Efficacy of goal-directed minimally invasive surgery simulation training with the Lübeck Toolbox-Curriculum prior to first operations on patients: Study protocol for a multi-centre randomized controlled validation trial (NOVICE)

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ABSTRACT

Background: Minimally invasive surgery (MIS) procedures require special psychomotoric skills. Learning of these MIS basic skills is often performed in the operating room (OR). This is economically inefficient and could be improved in terms of patient safety. Against the background of this problem, various MIS simulators have been developed to train MIS basic skills outside the OR. Aim of this study is to evaluate to what extent MIS training programs and simulators improve the residents' skills in performing their first MIS procedures on patients.
Method: The current multicentric RCT will be performed with surgical residents without prior active experience in MIS (n = 14). After the participants have completed their first laparoscopic cholecystectomy as baseline evaluation (CHE I), they will be randomized into two groups: 1) The intervention group will perform the *Lübeck Toolbox curriculum*, whereas 2) the control group will not undergo any MIS training. After 6 weeks, both groups will perform the second laparoscopic CHE (CHE II). Changes or improvements in operative performance (between CHE I and CHE II) will be analyzed and evaluated according to the *Global Operative Assessment of Laparoscopic Skill* (GOALS) Score (*primary endpoint*).
Discussion: The multicentric randomized controlled trial will help to determine the value of MIS training outside the operation room. Proof of effectiveness in practice transfer could be of considerable relevance with regard to an integration of MIS training programs into surgical education.

1. Background

In comparison to open surgical techniques minimally invasive surgery (MIS) procedures require additional psychomotoric skills often referred to as MIS basic skills. [1]. MIS basic skills include the coping with different haptic competencies, the fact that opposite movements have to be applied to the instruments fixed at the level of the body wall (*fulcrum effect*) and the cognitive transfer of a two-dimensional monitor image to the three-dimensional surgical field. Completion of the learning process of these basic MIS skills takes a lot of time and practice [1]. Surgical training is currently mainly performed in the conventional teacher-learner mode. However, personal resources and time are often limited due to the increasing economic pressure in hospitals [1,2].

Against this background, various virtual reality (VR)- and/or video-/box-trainers and MIS training curricula have been developed in recent years for residents to learn basic MIS skills outside the operation room (OR) in a safe and standardized environment [3–5]. Recently, we devised a comprehensive, strictly defined and

goal-directed curriculum for the acquisition of minimally invasive basic skills (http://www.luebeck-toolbox.com) [6,7]. The Lübeck Toolbox (LTB) curriculum encompasses a box-trainer, six iteratively developed tasks, pre-defined expert-levels for each task as well as online video-tutorials and documentation material for the training progress. The goals for each task were based on a benchmark-study with experts in MIS followed by a prospective validation study with MIS novices [6,7]. In that study all MIS novices successfully completed the curriculum [7]. Consequently, the approach provides an adaptation of MIS basic skills regardless to the talent of the individual trainee. In addition we previously demonstrated the transferability of the LTB-based skills to an organic surgical model [6]. The LTB curriculum, however, so far has not been validated with regard to real OR performance in a prospective randomized study.

Several studies have demonstrated beneficial effect of MIS training outside the OR on MIS performance [8–13,6]. Mostly studies assessed MIS performance in the surgical laboratory as, i.e., a cholecystectomy (CHE) on a porcine model. However, transferability to the OR is essential to justify the implementation of MIS ex vivo training into surgical education. Indeed, there are some data from prospective randomized studies available focussing on the transferability of MIS ex vivo training to surgical performance in the OR on the patient:

The prospective randomized trials by Orzech et al. and Van Sickle et al. showed that ex vivo MIS training significantly improved surgical performance in intracorporal laparoscopic stitches during Nissen fundoplication on patients in the OR [14,15]. Malik et al. demonstrated an improvement of surgical performance on surgical residents during dissection of gallbladder from the liver bed in the OR after the use of box simulators [16]. In addition, Palter et al. showed that a structured training and assessment curriculum significantly improved learning curves in five subsequent laparoscopic cholecystectomies on surgical residents compared to conventional trained residents [17]. In a further randomized controlled trial Palter et al. demonstrated same effect on residents performing MIS right hemicolectomy [18]. Sroka et al. randomized 19 training surgeons to undergo simulator training or not and analyzed OR performance in cholecystectomy before and after the curriculum [19]. In this study, the MIS performance increased significantly in both groups but the difference in the simulator group exceeded the other one. Furthermore, the effect of ex vivo MIS training also plays a relevant role for other surgical disciplines such as gynaecology and urology. Here, too, a positive effect of MIS training on OR performance has been shown in prospective randomized studies [20]. Despite this evidence the integration of ex vivo MIS training into formal residency training curricula is still lagging [21,22].

