed-study ($p < 0.001$). This might indicate that modifying the OSCE-based training approach based on experiences from the CoSeMed-study contributed to the significantly higher improvement of counseling skills in the CoDia-study intervention group compared to the CoSeMed-study intervention group. The modifications involved extending the OSCE-based training from approximately 1 hour to approximately 2.5 hours which incorporated a short lecture on structured pharmaceutical counseling based on the analytical checklist as well as instructor-guided presentations of OSCE encounters by students with feedback in addition to the peer-assisted formative OSCEs in groups. In particular, in the CoDia-study, after training on the OSCE cases in groups, 2 participants from each group presented their OSCE case to their peers and instructors. The presenters received not only feedback from their peers, but also were provided with feedback from the experienced instructors (pharmacists), who could correct peer feedback as needed. Observing the counseling of the other groups with the multiple OSCE cases and listening to the peer and instructor feedback may have reinforced a valuable learning effect. The above-mentioned comparison supports the assumption from the CoSeMed-

study in chapter 3 that longer training and more instructor-guided activities would lead to higher analytical checklist scores. However, when interpreting the comparison between the studies, it should be considered that the 2 studies focused on 2 different counseling topics (diabetes mellitus and self-medication), the analytical checklists differed in parts, and the procedure of the studies differed. In contrast to that, the assumption from CoSeMed-study that a longer training time would result in higher scores regarding communication skills (global rating scale score), was not supported by the CoDia-study. Although the CoDia-study intervention group showed a significantly greater increase in communication skills than the CoDia-study control group, the intervention groups of both the CoSeMed-study and CoDia-study achieved median global rating scale scores of 80% (IQR = 23.33% in the CoSeMed-study and 13.33% in the CoDia-study), showing no significantly higher increase in communication skills (p = 0.574) for the CoDia-study despite training for additional 1.5 hours. However, the small room for improvement in the global rating scale scores of the intervention groups of both studies should be taken into account. Also, it should be considered that the 2 studies focused on 2 different counseling topics and the procedure of the studies differed.

The CoDia-study was designed to avoid the decreased participating rate in the post-training OSCE seen in the CoSeMed-study by conducting it mid-semester. Moreover, for the CoDia-study, 3 observers and more SPs were available, allowing more students to participate in this study than in the CoSeMed-study. Furthermore, in the CoDia-study the assessment of participants' diabetes knowledge with multiple-choice tests and surveys regarding their preparation for the OSCEs were added in contrast to the CoSeMed-study.

Regarding the control groups of the CoDia-study and the CoSeMed-study, a significant increase was only observed for the self-assessment questionnaire score (self-confidence or self-perceived proficiency) in the control group of the CoDia-study, while the control group of the CoSeMed-study showed a significant increase in all 3 evaluations (counseling skills, communication skills, and self-confidence/self-perceived proficiency). This might be due to the different activities performed by the control groups in these studies, different procedures of the studies, and different counseling topics. The CoSeMed-study control group was

trained on handling SmPCs of OTC drugs and collecting counseling-relevant information on OTC drugs, which might have improved students' counseling skills compared to this study, in which the control group solved diabetes mellitus patient cases by preparing SOAP notes and discussed their solutions. SmPCs provide health professionals the scientific information necessary for the safe use of a medicinal product.[219] Working with SmPCs might have increased students' awareness of important aspects in self-medication (eg, contraindications, interactions, adverse drug reactions, dosage, and duration) and allowed them to apply these insights to patient counseling during the OSCEs, which might be an explanation for the significant increase in the analytical checklist score in the CoSeMed-study control group. However, the comparison between the 2 studies should be interpreted with caution due to the different counseling topics, the difference in the procedure of studies, and the different training approaches.

This study is not without limitations. Potential inter-observer bias from the use of 3 observers instead of 1 was overcome by maintaining the same observer for each participant between the summative pre- and post-training OSCEs. Additionally, it was sought to minimize the possible inter-/intra-observer variability by providing examples of correct statements for every item on the analytical checklist and instructions for filling out both the analytical checklist and global rating scale. The use of 3 observers who had experience in OSCE assessment facilitated the execution of summative OSCEs with 49 students within a limited timeframe. Furthermore, the analytical checklist was only exposed to the intervention group during the OSCE training. This could have biased the results of the summative post-training OSCEs as the control group was unaware of the analytical checklist and the criteria for the counseling performance during the OSCEs. However, Cole et al had indicated in their controlled study that despite such exposure of scoring rubric in both the intervention and control group there was a significant difference between the groups that indicated the benefit of the peer-led station training (intervention group). In particular, they compared the OSCE scores of students who attended a peer-taught training session to the scores of students who did not attend the session. Both groups were provided with scoring rubrics during the semester. Although differences in student scores for each skill were not statistically significant between both groups, they found a

significant difference in the overall OSCE score favoring the group which attended the training session.[213] Thus, it might be speculated that the knowledge of the analytical checklist has not substantially affected the performance of the intervention group compared to the control group in the present study. Moreover, this was the third OSCE study at the university's faculty, as such students from prior semesters may have provided information about study content and checklists to the current students. However, the effects from this appear to be low, as pre-training scores on the analytical checklists from the SiGDia-study, CoSeMed-study, and CoDia-study were similar.

4.5 Conclusion

Counseling patients on medications is one of the key tasks of community pharmacists.[17,18] As the majority of pharmacists in Germany work in community pharmacies,[71] it is vital to prepare pharmacy students appropriately to provide adequate counseling right from the beginning of their working life. This study demonstrated that the applied OSCE-based training approach provides effective training of counseling and communication skills in the field of diabetes mellitus in a safe environment without jeopardizing patients. These results recommend the widespread use of such a competency-based educational approach in the pharmacy curriculum for teaching counseling.

4.6 Disclosure

Parts of this chapter were previously published as “Farahani I, Farahani S, Deters MA, Schwender H, Laeer S. Efficacy of an objective structured clinical examination training approach for training pharmacy students in diabetes mellitus counseling: a randomized controlled trial. *Pharmacy (Basel)*. 2020;8(4):229. doi:10.3390/pharmacy8040229.” The author of this dissertation had a lead role in and substantially contributed to the conceptualization, methodology, formal analysis, investigation, data curation, visualization, writing - original drafts, as well as writing - review and editing.

5. Implementation of OSCEs in Clinical Pharmacy Education

Following an intensive evaluation of this work (Appendix 18), which showed OSCEs to be an effective and student-appreciated teaching tool for conveying patient counseling skills to pharmacy students, OSCEs have become progressively integrated into the eighth-semester clinical pharmacy course at Heinrich Heine University Düsseldorf since the 2019/2020 winter semester (Figure 5-1).

5.1 Implementation of OSCEs in the 2019/2020 Winter Semester and 2020 Summer Semester

In the 2019/2020 winter semester and the 2020 summer semester, OSCEs on patient counseling out of a case pool, covering cases on self-medication requests, filling in prescriptions, or patients asking for advice/medical products for treating an issue aroused from a chronic disease or prescription drugs, were performed. During the OSCEs, at least 1 faculty member completed a short global checklist. The global checklist was developed by the faculty, especially for that course. Another faculty member portrayed the SP. The students received feedback from the faculty members immediately after completing the OSCE. In the 2019/2020 winter semester OSCEs, 2 students completed the OSCEs at 1 appointment, with 1 of them completing 1 OSCE case while the other student was watching, and afterward the other student completed a different OSCE case from the case pool while the previous student was watching. The 2019/2020 winter semester OSCEs were performed under rather examination-like conditions and did not influence the passing of the course. In the 2020 summer semester, each student attended the appointment alone, due to coronavirus disease 2019 (COVID-19) restrictions, and completed 2 OSCE cases from the OSCE case pool. cases. The 2020 summer semester OSCEs were part of the end-of-term exam.

5.2 Implementation of OSCEs in the 2020/2021 Winter Semester

In the 2020/2021 winter semester, OSCEs were set to be implemented in a training setting using a more comprehensive approach resembling the work described in this dissertation. The OSCEs on counseling were to cover several indications on self-medication and prescription drugs, as requested by the participants of the studies of this work (see chapter 2 section 2.3.6 and chapter 4 section 4.3.7). However, COVID-19 restrictions resulted in the OSCE training being performed online. The online OSCEs were performed by 46 students (in the scope of the clinical pharmacy course) using the web conferencing application Cisco Webex.[220] The online OSCE-based training encompassed 2 phases. The first phase consisted of 2 online training days, with each student attending both training days. The second phase, the online assessment days, took place during 4 days, with each student attending 1 appointment at 1 of the 4 assessment days. As this was the first time to implement OSCEs in an online format at the faculty and to minimize potential technical issues due to the lack of experience with the technical application, the training approach varied from the one described in chapter 4.

The training days were designed as an autonomous, online, peer-learning environment and intended to prepare the students for the online OSCE assessment. Each of the 2 training days comprised 8 OSCE cases dealing with self-medication requests, filling in prescriptions, or patients asking for advice/medical products for treating an issue aroused from a chronic disease or prescription drugs. The following topics were covered: headache, conjunctivitis, diarrhea, obstipation, athlete's foot, cough, hoarseness, heartburn, hypertension, heart failure, depression, helicobacter pylori infection, urinary tract infection, human immunodeficiency virus, diabetes mellitus, and schizophrenia. Courses on self-medication and the respective diseases were completed prior to the OSCEs. At the beginning of each training day, all students attended a Cisco Webex meeting that briefly introduced the process of the online OSCEs. The semester subsequently was divided into 11 virtual subgroups (“breakout sessions”) comprising 4 to 5 students. Each virtual subgroup was supposed to solve the same OSCE case in peer interaction with 1 student in the subgroup portraying the SP, another portraying the pharmacist, and the remainder

observing the performance using global analytical checklists and providing feedback. All students were supposed to rotate the roles in their respective subgroups. Every 30 minutes a new OSCE case file consisting of a case description with patient profile and candidate instruction, and relevant SmPCs were provided for download. Additionally, during the training days, a global analytical checklist for self-medication or prescription drugs was uploaded for students. The global analytical checklists were minimally modified from the CoSeMed-study and CoDia-study, respectively. As the global analytical checklists were not case-specific, students needed to apply the global analytical checklists accordingly to the specific case. In contrast to OSCE training approaches investigated in the SiGDia-study, CoSeMed-study, and CoDia-study, the students did not receive faculty member feedback on the training days and these days focused on the solving of OSCE cases through peer interaction solely. However, faculty members were available for coordination, technical support, and to answer questions regarding the seminar procedure. The training days were accompanied by 1 to 2 technical faculty staff members and 2 to 3 faculty members.

The online OSCEs on the assessment days (second phase) were formative, occurring in an examination-like environment, but did not affect the passing of the course. They were intended to provide students with feedback to correct mistakes and reinforce good performance as part of students' learning process.[111] Each student attended 1 online OSCE appointment consisting of 2 stations on counseling on 1 of the 4 assessment days. The OSCE cases at the stations were similar to or the same as those used during the training days. One faculty member performed the role of the SP. Immediately after a joint discussion among the faculty members (with the student being in another online room), feedback was provided to the student based on the respective global analytical checklist. The examination day was accompanied by 2 technical faculty staff members and 2 to 4 faculty members.

The use of online OSCEs, both before[221] and during[222,223] the COVID-19 pandemic has been described. Online OSCEs have several advantages, including reducing the requirement for traveling to campus[221] and, in the case of

the COVID-19 pandemic, the ability to be performed under restrictive conditions (eg, reduced capacities or lockdowns).

The OSCE training approaches described in this work (chapters 2, 3, and 4) included peer learning–based OSCE group training. Also, the 2020/2021 winter semester implementation was focused on peer learning–based OSCE group training. In the studies presented in this dissertation, the students could ask questions during the group work on OSCE cases, while this option was not available during 2020/2021 winter semester despite frequent requests to the faculty members. Moreover, the SiGDia-study and CoDia-study involved presenting OSCE cases in front of the plenum. This allowed students to receive a large amount of feedback from the instructors, as well as peers which could also be corrected by instructors. Students were also able to witness a large number of OSCE cases without completing all of them as a participant, allowing them to learn by observing their peers' strengths and weaknesses. The experiences from the first run of online OSCEs indicated that the technological application allows for the implementation of online OSCE training in the format and extent of training investigated in the CoDia-study. Consequently, to achieve maximal benefit from this educational approach, future implementation of OSCE training (whether it be online or in person) should make faculty members available for questions and guidance to facilitate the group approach during the group training and should apply the elements of instructor-guided presentations of OSCE cases by students in front of the plenum, as evaluated in chapter 4 of this dissertation and shown to be effective.