A limitation of the prospective randomized studies investigating on the transferability of MIS training to the OR was that study populations were not homogenous as the participants were at very different levels of surgical education from the first to fourth year of surgical education [14–20]. In particular, most study participants had MIS experience in the operating room before. Indeed, there is a lack of prospective randomized controlled studies investigating the impact of MIS-skills training on residents without any previous MIS experience in performing their first MIS procedure on patients. The demonstration of evidence in this defined scenario could further strengthen the need to implement MIS simulation training in formal residency training curricula, in particular prior to first MIS experience in the OR.

In consequence, we conduct a prospective randomized trial to validate the efficacy of goal-directed minimally invasive surgery simulation training with the Lübeck Toolbox-curriculum to the first surgical procedures of surgical residents in the OR.

2. Materials and design

2.1. Objectives

Primary objective of the study is to examine whether study participants with no prior experience in MIS perform better in laparoscopic MIS on a patient when they attended the LTB-MIS training beforehand (group A). The control group does not perform any MIS training (group B). The highly standardized LTB curriculum takes about six weeks to complete [6]. The operative performance in both groups will be evaluated for the procedure of a laparoscopic cholecystectomy (CHE) on a patient in the OR. As baseline of MIS performance, all participants perform a laparoscopic CHE on a patient at the beginning of the study with an experienced consultant surgeon assisting (pre-test). Following the pre-test, the participants undergo either MIS training (group A/intervention group) or no MIS training. Six weeks after, all participants perform a second laparoscopic CHE (post-test) (Fig. 1). The video material of the CHE procedures will be saved. Then, the MIS performance of both groups will be evaluated and compared using the validated *Global Assessment Tool for Evaluation of Intraoperative Laparoscopic Skills* (GOALS)-Score [23] (Table 2). In addition to the analysis of the video-documented surgery, operational performance will also be determined by the following two parameters: 1) the number and duration of takeovers by the experienced surgeon who assists the operation 2) (potential) termination of the operation by the participants.

3. Study design

This is a registered prospective, multi-centre, two-arm, parallel-group randomized controlled trial (NCT03040544). The study was approved by the Ethics Committee of the Universität zu Lübeck (ethics committee protocol #16–316). In addition, the according respective local ethics committees must approve participation of centres before we begin recruitment at those centres. The study protocol is designed in accordance with the SPIRIT Guidelines (see populated SPIRIT checklist additional file 1).

3.1. Setting

The multi-centre study is carried out in several departments of general and visceral surgery in Germany. For individual participants, the study is conducted on site in the clinic where he or she undergoes surgical education for general and/or visceral surgery. The participating centres hold the appropriate equipment to perform MIS procedures and have the technology to save the operation videos digitally and transfer them to a digital data medium. Furthermore, the departments hold an LTB system for MIS training. Alternatively, a LTB system for the study by the conducting centre, University Medical Centre Schleswig-Holstein Campus Lübeck, Department of Surgery, will be provided.