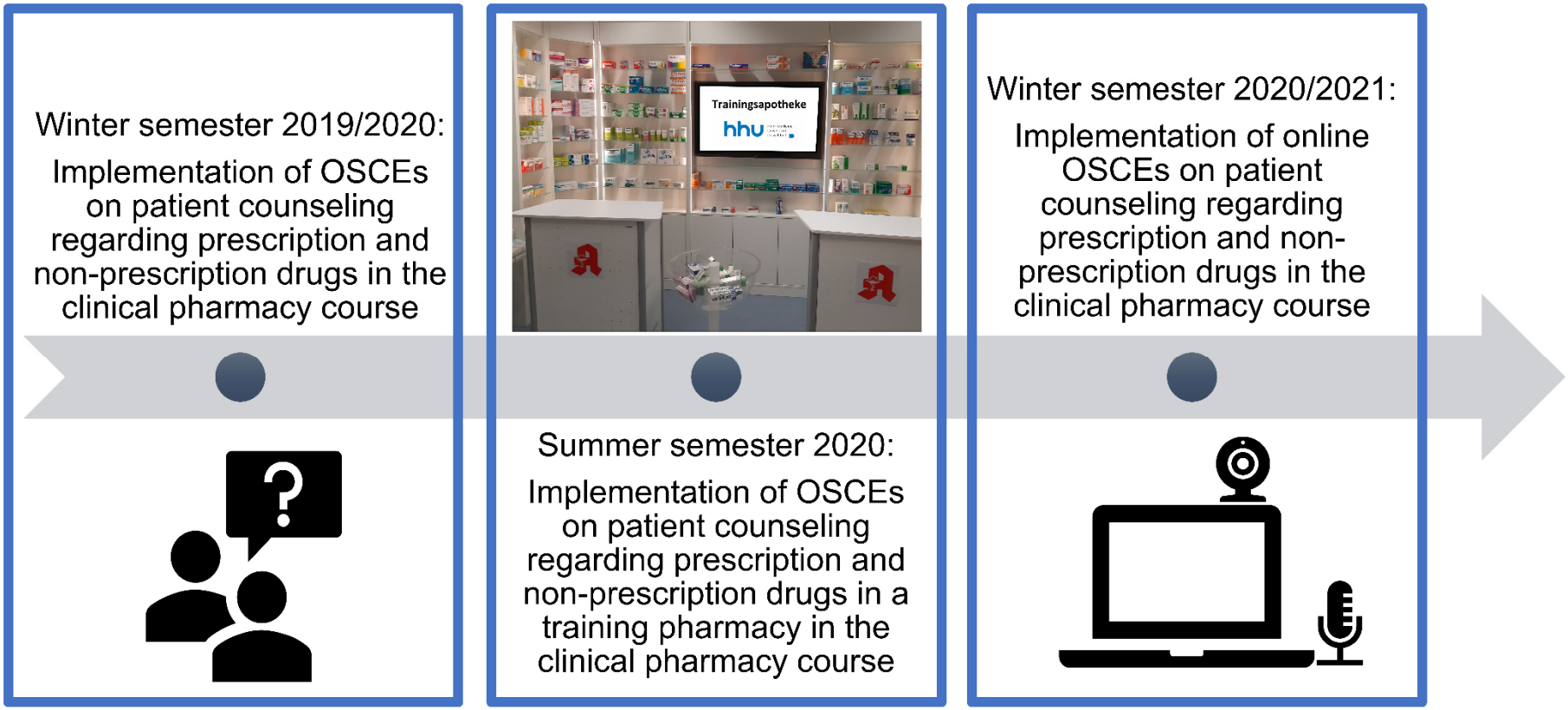

Figure 5-1: Timeline of the Implementation of OSCEs in the Clinical Pharmacy Course

OSCE = objective structured clinical examination

6. Overall Discussion and Perspective

This dissertation evaluated and applied OSCE-based training for pharmacy students to promote patient-oriented and competency-based education in the German pharmacy curriculum. The OSCE-based training involved chronic disease (diabetes mellitus; SiGDia-study and CoDia-study) and self-medication (CoSeMed-study) counseling. This work showed that OSCE-based training is a valuable method to prepare pharmacy students for a key task as pharmacists—counseling.

Overall, this work demonstrated that OSCE-based training is effective in teaching pharmacy students counseling skills and can consequently contribute to patient-oriented and competency-based education in the German university pharmacy curriculum. In all 3 studies, OSCE-based training led to an improvement in pharmacy students' counseling skills, communication skills, and self-confidence/self-perceived proficiency. The first study, which used a single-group design, indicated that an OSCE-based training approach could improve students' counseling skills and was strongly supported by the results of the 2 subsequent controlled studies. In both controlled studies, the groups receiving OSCE-based training showed significantly higher increases in counseling skills and self-confidence/self-perceived proficiency compared to the respective control group. While the CoSeMed-study intervention group did not show a significantly higher increase in communication skills compared to the control group, the CoDia-study intervention group did. Furthermore, the respective OSCE-based educational approach was well received by the pharmacy students across all 3 studies.

As the OSCE-based training approaches in this dissertation focused on peer learning, it was feasible with a limited number of available staff, making it cost-effective, as described by Bevan et al.[120] To evaluate the OSCE-based training approaches, summative pre- and post-training OSCEs were conducted, which required more staff than during the OSCE training. Staff were particularly needed for the role of the observers and SPs, as well as coordinating staff. Some of these roles were performed by previously instructed students due to staff limitations. In addition, the limited number of staff meant that students could complete only 1 OSCE station during summative OSCEs, designed to mimic a realistic, full

consultation, in each summative pre- and post-training OSCE. For example, in the CoDia-study, in which 49 students were included in the analyses (the time schedule of OSCEs was set for approximately 55 students), 3 faculty members were engaged as observers. Furthermore, 3 pharmacy students from the semester and 4 faculty members took turns performing the role of the patient and were consequently part-time staff. Fewer staff members participated in these 3 studies compared to reports in the literature;[89] nevertheless the organization allowed the most gain from limited resources. In contrast to the summative OSCEs, during OSCE training, students could witness more than 1 OSCE case due to the group-based approach. Having this in mind, group-based and peer-based approaches should be considered when implementing OSCE training in the curriculum.

One strength of this dissertation is the broad range of student-related outcomes assessed by all 3 studies, which is underrepresented in the literature particularly for formative OSCEs. Both the efficacy of the educational approach and the students' views on the approach, in terms of satisfaction/acceptance and self-confidence/self-perceived proficiency were assessed. Thus, the results of this work contribute to the evaluation of OSCEs as a learning tool for pharmacy students. In general, the participants appreciated the practical relevance of the educational approach and the ability to train counseling skills. Furthermore, the majority of participants in all 3 studies agreed to some extent that OSCEs should be implemented in future clinical pharmacy courses. Along with improving skills and self-confidence, students' positive attitude towards the OSCE-based training approach favors its application in pharmacy education. Based on these positive results, OSCEs were successfully implemented as a patient-oriented, competency-based educational technique in the clinical pharmacy course at Heinrich Heine University Düsseldorf.

The OSCE-based training approach examined in this dissertation is a step towards closing the gap in patient-oriented education in the university's pharmacy curriculum. This training approach has been predominantly well received and welcomed by pharmacy students at Heinrich Heine University Düsseldorf. Other patient-oriented and competency-based educational approaches should be promoted in the German pharmacy curriculum to prepare pharmacy students

from the outset of their careers. The OSCE-based training approach could be expanded to a wide range of subject areas including, but not limited to, stations on nutrition, emergency contraception, and smoking cessation counseling, simple health tests (eg, blood lipid levels assessment), medication analysis, interprofessional collaboration, and first aid. The latter 3 subjects have already been initiated in elective courses at Heinrich Heine University Düsseldorf. Additionally, expanding OSCEs to include hospital pharmacist-related stations should be considered. Before integrating such an educational approach on other clinical skills than counseling, the approach should be studied regarding efficacy as well as acceptance. Applying such a patient-oriented, competency-based educational approach to academic pharmacy education could help expand clinical pharmacy services in Germany and obtain the maximum benefit from pharmacist competencies in patient care.

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3. Farahani I, Farahani S, Deters MA, Schwender H, Laeer S. Training pharmacy students in self-medication counseling using an objective structured clinical examination–based approach. *J Med Educ Curric Dev*. 2021;8:1-9. doi:10.1177/23821205211016484
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5. Farahani S, Farahani I, Deters MA, Schwender H, Burckhardt BB, Laeer S. Blended learning on blood pressure measurement: investigating two in-class strategies in a flipped classroom-like setting to teach pharmacy students blood pressure measurement skills. *Healthcare (Basel)*. 2021;9(7):822. doi:10.3390/healthcare9070822

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9. Appendix

Appendix 1: Self-Assessment Questionnaire of the Single Group Study on OSCE Training for Diabetes Counseling Integrated into a Blended Learning Setting (SiGDia-Study)

Self-assessment questionnaire Diabetes

Pseudonym:

Klinische Pharmazie & Pharmakotherapie

Heinrich Heine Universität Düsseldorf

Please tick one box (do not tick between the boxes!):

	How do you rate your counseling competence in the following areas:			
1	**Counseling on DM Typ 1 and 2**	very bad	□ □ □ □ □ □	very good
	Psychomotor goals			
2	Handling of blood glucose meters	very bad	□ □ □ □ □ □	very good
3	Handling of blood pressure measurement devices	very bad	□ □ □ □ □ □	very good
4	Handling of insulin pens and pumps	very bad	□ □ □ □ □ □	very good
5	Dealing with emergency situations	very bad	□ □ □ □ □ □	very good
	Affective goals for patient-centered counseling: How do you rate your competence to...			
6	... set goals?	very bad	□ □ □ □ □ □	very good
7	... motivate patients to conduct their therapy?	very bad	□ □ □ □ □ □	very good
8	... listen actively?	very bad	□ □ □ □ □ □	very good
9	... lead through questions?	very bad	□ □ □ □ □ □	very good
	Cognitive goals for patient-centered counseling: How do you rate your competence to...			
10	... structure counseling according to the time available?	very bad	□ □ □ □ □ □	very good
11	... provide correct, relevant and useful information in the consultation?	very bad	□ □ □ □ □ □	very good

www.hhu.de

DM = diabetes mellitus

In the study, the German version was used.