3.2. Participants

The study is addressed to surgical residents who undergo surgical education for general and/or visceral surgery. The inclusion and exclusion criteria are shown in Table 1. Here, it should be emphasized that, at the beginning of the study, participants are not allowed to have performed any prior MIS simulation training or any MIS procedure. The declaration of informed consent of all potential participants will be obtained by the local attending surgeon in charge of training.
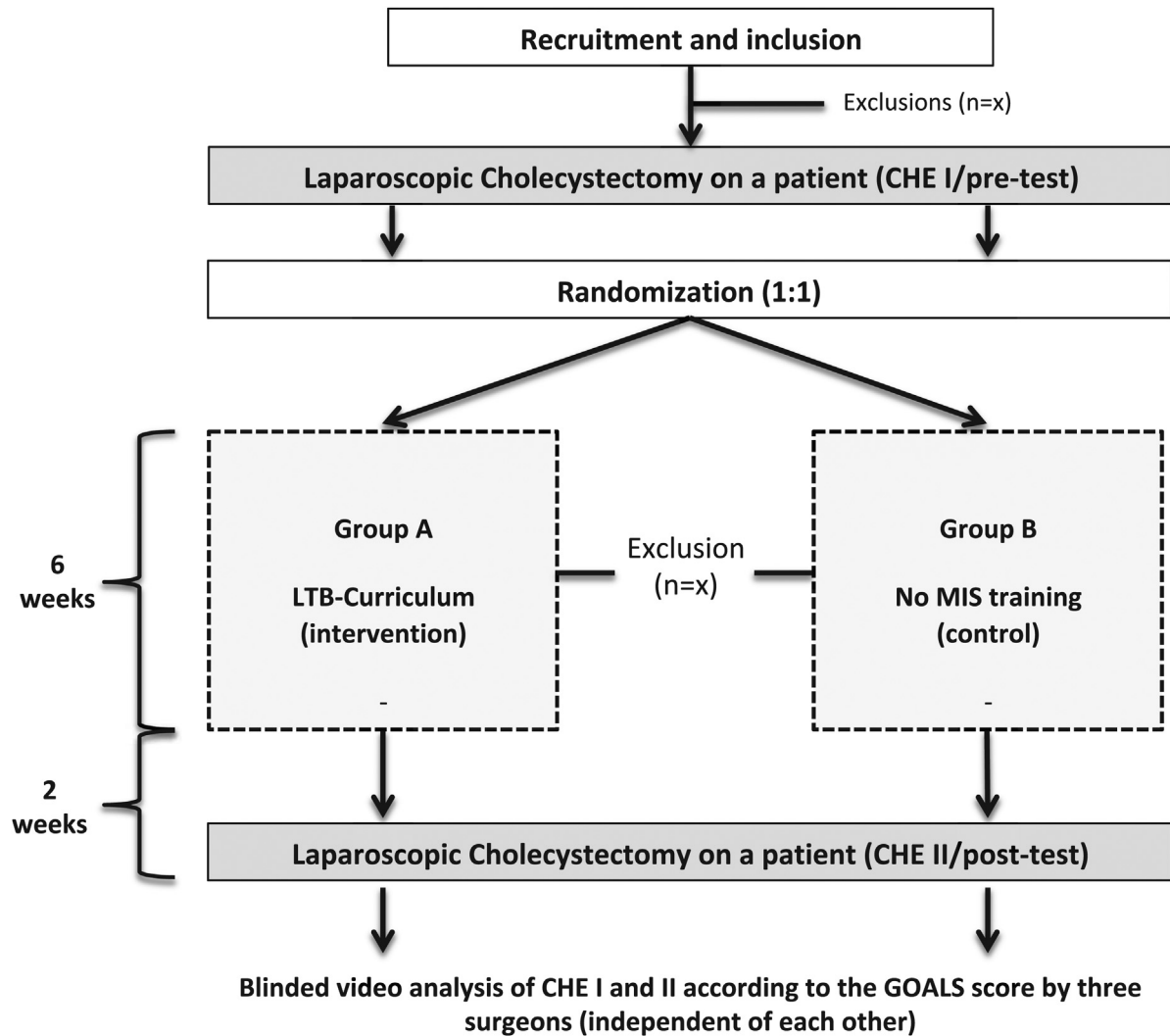
Fig. 1. Flowchart of the study design and the course of the study.

Table 1
Inclusion and exlusion criteria for participation in the NOVICE study.

no motor or sensory restrictions when using surgical instruments
no previous performed MIS simulation training
no previous performed MIS procedure(any previous <u>assisted</u> MIS procedures are not an exclusion criterion)
residents in surgical education for general or visceral surgery in Germany