Appendix 2: Satisfaction Survey of the Single Group Study on OSCE Training for Diabetes Counseling Integrated into a Blended Learning Setting (SiGDia-Study)

KLINISCHE PHARMAZIE & PHARMAKOTHERAPIE

HEINRICH HEINE UNIVERSITÄT DÜSSELDORF

Fragebogen zur Evaluation des OSCE-Seminars im Sommersemester 2018

Die Bewertung erfolgt im Schulnoten-System:

1 = Trifft voll zu, 2 = Trifft zu, 3 = Trifft eher, 4 = Trifft eher nicht zu, 5 = Trifft nicht zu, 6 = Trifft gar nicht zu

Bitte kreuzen Sie die zutreffenden Felder an.

1) Die Beschäftigung mit den Seminarinhalten bereitete mir Freude.
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

2) Das OSCE-Seminar hat mir Spaß gemacht.
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

3) Durch das OSCE-Seminar haben sich meine klinischen Fähigkeiten verbessert.
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

4) Durch das OSCE-Seminar haben sich meine kommunikativen Fähigkeiten verbessert.
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

5) Das OSCE-Seminar hat viel praxisbezogenes Wissen vermittelt.
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

6) Das OSCE-Seminar hat mir Sicherheit im Umgang mit Patienten in der Apotheke vermittelt.
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

7) Das OSCE-Seminar sollte in der Zukunft als fester Bestandteil in das Seminar Klinische Pharmazie implementiert werden.
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

8) Am OSCE-Seminar hat mir folgendes besonders gut gefallen:

_____
_____
_____

9) Folgendes würde ich ändern:

_____
_____
_____

10) Weitere Anmerkungen:

_____
_____
_____
_____

Vielen Dank!

Appendix 3: Example of a Case Description of the Single Group Study on OSCE Training for Diabetes Counseling Integrated into a Blended Learning Setting (SiGDia-Study)

Case: Implementation of metformin

KLINISCHE PHARMAZIE & PHARMAKOTHERAPIE

HEINRICH HEINE UNIVERSITÄT DÜSSELDORF

Information für Apotheker	
Aufgabenstellung	Bitte beraten Sie die Patientin.
Zeit	Maximal 10 Minuten
Ort	Apotheke
Der Patient	
Alter	32 Jahre
Größe / Gewicht / BMI	167 cm, 76 kg, BMI 27

Appendix 4: Results of the Self-Assessment Questionnaire in the Single Group Study on OSCE Training for Diabetes Counseling Integrated into a Blended Learning Setting (SiGDia-Study) – Additional Analysis

Evaluation type	Pre-training score in %		Post-training score in %		*p*-value [a]	Score difference in percentage points	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		Mean (SD)	Median (IQR)
Self-assessment question-naire (N = 43 [b])	42.62 (19.03)	43.64 (32.73)	62.20 (13.03)	61.82 (14.55)	$p < 0.001$	19.58 (21.61)	20 (27.27)

SiGDia-study = single group study on OSCE training for diabetes counseling integrated into a blended learning setting; SD = standard deviation, IQR = interquartile range.

[a] A one-sided Wilcoxon signed rank test applied to the differences between pre- and post-training scores with a significance level of alpha = 0.05 was used.

[b] Only participants who filled out the self-assessment questionnaire completely are included in this analysis.

Appendix 5: Topics of Comments from Free-Text Items of the Satisfaction Survey in the Single Group Study on OSCE Training for Diabetes Counseling Integrated into a Blended Learning Setting (SiGDia-Study)

Free-text item	Topic of comments	Number of comments on the topic
I particularly liked the following at the OSCE seminar:	Gaining first impressions of practice and counseling in the community pharmacy	5
	Training or simulating counseling	5
	Structured patient counseling	5
	Practical tips	5
	E-learning	4
	Training communication	3
	Practical relevance	3
	Working in groups	2
	Motivation of instructor	2
	Intensive dealing with one topic	1
	Possibility to ask questions at any time	1
I would suggest the following changes/ further comments [a]:	Additionally other diseases should be included, less diabetes	11
	More precise information about the process flow of the seminar	5
	The checklist was not always practical	3
	Improve some aspects of the e-learning and online test	3
	The training approach should be offered in the 7th semester as it is time-consuming and students want to use the time for learning for the final state examination (*2. Staatsexamen*) instead	3
	Avoiding listening to the same counseling	3
	More training	2
	Less presentations	2
	No presenting of students worked out solution approach in front of the peers	2

[Continuation of Appendix 5]

Free-text item	Topic of comments	Number of comments on the topic
I would suggest the following changes/ further comments [a]:	Shorter intervals between OSCEs	2
	More complicated OSCE cases	1
	Discuss blood glucose testing and insulin injections	1
	Too many groups, better a fixed group	1
	The group sizes were partly too large, possibly more cases in a large semester	1
	Providing feedback regarding the summative pre-training OSCE	1
	The cases should be designed more differently so that the consultations are not too similar	1
	Too much OSCEs	1
	Discuss checklists and the process of the OSCEs in more detail	1
	Provision of guidelines for training purposes	1
	Provision of solutions for the cases	1
	Pressure because of checklist	1
	Less breaks	1

OSCE = objective structured clinical examination.

[a] For analysis, the items “I would change the following” and “further comments” were summarized.

Appendix 6: Global Analytical Checklist of the Randomized Controlled Study on OSCE Training for Self-Medication Counseling (CoSeMed-Study)

Section 1: Greeting: The pharmacist …	**Addressed**		**Comments**
1.1 Introduces themselves			
1.2 Identifies the patient			
1.3 Checks/adds to the patient's record			
Section 2: Medical history: The pharmacist …	**Addressed**		**Comments**
2.1 Asks which prescription drugs the patient is taking			
2.2 Asks which self-medication products including phytotherapeutics, etc. the patient is taking			
2.3 Asks about other medical conditions (i.e. chronic diseases, allergies, pregnancy/lactation period, kidney/liver diseases)			
[a] 2.4 Asks about present symptoms (checks patient's self-diagnosis)			
2.5 Asks how long the symptoms have been present			
2.6 Asks how often the symptoms appear			
2.7 Asks when the symptoms appear			
2.8 Asks about accompanying symptoms			
2.9 Asks whether the symptoms have already been clarified by a physician			
2.10 Asks if something has been already done about the symptoms			
2.11 Checks whether it is a first-time application			
2.12 Conducts detection screening measures/Provides first aid			
Section 3.1: Initiation of the therapy: The pharmacist …	**Addressed**	**Correct**	**Comments**
3.1.1 Provides information about the effect and benefit of the drug			
3.1.2 Explains the correct single dose			
3.1.3 Explains the maximum daily dose			
3.1.4 Explains the dosing interval			
3.1.5 Provides specific information on drug use (inhalation, spray, injection; ingestion with or without food)			
3.1.6 Explains the duration of the therapy			
3.1.7 Explains the correct drug storage			
3.1.8 Explains how the drug can be disposed of properly			
3.1.9 Explains possible monitoring activities associated with the drug therapy			
3.1.10 Supports adherence (memo-techniques/smart pill boxes)			
3.1.11 Explains potential side effects that are relevant			
3.1.12 Informs about the possible duration of the potential side effects			
3.1.13 Explains how the patient should behave in the case of adverse drug reactions			
3.1.14 Explains how the patient should behave in the case of drug interactions			
3.1.15 Gives additional important information/warnings			
Section 3.2: Implementation of the therapy: The pharmacist…	**Addressed**	**Correct**	**Comments**
3.2.1 Asks about any benefits the patient experienced when taking the drug/ experiences with the drug			
3.2.2 Asks the patient how they dose the drug			
3.2.3 Gives the patient information about the maximum daily dose			
3.2.4 Gives the patient information about the dose interval			
3.2.5 Identifies how the patient took the drug			