3.3. Laparoscopic CHE on a patient

MIS performance of participants will be evaluated for a laparoscopic CHE on a patient in a real surgical environment. In order to ensure comparable operating conditions for the participants, the following criteria for patient selection are defined: (1) the indication for the CHE is symptomatic cholecystolithiasis (without signs of cholecystitis). (2) The patients did not have any previous abdominal operation or have no adhesions in the upper abdomen, as evaluated after insertion of the laparoscopic camera. (3) The patients do not take drugs that influence blood clotting or platelet aggregation and (4) do not suffer from chronic infectious diseases (e.g. HIV, hepatitis B, C, D, E) or (5) acute or chronic liver disease. The operation is assisted by a surgeon who holds the formal autho-

rization for surgical education in visceral and/or general surgery in the participating clinic (hereafter named as attending surgeon) employed at the respective department participating in the study. The attending surgeon can take over the operation at any time and perform surgical steps independently, according to his/her judgement with regard to the individual situation. The percentage of the participants' operating time of the total time for the CHE as well as the number of takeovers by the attending surgeon, are documented during the operation. A possible complete takeover and completion of the operation by the attending surgeon or a conversion to laparotomy will also be documented, but does not lead to exclusion from the study. The operation will be continuously recorded digitally and transferred to a digital data medium. The above listed criteria apply to both CHE I (pre-test) and CHE II (post-test). Immediately after the operation, the documentation forms will be filled in by the attending surgeon including following study parameters: the 5th domain of the GOALS score (*autonomy,* Table 2), time and percentage of the participants' operating time during the total time of the CHE, number of takeovers by the attending surgeon, total operation time, potential complete takeover by the attending surgeon and conversion to laparotomy. After the second CHE (CHE II, post-test) the following additional parameters are documented by the participant: age, sex, dominant hand, number of MIS procedures as assistant during the study period,

Table 2
Global Assessment Tool for Evaluation of Intraoperative Laparoscopic Skills (GOALS) Score (according to [23]).

Domain	1 point	3 points	5 points
Depth perception	Constantly overshooting target, hits backstops, wide swings, slow to correct	Some overshooting or missing plane but corrects quickly	Accurately directs instruments in correct plane to target
Bimanual dexterity	Use of one hand, ignoring non-dominant hand, poor coordination between hands	Use of both hands but does not optimize interactions between hands to facilitate conduct of operation	Expertly uses both hands in a complementary manner to provide optimal working exposure
Efficiency	Uncertain, much wasted effort, many tentative motions, constantly changing focus of operation or persisting at a task without progress	Slow but planned and reasonably organized	Confident, efficient and safe conduct of operation, maintaining focus on component of procedure until better done by another approach
Tissue handling	Rough, tears tissue by excessive traction, injures adjacent structures, poor control of coagulation device (recoil), grasper frequently slips off	Handles tissue reasonably well with some minor trauma to adjacent tissues	Handles tissue very well with appropriate traction on tissue and negligible injury of adjacent structures. Uses energy sources appropriately but not excessively
Autonomy	Unable to complete entire procedure, even in a straightforward case and with extensive verbal guidance	Able to complete operation safely with moderate prompting	Able to complete operation independently without prompting

active practice of a musical instrument, regular practice of handicrafts, or regular practice of video/computer games.

3.4. Assessment of MIS performance

Primarily, the MIS performance of the study participants for the laparoscopic CHE will be assessed by three independent experienced MIS surgeons applying the standardized and validated GOALS Score to the video-documented procedures [23,24]. The determination of the GOALS scores by the three MIS surgeons will be performed blinded and independent from each other. For evaluation of the *inter-rater reliability* of the GOALS-Score the *intraclass correlation* will be calculated. The analysis of the surgical videos is performed when all study participants have completed the study to ensure that video ratings do not affect the course of the study.

The GOALS score is based on the concept that MIS performance can be evaluated in five distinct categories called domains [23]. These five domains include depth perception, bimanual dexterity, efficiency, tissue handling and autonomy. Each domain is scored with an integer rating from 1 to 5 points. The domains are evaluated on a Likert-scale, according to which 1, 3 or 5 points can be achieved in each domain. The points in each domain are added to sum up in a total score of 5 to 25 [23] (Table 2). Since the fifth domain of the GOALS score (autonomy) cannot be evaluated by analysis of the video material, it is determined by the attending surgeon assisting the CHEs I and II, respectively.

Secondary, MIS performance will be assessed by percentage of the participants' operating time of the total time of the CHE, number of takeovers by the attending surgeon, total operation time, potential complete takeover by the attending surgeon and conversion to laparotomy.