3.2.6 Gives the patient information about the duration of the therapy			
3.2.7 Identifies how the patient has stored the drug			
3.2.8 Identifies how the patient disposes of the drug			
3.2.9 Checks whether the patient has performed appropriate monitoring			
3.2.10 Repeats adherence supporting measures			
3.2.11 Identifies and helps to resolve side effects			
3.2.12 Identifies the duration of the side effects			
3.2.13 Asks the patient how they managed side effects			
3.2.14 Identifies interactions			
3.2.15 Asks the patient how they managed drug interactions			
3.2.16 Provides further important information / warning notices			
3.2.17 Adds/corrects incorrect use of the drug/information given by the patient			
[b] Section 4: Additional recommendations	**Addressed**	**Correct**	**Comments**
4.1 Explanation and distribution of information material			
4.2 Additional recommendations/supportive measures			
Section 5 - Risk communication: The Pharmacist ...	**Addressed**		**Comments**
5.1 Decides against self-medication because the limits of self-medication have been exceeded			
5.2 Decides for self-medication, as the limits of self-medication are not exceeded			
5.3 Decides against dispensing the drug because it is unsuitable and recommends another drug			
5.4 Decides to dispense the drug because it is suitable			
5.5 Shares risk information with relevant persons (e.g. family, doctor, emergency doctor, authorities)			
Section 5: Risk communication: The pharmacist …	**Addressed**	**Correct**	**Comments**
5.6 Tells the patient when to contact the physician if symptoms persist			
Section 6 - Goal Setting: The pharmacist ...	**Addressed**		**Comments**
6.1 Sets individual goals			
Section 7 - Patient involvement: The pharmacist ...	**Addressed**		**Comments**
7.1 Asks the patient for open questions			
Section 7 - Patient involvement: The pharmacist ...	**Addressed**	**Correct**	**Comments**
7.2 Takes into account the patient's questions during the consultation			
Section 7 - Patient involvement: The pharmacist ...	**Addressed**		**Comments**
7.3 Informs the patient that they should contact the pharmacist or physician in the case of questions			
Section 8 - Additional questions that may be necessary in the specific case	**Addressed**		**Comments**
8.x			
Sum			

[a] Depending on the case, this item could be divided into several items to received specific information about the symptoms. [b] Depending on the case, only the checkbox “addressed” or both “addressed” and “correct” were available.

In the study, the German version was used and adapted to the cases.

Appendix 7: Satisfaction Survey of the Randomized Controlled Study on OSCE Training for Self-Medication Counseling (CoSeMed-Study)

KLINISCHE PHARMAZIE & PHARMAKOTHERAPIE

HEINRICH HEINE UNIVERSITÄT DÜSSELDORF

Fragebogen zur Evaluation des OSCE-Seminars im Wintersemester 2018/19

1 = Trifft gar nicht zu, 2 = Trifft nicht zu, 3 = Trifft eher nicht zu, 4 = Trifft eher, 5 = Trifft zu, 6 = Trifft voll zu

Bitte kreuzen Sie die zutreffenden Felder an.

1) Das OSCE-Seminar hat mir Spaß gemacht.	☐ 1 Trifft gar nicht zu	☐ 2 Trifft nicht zu	☐ 3 Trifft eher nicht zu	☐ 4 Trifft eher zu	☐ 5 Trifft zu	☐ 6 Trifft voll zu
2) Während der OSCEs konnte ich meine Stärken und Schwächen feststellen.	☐ 1 Trifft gar nicht zu	☐ 2 Trifft nicht zu	☐ 3 Trifft eher nicht zu	☐ 4 Trifft eher zu	☐ 5 Trifft zu	☐ 6 Trifft voll zu
3) Das OSCE-Seminar hat mir Sicherheit im Umgang mit Patienten in der Apotheke vermittelt.	☐ 1 Trifft gar nicht zu	☐ 2 Trifft nicht zu	☐ 3 Trifft eher nicht zu	☐ 4 Trifft eher zu	☐ 5 Trifft zu	☐ 6 Trifft voll zu
4) Die OSCE-Fälle waren praxisnah.	☐ 1 Trifft gar nicht zu	☐ 2 Trifft nicht zu	☐ 3 Trifft eher nicht zu	☐ 4 Trifft eher zu	☐ 5 Trifft zu	☐ 6 Trifft voll zu
5) Die OSCE-Fälle waren zu einfach.	☐ 1 Trifft gar nicht zu	☐ 2 Trifft nicht zu	☐ 3 Trifft eher nicht zu	☐ 4 Trifft eher zu	☐ 5 Trifft zu	☐ 6 Trifft voll zu

6) Die OSCE-Fälle waren zu schwierig.	☐ 1 Trifft gar nicht zu	☐ 2 Trifft nicht zu	☐ 3 Trifft eher nicht zu	☐ 4 Trifft eher zu	☐ 5 Trifft zu	☐ 6 Trifft voll zu
7) Zwei Tage für das OSCE-Seminar waren ausreichend.	☐ 1 Trifft gar nicht zu	☐ 2 Trifft nicht zu	☐ 3 Trifft eher nicht zu	☐ 4 Trifft eher zu	☐ 5 Trifft zu	☐ 6 Trifft voll zu
8) OSCEs sollten zum Training der Beratungskompetenz in Zukunft als fester Bestandteil in das Seminar Klinische Pharmazie implementiert werden.	☐ 1 Trifft gar nicht zu	☐ 2 Trifft nicht zu	☐ 3 Trifft eher nicht zu	☐ 4 Trifft eher zu	☐ 5 Trifft zu	☐ 6 Trifft voll zu

9) Am OSCE-Seminar hat mir folgendes besonders gut gefallen:

_____
_____
_____

10) Folgendes würde ich ändern:

_____
_____
_____

Vielen Dank!

Appendix 8: Case Description of the Randomized Controlled Study on OSCE Training for Self-Medication Counseling (CoSeMed-Study)

KLINISCHE PHARMAZIE & PHARMAKOTHERAPIE

HEINRICH HEINE UNIVERSITÄT DÜSSELDORF

Information für Apotheker	
Aufgabenstellung	Bitte beraten Sie die Patientin/ den Patienten.
Zeit	Maximal 6 Minuten
Ort	Apotheke
Patientenmerkmale	Alter: 30 Jahre Geschlecht: männlich

Appendix 9: Topics of Comments from Free-Text Items of the Satisfaction Survey in the Randomized Controlled Study on OSCE Training for Self-Medication Counseling (CoSeMed-Study)

Free-text item	Topic of comments	Number of comments on the topic
I particularly liked the following at the OSCE seminar:	Patient counseling	4
	Receiving feedback after summative post-training OSCE	4
	Friendly faculty members	3
	Guidance for counseling	2
	Practical relevance	1
I would change the following:	Long waiting times for the summative OSCEs	8
	OSCE cases were too easy or not realistic	5
	Training on the summary of product characteristics was unnecessary (control group's training)	4
	Provide a better introduction to the process of the seminar	2
	Provide explanation/training on counseling in groups before summative OSCEs	2
	Provision of "good" counseling in video or live during the training	1
	The training was too short	1
	Offer a continuous training	1
	Provide feedback after the summative pre-training OSCE	1
	Providing a summary on counseling at the end of the seminar	1
	Student would like to be informed about the results of the study	1
	There should be a few days distance between the formative OSCEs and the summative post-training OSCE	1

OSCE = objective structured clinical examination.
The survey did not differentiate between the intervention group and the control group.