3.5. Study period for group a (intervention group) and group B (control group)

After CHE I (pre-Test) and randomization to group A or B the participants either perform the LTB curriculum (group A) or no MIS training (group B). For both groups a study period of 8 weeks is defined: Whereas group A has six weeks to complete the LTB curriculum, group B will have a waiting period of 6 weeks without any MIS training. Afterwards, both groups must perform the second CHE II within the following two weeks (post-test) (Fig. 1). The following exclusion criteria are defined for the study period: the participants are not allowed to perform any MIS training (except the LTB curriculum/group A) or any MIS procedure (except

CHE I and II). However, the participants are allowed to participate in MIS procedures as first or camera guiding assistant.

3.6. Randomization

Due to the small number of participants in the individual departments, randomization takes place without stratification as permutation of blocks of different lengths with a 1:1 ratio. The list is generated at the biostatistics department (RV) using the software RITA (StatSol, Germany). After the participants have performed the pre-test (CHE I), an employee (MT) of the department of surgery in Lübeck, will open the next consecutively numbered, opaque, sealed envelope that conceals the allocation. Then, participants will be informed into which group they were randomized.

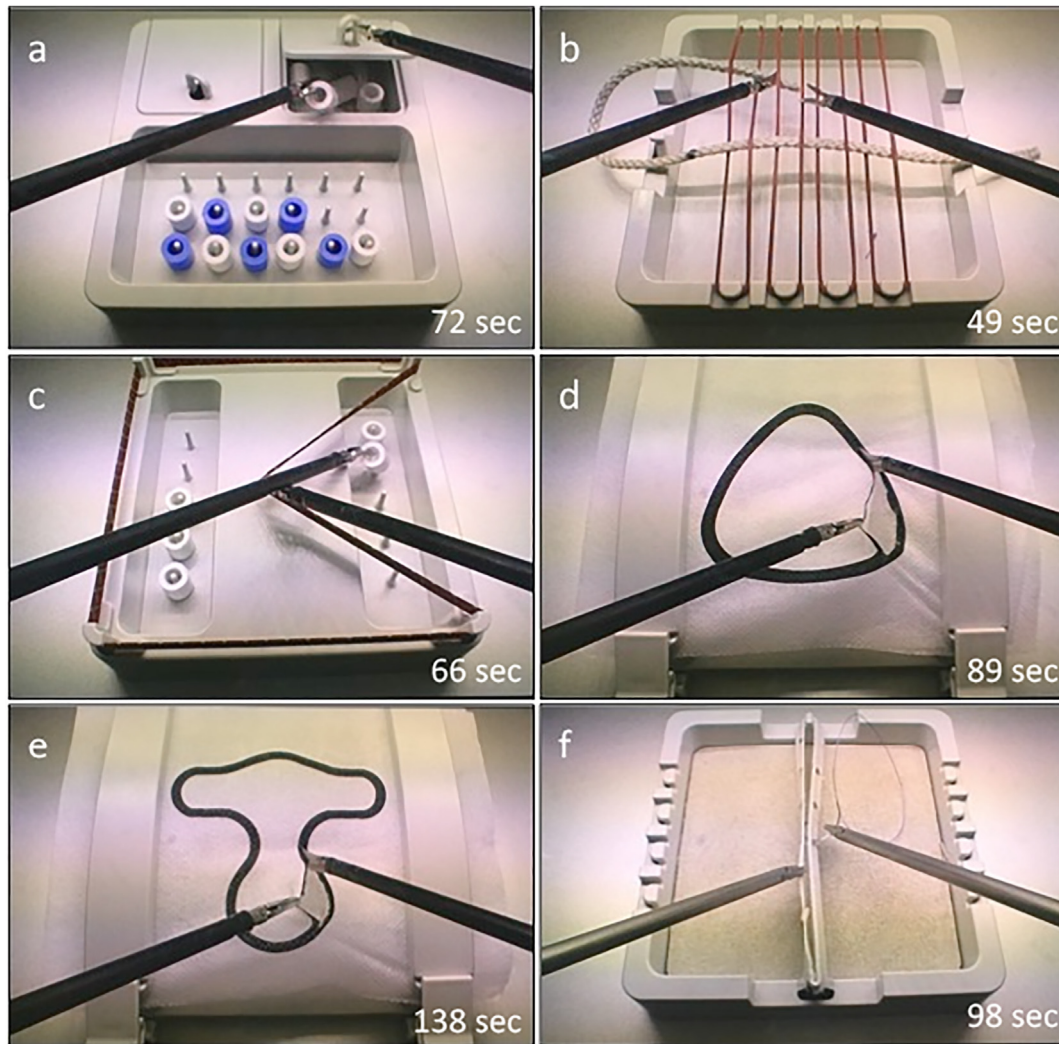### 3.7. Lübeck Toolbox (LTB) curriculum

Group A will perform the MIS training according to the LTB Curriculum. The LTB Curriculum is a video training platform with an integrated camera and light source. The position of the camera and the monitor are standardized and identical for the entire curriculum. The curriculum comprises six subsequent exercises (Fig. 2).

In the current study, the curriculum will be carried out as previously described [6 7].

Based on a preceding pilot study (unpublished data) to determine the optimal time schedule for MIS simulator training, the following practice intervals are defined for the current study: A maximum of three exercise units per day may be performed, there must be a break of at least 60 minutes between each exercise unit, the interval between individual exercise units may not exceed 3 days. The LTB curriculum includes video tutorials for each exercise, which explain the rules of each exercise and provide instructions on how to efficiently practice and complete each exercise. The latter factors are watched redundantly throughout the curriculum at pre-defined task repetitions. Based on data from our preceding prospective study, the inclusion of comprehensive video tutorials into a simulation curriculum lead to more efficient and more precise performance in MIS training than watching no tutorials (*accepted manuscript*) [34].

3.8. Primary outcome measure

The primary outcome measure is the operative performance of the study participants during the laparoscopic CHE on a patient based on the standardized and validated GOALS score. Changes

Fig. 2. The Lübeck Toolbox (LTB) curriculum. The curriculum consists of six subsequent exercises, including a) 'pack your luggage', b) 'weaving', c) 'Chinese jump rope', d) 'Triangle Cut', e) 'Hammer Cut' and e) 'Suturing', in which defined target times must be achieved in order to continue with the next exercise. The target times for each exercise were based on a benchmark-study with experts in MIS and are shown in the figure

or improvements in the GOALS score of CHE I to CHE II will be compared between group A and B.

3.9. Secondary endpoints

Individual domains of the GOALS score will be evaluated separately, as secondary endpoints, as well as operative time, percentage of the participants' operating time in the total time of the CHE, number of takeovers by the attending surgeon and potential conversion to laparotomy during the CHE. In addition, operative performance will be examined by sex-, dominant hand- and age-dependent subgroup analysis, correlation with activities and hobbies (in particular playing an instrument, handicrafts and computer games) and possible differences and bias between video ratings by calculation of inter-rater reliability. Additional study parameters include experience dependent subgroup analyses by determining the number of participated MIS procedures as first assistant. Furthermore, sensitivity analyses will use the per-protocol and the as-treated data.

3.10. Statistics

Mean values and standard deviation for continuous data and absolute and relative frequencies for categorical data will be used to describe the distribution of parameters of interest. The modified intention-to-treat data set (mITT), which will be the basis of the primary statistical analysis, includes all randomized subjects that will have met all inclusion criteria, no exclusion criteria and performed CHE I and II. The primary analysis will be performed by the *U-test* and the *associated Hodges-Lehmann confidence interval* of individual GOALS score improvements. Since only one confirmatory statistical test is planned, this will be carried out at the unadjusted significance level of 5%. No interim analysis is planned, as it would rely on too few cases. In addition, the GOALS score of CHE II will be analyzed as a covariance analysis with the GOALS score of CHE I as a covariable. The distribution of secondary endpoints will be analyzed descriptively by median and quartiles and Hodges-Lehman-confidence intervals for continuous data and by percentages, their differences and 95%-confidence intervals for these for categorical data. Inter-rater reliability will be analysed using the *intraclass correlation*. For values above 0.65, an assessment instrument, i.e. GOALS score, is considered reliable (maximum value 1.0).