Appendix 10: Global Analytical Checklist of the Randomized Controlled Study on OSCE Training for Diabetes Counseling (CoDia-Study)

Section 1: Greeting:	**Addressed**		**Comment**
1.1 The pharmacist introduces themselves			
1.2 The pharmacist identifies the patient			
1.3 The pharmacist checks/adds to the patient's record			
Section 2: Medical history: The pharmacist …	**Addressed**	**Correct**	**Comment**
2.1 Asks about the reason for prescription/checks self-diagnosis			
2.2 Finds out whether the drug was prescribed for the first time			
2.3 Asks about the information already provided by the physician			
2.4 Asks about other prescription drugs			
2.5 Asks about other self-medication products, phytotherapeutics, etc.			
2.6 Asks about relevant medical conditions (i.e. chronic diseases, allergies, pregnancy/lactation, kidney/liver impairment)			
2.7 Tells the patient the name of the active substance			
Section 3.1: Initiation: The pharmacist …	**Addressed**	**Correct**	**Comment**
3.1.1 Explains the benefits of the drug therapy			
3.1.2 Explains the correct dosage			
3.1.3 Provides advices for the correct use of the drug			
3.1.4 Explains the duration of the therapy			
3.1.5 Explains the correct drug storage			
3.1.6 Provides advices regarding monitoring activities			
3.1.7 Provides advices regarding memo-techniques			
3.1.8 States potential adverse drug reactions that may occur			
3.1.9 Informs about the possible duration of potential adverse drug reactions			
3.1.10 Explains how to proceed in the case of side effects			
3.1.11 Explains how the patient should behave in the case of drug interactions			
Section 3.2: Implementation: The pharmacist…	**Addressed**	**Correct**	**Comment**
3.2.1 Asks about benefits the patient experienced during the therapy with the drug			
3.2.2 Asks how often the drug is taken			
3.2.3 Asks how the drug is taken			
3.2.4 Identifies how often the patient had not taken the drug			
3.2.5 Identifies where the patient has stored the drug			
3.2.6 Checks that appropriate monitoring has occurred			
3.2.7 Repeats memo-techniques			
3.2.8 Adds/corrects incorrect use of the drug/information provided by the patient (3.2.1 - 3.2.7)			
3.2.9 Identifies adverse drug reactions and interactions that were experienced			
3.2.10 Identifies the duration of side effects			
3.2.11 Asks how side effects that occurred were managed			
3.2.12 Asks how drug interactions that occurred were managed			
3.2.13 Adds/corrects incorrect handling of side effects/interactions			
Section 3.3: Prevention: The pharmacist talks about …	**Addressed**	**Correct**	**Comment**
3.3.1 Smoking cessation			
3.3.2 Overweight			
3.3.3 Physical exercise			
3.3.4 Diet			
3.3.5 Alcohol consumption			
Section 4: Goal setting: The pharmacist …	**Addressed**		**Comment**
4.1 Sets individual goals			

Section 5: Patient involvement: The pharmacist …	**Addressed**	**Correct**	**Comment**
5.1 Inquires the patient about open questions			
5.2 Takes patient's questions into account			
Section 6: Risk communication: The pharmacist …	**Addressed**		**Comment**
6.1 Shares risk information with relevant persons (e.g. family, physicians, emergency doctor, authorities)			
6.2 Informs the patient that they should contact the pharmacist or physician in the case of questions			
Sum			

In the study, the German version was used and adapted to the cases.

Appendix 11: Multiple-Choice Test 1 of the Randomized Controlled Study on OSCE Training for Diabetes Counseling (CoDia-Study)

Wissenstandserhebung Station 2

Teilnehmer-Code: _____

Datum: _____

Bitte kreuzen Sie die richtige Antwort an. **Es immer nur eine Antwort korrekt.**

1.) Was trifft zum HbA1c-Wert zu?
   (A) Zur Prävention von Folgekomplikationen für Patienten mit Typ 2 Diabetes mellitus sollte der HbA1c-Wert im Bereich 6,5 – 7,5 % unter Berücksichtigung individueller Therapieziele liegen.
   (B) Der HbA1c-Wert gibt Angaben über aufgetretene Hypoglykämien oder Hyperglykämien.
   (C) Der HbA1c-Wert ist eine Momentaufnahme und gibt den Glukosespiegel der letzten paar Minuten wieder.
   (D) Ein HbA1c-Wert unter 6,5% ist ein Diagnosekriterium für Diabetes mellitus.

2.) Welche Aussage zur Hypoglykämie trifft zu?
   (A) Eine Erstbehandlung einer Hypoglykämie sollte idealerweise mit fetthaltigen Lebensmitteln erfolgen, um die Resorption zu beschleunigen.
   (B) Eine milde Hypoglykämie sollte nicht behandelt werden.
   (C) Eine mögliche Ursache für eine Hypoglykämie ist das Vergessen einer Insulininjektion.
   (D) Typische Symptome einer Hypoglykämie sind u.a. Zittern, Schwitzen, Heißhunger und Schwindel.

3.) Welche Aussage zum Typ 2 Diabetes mellitus trifft zu?
   (A) Therapie der ersten Wahl für Typ 2 Diabetes mellitus ist Metformin.
   (B) Patienten mit Typ 2 Diabetes mellitus sollten Ihre Blutglukose häufiger kontrollieren als Patienten mit Typ 1 Diabetes mellitus, vor allem wenn sie mit Metformin behandelt werden.
   (C) Typ 2 Diabetes mellitus manifestiert sich in der Regel akut und innerhalb von wenigen Tage.
   (D) Patienten mit Typ 2 Diabetes mellitus erleiden keine Hypoglykämie.

4.) Was trifft die Anwendung des Insulins zu?
   (A) Insulin, was nicht in Gebrauch ist, sollte möglichst bei 0°C gelagert werden.
   (B) Insulin wird in der Regel in das Unterhautfettgewebe injiziert.
   (C) Die Insulinabsorption wird durch Wärme verlangsamt.
   (D) Eine Injektion von Insulin in den Bauch führt zu einer sehr langsamen Absorption.

Appendix 12: Multiple-Choice Test 2 of the Randomized Controlled Study on OSCE Training for Diabetes Counseling (CoDia-Study)

Wissenstandserhebung Station 2

Teilnehmer-Code: _____

Datum: _____

Bitte kreuzen Sie die richtige Antwort an. **Es ist immer nur eine Antwort korrekt.**

1.) Welche Aussage zum Diabetes mellitus trifft zu?
   (E) Leitsymptom des Diabetes mellitus ist eine Hypoglykämie.
   (F) Langfristige Folgeerkrankungen können Mikro- und Makroangiopathien sein.
   (G) Bei einem Typ 1 Diabetes mellitus liegt in der Regel eine Insulinresistenz vor.
   (H) Typ 1 Diabetes mellitus manifestiert sich meist erst im Erwachsenenalter.

2.) Welche Aussage zu Metformin trifft zu?
   (E) Metformin sollte nicht mit Insulin kombiniert werden.
   (F) Metformin führt zur Gewichtszunahme.
   (G) Metformin in der Monotherapie führt nicht zu Hypoglykämien.
   (H) Metformin ist Mittel der 1. Wahl zur Behandlung des Typ 1 Diabetes mellitus.

3.) Welche Aussage zu Sulfonylharnstoffen trifft zu?
   (E) Sulfonylharnstoffe bewirken eine Senkung der Insulinsekretion.
   (F) Eine häufige Nebenwirkung der Sulfonylharnstoffe ist die Hyperglyämie.
   (G) Sulfonylharnstoffe sind nicht insulinotrop.
   (H) Sulfonylharnstoffe können zu einer Gewichtszunahme führen.