3.11. Data management

The data of the participants will be pseudonymized on site in the participating centre. Password-protected access to the identification list is only available to the respective centres on site. After

data collection, the data will be anonymized and archived for another 10 years. The data will be collected on test sheets on paper, checked for plausibility and stored on a computer protected against unauthorized use with a password. The data will be checked for transmission errors by a second person and passed on only to the statistician of the study. As the primary endpoint is centrally adjudicated, no audits are planned.

3.12. Sample size determination

The sample size was calculated on the basis of published data on the GOALS score and validation studies of the LTB curriculum. A similar trial [17] had a waiting group of 8 participants. Those achieved a mean increase of 1.8 (+/- 2.1) points on the GOALS scale. The mean GOALS scores were 12 before and 13.8 after waiting. The training group of that trial had higher increases with SD 1.3 points. In our single-arm pilot study, 30 MIS novices, medical students, increased their mean GOALS score observed during a laparoscopic CHE on a porcine model from 10.9 by 7.1 (+/- 3.16) to 18.0 after LTB curriculum training. Consequently, as an effect size to be detected, 7.1–1.8 = 5.3 points were assumed as the difference between the improvements of the study groups. The sample size per study group required to demonstrate a difference of 5.3 points with a power of 80% is 6 per study group. The standard deviation was assumed to be 2.1 points for group A and 3.16 points for group B. The *two-sided t-test according to Satterthwaite* and a significance level of 0.05 were used for sample size determination [25]. In order to compensate for the lower efficiency of the *U-test* compared to the *t-test*, the sample size was increased by 5%. Since some missing values are also to be expected, 1:1 randomization is continued until the smaller group has 7 observations for analysis. Any overrun will be followed up and included in the analysis.

4. Discussion

This study aims to examine whether the standardized LTB MIS training curriculum improves performance of MIS inexperienced surgical residents prior to their first MIS procedure in the operating room in comparison to not undertaking LTB-based simulation training.

Generally, for MIS procedures, the surgeon requires additional psychomotoric skills in comparison to open surgery to perform the operation safely and efficiently [1]. These MIS basic skills can be efficiently well learned outside the operation room by MIS virtual reality (VR)- and/or video-/box-trainers [3 4 5]. This aspect resulted in the development of various simulation devices and curricula in order to train and further improve MIS skills.

Simulation of laparoscopic demands is a good option for the education of surgeons in a safe environment [8]. Still, according to van Dongen et al., the implementation of simulator practice into the surgical curriculum seems to be difficult [22]. Several studies demonstrated that surgeons profit from MIS training outside the operation room [8–13,6]. Even more, prospective randomized studies showed beneficial effect of MIS training with regard to its direct transferability to real surgical environments [14–20,3]. However, as a limitation, these studies included residents with very different MIS experiences prior to training on a simulator. In particular, most study participants had MIS experience in the operating room before study inclusion. Based on our very own experience with the MIS LTB simulation system we believe that surgical residents benefit from a standardized simulation training outside the OR before starting to perform their first MIS procedures on patients. The presented study addresses this concept of MIS simulation training and its direct transferability to the OR.

However, in our study protocol we included a first laparoscopic CHE as a baseline evaluation. This is in contradiction to the desired sequence of MIS training before the first MIS experience in the OR. The reasons for implementing of the CHE I are as follows: The inclusion of a baseline evaluation is analogous to previously published studies on the effect of MIS training on surgical performance [16,19]. By a baseline evaluation we aimed to exclude individual participant depending factors that may influence MIS performance at the beginning of the study. These factors include the number of assisted MIS procedures, playing a musical instrument or video games, which positively influence MIS performance [26,27]. Additionally, it is also well known that surgical residents are differently talented in performing MIS [28]. By determining the differences in GOALS score between CHE I and II, we aim to compare the improvement in MIS performance and thereby to exclude different talents of the participants in MIS.

Proving a positive effect of MIS training on real MIS procedures could underline and fortify the need of an implementation of MIS simulation training into surgical education. As an positive example, the Fundamentals of Laparoscopic Surgery (FLS) program has been integrated into the surgical residency program by the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) and the American College of Surgeons (ACS) [29,25,30]. In contrast, in Germany MIS simulation training is still not incorporated into surgical residency curriculum. This fact does further underline the need to conduct this study.