4.) Welche Aussage zu Antidiabetika trifft zu?
   (A) SGLT2-Inhibitoren sind insulinotrop.
   (B) Alpha-Glukosidase-Hemmer reduzieren postprandiale Blutzuckerspitzen.
   (C) DPP4-Inhibitoren hemmen die Wirkung der Inkretine.
   (D) Glinide sind nicht insulinotrop.

Appendix 13: Preparation Questionnaire 1 of the Randomized Controlled Study on OSCE Training for Diabetes Counseling (CoDia-Study)

Fragebogen OSCE-Seminar

Code:

Datum:

1.) Haben Sie sich auf das Beratungsgespräch am 20.05.2019 vorbereitet?
- □ Ja
- □ Nein

2.) Mit welchen Unterlagen haben Sie sich auf das Beratungsgespräch am 20.05.2019 vorbereitet?
- □ Herausgegebenes Handout zum Diabetes mellitus
- □ Internet
- □ Lehrbücher
- □ Sonstiges:
  _____
  _____

3.) Wie lange haben Sie sich auf das Beratungsgespräch am 20.05.2019 vorbereitet?
- □ ≤ 30 Minuten
- □ > 30 Minuten – ≤ 1 Stunde
- □ > 1 Stunde – ≤ 2 Stunden
- □ > 2 Stunden – ≤ 3 Stunden
- □ > 3 Stunden

Appendix 14: Preparation Questionnaire 2 of the Randomized Controlled Study on OSCE Training for Diabetes Counseling (CoDia-Study)

Fragebogen OSCE-Seminar

Code:

Datum:

1.) Haben Sie sich auf das Beratungsgespräch am 03.06.2019 vorbereitet?
- □ Ja
- □ Nein

2.) Mit welchen Unterlagen haben Sie sich auf das Beratungsgespräch am 03.06.2019 vorbereitet?
- □ Herausgegebenes Handout zum Diabetes mellitus
- □ Internet
- □ Lehrbücher
- □ Sonstiges:
  _____
  _____
  _____

3.) Wie lange haben Sie sich auf das Beratungsgespräch am 03.06.2019 vorbereitet?
- □ ≤ 30 Minuten
- □ > 30 Minuten – ≤ 1 Stunde
- □ > 1 Stunde – ≤ 2 Stunden
- □ > 2 Stunden – ≤ 3 Stunden
- □ > 3 Stunden

Appendix 15: Satisfaction Survey of the Randomized Controlled Study on OSCE Training for Diabetes Counseling (CoDia-Study)

Fragebogen zur Evaluation des OSCE-Seminars zum Diabetes mellitus im Sommersemester 2019

OSCEs, „Objective structured clinical examinations“, sind eine Methode zur Bewertung klinischer Kompetenzen in einer simulierten Umgebung [1,2]

Schulungsgruppe:

☐ Simulation von Beratungsgesprächen ☐ Diabetes-Patientenfälle im SOAP-Schema

1) Ich hatte Interesse am OSCE-Seminar.	☐ Trifft gar nicht zu	☐ Trifft nicht zu	☐ Trifft eher nicht zu	☐ Trifft eher zu	☐ Trifft zu	☐ Trifft voll zu
2) Durch das OSCE-Seminar haben sich meine klinischen Fähigkeiten verbessert.	☐ Trifft gar nicht zu	☐ Trifft nicht zu	☐ Trifft eher nicht zu	☐ Trifft eher zu	☐ Trifft zu	☐ Trifft voll zu
3) Durch das OSCE-Seminar haben sich meine kommunikativen Fähigkeiten verbessert.	☐ Trifft gar nicht zu	☐ Trifft nicht zu	☐ Trifft eher nicht zu	☐ Trifft eher zu	☐ Trifft zu	☐ Trifft voll zu
4) Das OSCE-Seminar hat mir praxisbezogenes Wissen vermittelt.	☐ Trifft gar nicht zu	☐ Trifft nicht zu	☐ Trifft eher nicht zu	☐ Trifft eher zu	☐ Trifft zu	☐ Trifft voll zu
5) Die OSCE-Fälle waren zu einfach.	☐ Trifft gar nicht zu	☐ Trifft nicht zu	☐ Trifft eher nicht zu	☐ Trifft eher zu	☐ Trifft zu	☐ Trifft voll zu
6) Das OSCE-Seminar hat mir Sicherheit im Umgang mit Patienten in der Apotheke vermittelt.	☐ Trifft gar nicht zu	☐ Trifft nicht zu	☐ Trifft eher nicht zu	☐ Trifft eher zu	☐ Trifft zu	☐ Trifft voll zu

7) OSCEs/Simulationen zu Beratungssituationen sind überflüssig, da man bei der Beratung nichts falsch machen kann.	☐ Trifft gar nicht zu	☐ Trifft nicht zu	☐ Trifft eher nicht zu	☐ Trifft eher zu	☐ Trifft zu	☐ Trifft voll zu
8) OSCEs sollten zum Training der Beratungskompetenz in Zukunft als fester Bestandteil in das Seminar Klinische Pharmazie implementiert werden	☐ Trifft gar nicht zu	☐ Trifft nicht zu	☐ Trifft eher nicht zu	☐ Trifft eher zu	☐ Trifft zu	☐ Trifft voll zu

9) Am OSCE-Seminar hat mir folgendes besonders gut gefallen:

_____
_____
_____

10) Folgendes würde ich ändern:

_____
_____
_____

Vielen Dank!

[1] Hodges B, McIlroy JH. Analytic global OSCE ratings are sensitive to level of training. *Med Educ*. 2003; 37(11):1012–6. doi:10.1046/j.1365-2923.2003.01674.x.

[2] Khan KZ, Ramachandran S, Gaunt K, Pushkar P. The Objective Structured Clinical Examination (OSCE): AMEE Guide No. 81. Part I: an historical and theoretical perspective. *Med Teach*. 2013; 35(9):e1437-46. doi:10.3109/0142159X.2013.818634.

Appendix 16: Example of a Case Description of the Randomized Controlled Study on OSCE Training for Diabetes Counseling (CoDia-Study)

Case: Initiation of dapagliflozin

KLINISCHE PHARMAZIE & PHARMAKOTHERAPIE

HEINRICH HEINE UNIVERSITÄT DÜSSELDORF

Information für Apotheker	
Aufgabenstellung	Bitte beraten Sie die Patientin/ den Patienten.
Zeit	Maximal 10 Minuten
Ort	Apotheke
Der Patient	
Alter	35 Jahre
BMI	BMI 28 kg/m²

Appendix 17: Topics of Comments from Free-Text Items of the Satisfaction Survey in the Randomized Controlled Study on OSCE Training for Diabetes Counseling (CoDia-Study)