Beside beneficial effects on residenťs surgical performance in the OR, MIS simulation training has the potential to translate into improved patient safety, decreased OR resources, and better patient outcomes [3]. In this context, the following ethical aspect of our study should be considered: Patients in the control group could have a disadvantage compared to the intervention group performing the LTB curriculum. However, in Germany there is still no need of ex vivo MIS training in formal residency training curricula [21]. Consequently, the control group reflects the standard surgical education situation of MIS in Germany. In the current study in both groups the CHE will be assisted by a surgeon who holds the formal authorization for surgical education in visceral and/or general surgery in the participating clinic. In Germany, this authorization requires a high degree of surgical experience and aptitude. Finally, the attending surgeon has both a high level of surgical expertise and a high experience in surgical education. Beside patient safety aspects, this should further ensure that all participants have the same standard of assisting in the CHE.

Most of the diverse VR- and video/box simulators do not offer defined curricula and those that do, are based on limited data with limited validity [21]. In order to examine the effect of MIS training on surgical performance in clinical trials, it is important to use validated, standardized and thus comparable training programs [31]. Furthermore, goal-directed proficiency-based training has been demonstrated to increase trainee motivation, including attendance to the curriculum's schedule, entailing better performance in comparison to training without defined objectives [31,32]. In the current study we used the LTB curriculum for the acquisition of MIS skills. In order to find widely accepted implementation face, content, construct, concurrent and predictive validity should have been demonstrated for the given device and curriculum [26]. So far, face, content and construct validity could be shown for the LTB curriculum. The goals for each of the six tasks of the LTB curriculum are based on a benchmark-study with n = 15 MIS experts followed by a prospective validation study with n = 30 novices [6]. The current prospective randomized trial could further verify the gain in MIS performance due to the LTB curriculum in a real surgical environment and cover the important aspect of predictive validity of the LTB curriculum.

At this point, we see the following possible limitations of the study: The participants will be not blinded, but will be informed in which group of the study they will be assigned to and know

the course of the study. This could have an influence on the MIS performance of the participants (*performance bias*). Furthermore, the 5th domain of the GOALS-score (*autonomy*) will be determined by the attending surgeon assisting the laparoscopic CHE of the participant as first assistant. Since it is logistically almost impossible to blind the attending surgeon to whether the study participant had been randomized to undergo the curriculum or not, especially in smaller hospital units, the attending surgeon knows which intervention a participant received and which MIS procedure (CHE I or CHE II) has been performed, when determing the 5th domain of the GOALS-score (*detection bias*). This could have an influence on the evaluation of the GOALS score overall. However, a potential digital recording of the verbal interactions between the participant and the attending surgeon, which would also allow a blinded analysis of the 5th domain of the GOALS score, is technically and logistically demanding and almost not feasible in a multicentric setting. There are data that direct assessment of MIS skills predicts the qualification of a surgeon more accurately than a video-based assessment [33]. However, it should be considered that direct raters may use different evaluation methods, thus introducing variations in ratings [33]. In the current study, the fact that the study is being conducted in a multi-centre setting could additionally lead to relevant differences in MIS assessments. And, direct observers onsite would know in which arm of the study the participants were randomised and which surgery was performed (CHE I versus II), which could have an influence on evaluation of MIS performance. For these reasons, we decided against a direct evaluation on site and favoured a blinded video analysis.

It has been described, that prospective studies which had been conducted under the involvement of an industrial co-operating partner more often report positive results than non-industry funded trials [6]. The funding source remained significantly associated with reporting of positive outcome in a multivariate analysis. Although the sole sponsor of the present study is the University Medical Centre Schleswig-Holstein, two of the co-authors (TL, HE) are co-founders of the LTB Ltd. company which may possibly imply the above mentioned bias with regard to the interpretation and presentation of the results. Further limitations are shortcomings of the protocol. It lacked provisions for dissemination, for amendments, and participant retention. Lastly, the trial is powered to detect a considerable effect that may be larger than the minimum clinically interesting difference.

In summary, this prospective multi-centre randomized controlled trial will help to determine the effect of MIS training outside the OR prior to the first operations on patients. Proof of effectiveness of MIS training as the LTB curriculum, with regard to its transferability to real surgical practice could be of considerable relevance for the implementation of MIS simulation training programs into the surgical residency curriculum.

5. Trial status

Recruitment started in May 2017 and is planned to be finished in May 2020.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.isjp.2020.02.004.

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