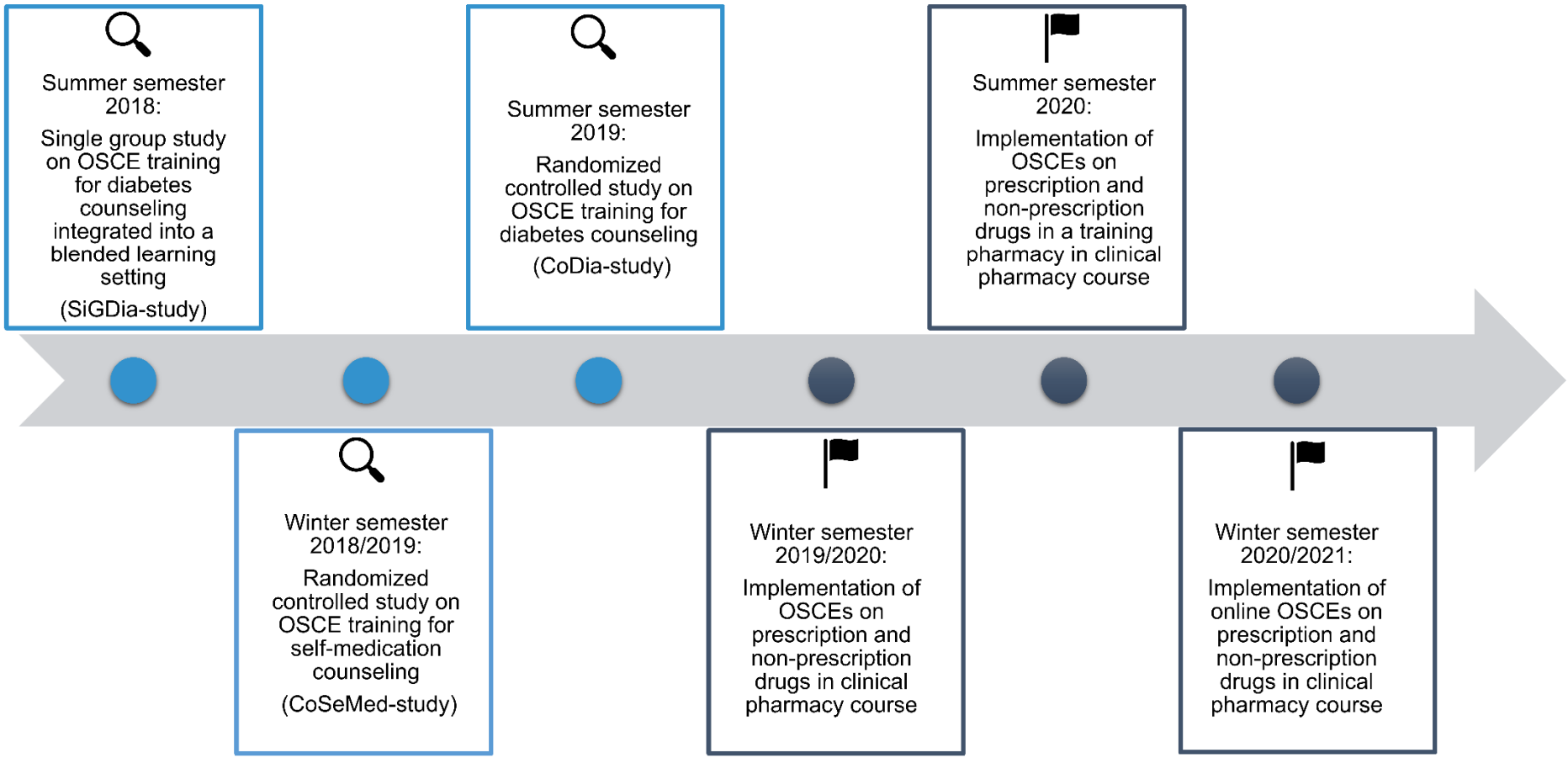
Free-text item	Group	Topic of comments	Number of comments on the topic
I particularly liked the following at the OSCE seminar:	Intervention group	The practical exercise/training of counseling (simulation)	6
		Practical relevance	6
		Checklist as a good guide	3
		Recognizing own abilities	2
		Questions were answered	1
		Feedback after the post-training OSCE	1
		Structure	1
		Imparting relevant pharmaceutical knowledge	1
	Control group	The practical exercise of counseling (simulation)	6
		Practical relevance	2
		Feedback	2
		Handout on diabetes	2
		Realistic	2
		Possibility to ask questions	1
		Diabetes mellitus counseling is important	1
		Acting skills of the supervisor	1

[Continuation of Appendix 17]

Free-text item	Group	Topic of comments	Number of comments on the topic
I would change the following:	Intervention group	Time schedules for the OSCEs should be optimized	6
		Checklists or OSCEs were not realistic	3
		All students should have the possibility to complete the OSCE training	1
		Cases were too monotonous	1
		The checklist should be handed out at the end to all participants in both groups	1
		The handout was too long	1
		Additional handout on the OSCE training is necessary as making notes during the training intervention was disliked by the student	1
		Preparing/accompanying seminar on counseling was desired	1
		Video on the perfect counseling was desired	1
		General introduction at the beginning with an explanation of the seminar procedure	1
		Facilities are not embodying a community pharmacy	1
		Exercise in the control group	1
	Control group	In the control group, preparing SOAP notes did not prepare for patient counseling, training counseling was demanded (as in the intervention group)	8
		Provision of guidance document (checklist)	3
		Several topics should be covered	2
		Time schedules for the OSCEs	2
		Other facilities	2
		Improvement of feedback	1
		Pre-training OSCEs should be skipped, consequently, first training then OSCE	1
		Omission of OSCEs	1

OSCE = objective structured clinical examination, SOAP = subjective, objective, assessment, plan.

Appendix 18: Timeline of OSCEs in Clinical Pharmacy at Heinrich Heine University Düsseldorf



OSCE = objective structured clinical examination; = study on OSCE training; = implementation of OSCEs.

10. List of Own Publications

Some parts of this dissertation were previously published in international peer-reviewed journals or were presented at conferences beforehand:

Original Publications in Peer-Reviewed Journals

1. Farahani I, Laeer S, Farahani S, Schwender H, Laven A. Blended learning: improving the diabetes mellitus counseling skills of German pharmacy students. *Curr Pharm Teach Learn*. 2020;12(8):963-974. doi:10.1016/j.cptl.2020.04.016
2. Farahani S, Farahani I, Burckhardt BB, Schwender H, Laeer S. Self-instruction video versus face-to-face instruction of pharmacy students' skills in blood pressure measurement. *Pharmacy (Basel)*. 2020;8(4):217. doi:10.3390/pharmacy8040217
3. Farahani I, Farahani S, Deters MA, Schwender H, Laeer S. Efficacy of an objective structured clinical examination training approach for training pharmacy students in diabetes mellitus counseling: a randomized controlled trial. *Pharmacy (Basel)*. 2020;8(4):229. doi:10.3390/pharmacy8040229
4. Farahani I, Farahani S, Deters MA, Schwender H, Laeer S. Training pharmacy students in self-medication counseling using an objective structured clinical examination–based approach. *J Med Educ Curric Dev*. 2021;8:1-9. doi:10.1177/23821205211016484
5. Farahani S, Farahani I, Burckhardt BB, Monser K., Laeer S. The development of an educational video on blood pressure measurement for

pharmacy students. *Adv Med Educ Pract*. 2021;12:655-663. doi:10.2147/AMEP.S302728

6. Farahani S, Farahani I, Deters MA, Schwender H, Burckhardt BB, Laeer S. Blended learning on blood pressure measurement: investigating two in-class strategies in a flipped classroom-like setting to teach pharmacy students blood pressure measurement skills. *Healthcare (Basel)*. 2021;9(7):822. doi:10.3390/healthcare9070822

Conference contributions

Farahani I, Laven A, Farahani S, Deters MA, Feickert M, Suessenbach FK, Schwender H, Laeer S. P33 Effectiveness of OSCEs in training German pharmacy students in consultation on self-medication – a randomised controlled investigation. *Arch Dis Child*. 2019;104(6):e30.2-e31. doi:10.1136/archdischild-2019-esdppp.71.

17th European Society for Developmental, Perinatal and Paediatric Pharmacology (ESDPPP) congress (May, 2019), Basel, Switzerland